Information about ADVAIR DISKUS

ADVAIR DISKUS 100/50, 250/50, 500/50

(fluticasone propionate 100, 250, 500 mcg and salmeterol 50 mcg inhalation powder)

What is the most important information I should know about ADVAIR DISKUS?
In patients with asthma, long-acting beta$_2$-agonist medicines such as salmeterol (one of the medications in ADVAIR®) may increase the chance of death from asthma problems. In a large asthma study, more patients who used salmeterol died from asthma problems compared with patients who did not use salmeterol. So ADVAIR is not for patients whose asthma is well controlled on another asthma controller medicine such as low- to medium-dose inhaled corticosteroids or only need a fast-acting inhaler once in a while. Talk with your doctor about this risk and the benefits of treating your asthma with ADVAIR.

ADVAIR should not be used to treat a severe attack of asthma or chronic obstructive pulmonary disease (COPD) requiring emergency medical treatment.

ADVAIR should not be used to relieve sudden symptoms or sudden breathing problems. Always have a fast-acting inhaler with you to treat sudden breathing difficulty. If you do not have a fast-acting inhaler, contact your doctor to have one prescribed for you.

What is ADVAIR DISKUS?
There are two medicines in ADVAIR: Fluticasone propionate, an inhaled anti-inflammatory belonging to a group of medicines commonly referred to as corticosteroids; and salmeterol, a long-acting, inhaled bronchodilator belonging to a group of medicines commonly referred to as beta$_2$-agonists. There are 3 strengths of ADVAIR: 100/50, 250/50, 500/50.

For Asthma
- ADVAIR is approved for the maintenance treatment of asthma in patients 4 years of age and older. ADVAIR should only be used if your doctor decides that another asthma controller medicine alone does not control your asthma or that you need 2 asthma controller medications.
- The strength of ADVAIR approved for patients ages 4 to 11 years who experience symptoms on an inhaled corticosteroid is ADVAIR DISKUS 100/50. All 3 strengths are approved for patients with asthma ages 12 years and older.

For COPD associated with chronic bronchitis
ADVAIR 250/50 is the only approved dose for the maintenance treatment of airflow obstruction in patients with COPD associated with chronic bronchitis. The benefit of using ADVAIR for longer than 6 months has not been evaluated. The way anti-inflammatories work in the treatment of COPD is not well defined.

Who should not take ADVAIR DISKUS?
You should not start ADVAIR if your asthma is becoming significantly or rapidly worse, which can be life threatening. Serious respiratory events, including death, have been reported in patients who started taking salmeterol in this situation, although it is not possible to tell whether salmeterol contributed to these events. This may also occur in patients with less severe asthma.

You should not take ADVAIR if you have had an allergic reaction to it or any of its components (salmeterol, fluticasone propionate, or lactose). Tell your doctor if you are allergic to ADVAIR, any other medications, or food products. If you experience an allergic reaction after taking ADVAIR, stop using ADVAIR immediately and contact your doctor. Allergic reactions are when you experience one or more of the following: choking; breathing problems; swelling of the face, mouth and/or tongue; rash; hives; itching; or welts on the skin.

Tell your doctor about the following:
- If you are using your fast-acting inhaler more often or using more doses than you normally do (e.g. 4 or more inhalations of your fast-acting inhaler for 2 or more days in a row or a whole canister of your fast-acting inhaler in 8 weeks' time), it could be a sign that your asthma is getting worse. If this occurs, tell your doctor immediately.
- If you have been using your fast-acting inhaler regularly (e.g., four times a day) Your doctor may tell you to stop the regular use of these medications.
- If your peak flow meter results decrease. Your doctor will tell you the numbers that are right for you.
- If you have asthma and your symptoms do not improve after using ADVAIR regularly for 1 week.
- If you have been on an oral steroid, like prednisone, and are now using ADVAIR. You should be very careful as you may be less able to heal after surgery, infection, or serious injury. It takes a number of months for the body to recover its ability to make its own steroid hormones after use of oral steroids. Switching from an oral steroid may also unmask a condition previously suppressed by the oral steroid such as allergies, conjunctivitis, eczema, arthritis, and eosinophilic conditions. Symptoms of an eosinophilic condition can include rash, worsening breathing problems, heart complications, and/or feeling of "pins and needles" or numbness in the arms and legs. Talk to your doctor immediately if you experience any of these symptoms.
- Sometimes patients experience unexpected bronchospasm right after taking ADVAIR. This condition can be life threatening and if it occurs, you should immediately stop using ADVAIR and seek immediate medical attention.
- If you have any type of heart disease such as coronary artery disease, irregular heart beat or high blood pressure, ADVAIR should be used with caution. Be sure to talk with your doctor about your condition because salmeterol, one of the components of ADVAIR, may affect the heart by increasing heart rate and blood pressure. It may cause symptoms such as heart fluttering, chest pain, rapid heart rate, tremor, or nervousness.
- If you have seizures, overactive thyroid gland, liver problems, or are sensitive to certain medications for breathing.
- If your breathing problems get worse over time or if your fast-acting inhaler does not work as well for you while using ADVAIR. If your breathing problems worsen quickly, get emergency medical care.
- If you have been exposed to or currently have chickenpox or measles or if you have an immune system problem. Patients using medications that weaken the immune system are more likely to get infections than healthy individuals. ADVAIR contains a corticosteroid (fluticasone propionate) which may weaken the immune system. Infections like chickenpox and measles, for example, can be very serious or even fatal in susceptible patients using corticosteroids.

How should I take ADVAIR DISKUS?
ADVAIR should be used 1 inhalation, twice a day (morning and evening). ADVAIR should never be taken more than 1 inhalation twice a day. The full benefit of taking ADVAIR may take 1 week or longer.

If you miss a dose of ADVAIR, just skip that dose. Take your next dose at your usual time. Do not take two doses at one time.

Do not stop using ADVAIR unless told to do so by your doctor because your symptoms might get worse.

Do not change or stop any of your medicines used to control or treat your breathing problems. Your doctor will adjust your medicines as needed.

When using ADVAIR, remember:
- Never breathe into or take the DISKUS® apart.
- Always use the DISKUS in a level position.
- After each inhalation, rinse your mouth with water without swallowing.
- Never wash any part of the DISKUS. Always keep it in a dry place.
- Never take an extra dose, even if you feel you did not receive a dose.
- Discard 1 month after removal from the foil overwrap.
- Do not use ADVAIR with a spacer device.

Children should use ADVAIR with an adult's help as instructed by the child's doctor.

Can I take ADVAIR DISKUS with other medications?
Tell your doctor about all the medications you take, including prescription and nonprescription medications, vitamins, and herbal supplements.

If you are taking ADVAIR, you should not take SEREVENT® DISKUS or Foradil® Aerolizer® for any reason.

If you take ritonavir (an HIV medication), tell your doctor. Ritonavir may interact with ADVAIR and could cause serious side effects. The anti-HIV medicines Norvir® Soft Gelatin Capsules, Norvir Oral Solution, and Kaletra® contain ritonavir.

No formal drug interaction studies have been performed with ADVAIR.

In clinical studies, there were no differences in effects on the heart when ADVAIR was taken with varying amounts of albuterol. The effect of using ADVAIR in patients with asthma while taking more than 9 puffs a day of albuterol has not been studied.

ADVAIR should be used with extreme caution during and up to 2 weeks after treatment with monoamine oxidase (MAO) inhibitors or tricyclic antidepressants since these medications can cause ADVAIR to have an even greater effect on the circulatory system.

ADVAIR should be used with caution in people who are taking ketoconazole (an antifungus medication) or other drugs broken down by the body in a similar way. These medications can cause ADVAIR to have greater steroid side effects.

Generally, people with asthma should not take beta-blockers because they counteract the effects of beta$_2$-agonists and may also cause severe bronchospasm. However, in some cases, for instance, following a heart attack, selective beta-blockers may still be used if there is no acceptable alternative.

The ECG changes and/or low blood potassium that may occur with some diuretics may be made worse by ADVAIR, especially at higher-than-recommended doses. Caution should be used when these drugs are used together.

In clinical studies, there was no difference in side effects when ADVAIR was taken with methylxanthines (e.g. theophylline) or with FLONASE®.

What are other important safety considerations with ADVAIR DISKUS?
Osteoporosis: Long-term use of inhaled corticosteroids may result in bone loss (osteoporosis). Patients who are at risk for increased bone loss (tobacco use, advanced age, inactive lifestyle, poor nutrition, family history of osteoporosis, or long-term use of drugs such as corticosteroids) may have a greater risk with ADVAIR. If you have risk factors for bone loss, you should talk to your doctor about ways to reduce your risk and whether you should have your bone density evaluated.

Glaucoma and cataracts: Glaucoma, increased pressure in the eyes, and cataracts have been reported with the use of inhaled steroids, including fluticasone propionate, a medicine contained in ADVAIR. Regular eye examinations should be considered if you are taking ADVAIR.

Lower respiratory tract infection: Lower respiratory tract infections, including pneumonia, have been reported with the use of inhaled corticosteroids including ADVAIR.

Blood sugar: Salmeterol may affect blood sugar and/or cause low blood potassium in some patients, which could lead to a side effect like an irregular heart rate. Significant changes in blood sugar and blood potassium were seen infrequently in clinical studies with ADVAIR.

Growth: Inhaled steroids may cause a reduction in growth velocity in children and adolescents.

Steroids: Taking steroids can affect your body's ability to make its own steroid hormones, which are needed during infections and times of severe stress to your body, such as an operation. These effects can sometimes be seen with inhaled steroids (but it is more common with oral steroids), especially when taken at higher-than-recommended doses over a long period of time. In some cases, these effects may be severe. Inhaled steroids often help control symptoms with less side effects than oral steroids.

Yeast infections: Patients taking ADVAIR may develop yeast infections of the mouth and/or throat ("thrush") that should be treated by their doctor.

Tuberculosis or other untreated infections: ADVAIR should be used with caution, if at all, in patients with tuberculosis, herpes infections of the eye, or other untreated infections.

What are the other possible side effects of ADVAIR DISKUS?
ADVAIR may produce side effects in some patients. In clinical studies, the most common side effects with ADVAIR included:

- Respiratory infections
- Throat irritation
- Hoarseness
- Sinus infection
- Yeast infection of the mouth
- Bronchitis
- Cough
- Headaches
- Nausea and vomiting
- Diarrhea
- Musculoskeletal pain
- Dizziness
- Fever
- Ear, nose, and throat infections
- Nosebleed

Tell your doctor about any side effect that bothers you or that does not go away. These are not all the side effects with ADVAIR. Ask your doctor or pharmacist for more information.

What if I am pregnant, planning to become pregnant, or nursing?
Talk to your doctor about the benefits and risks of using ADVAIR during pregnancy, labor, or if you are nursing. There have been no studies of ADVAIR used during pregnancy, labor, or in nursing women. Salmeterol is known to interfere with labor contractions. It is not known whether ADVAIR is excreted in breast milk, but other corticosteroids have been detected in human breast milk. Fluticasone propionate, like other corticosteroids, has been associated with birth defects in animals (e.g., cleft palate and fetal death). Salmeterol showed no effect on fertility in rats at 180 times the maximum recommended daily dose.

What other important tests were conducted with ADVAIR?
There is no evidence of enhanced toxicity with ADVAIR compared with the components administered separately. In animal studies with doses much higher than those used in humans, salmeterol was associated with uterine tumors. Your healthcare professional can tell you more about how drugs are tested on animals and what the results of these tests may mean to your safety.

For more information on ADVAIR DISKUS
This page is only a brief summary of important information about ADVAIR DISKUS. For more information, talk to your doctor. You can also visit www.ADVAIR.com or call 1-888-825-5249. Patients receiving ADVAIR DISKUS should read the medication guide provided by the pharmacist with the prescription.

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INFORMATION FOR PATIENTS
Ambien® ℂ
(zolpidem tartrate)

AMBIEN® (ZOLPIDEM TARTRATE) ℂ

INFORMATION FOR PATIENTS TAKING AMBIEN

Your doctor has prescribed Ambien to help you sleep. The following information is intended to guide you in the safe use of this medicine. It is not meant to take the place of your doctor's instructions. If you have any questions about Ambien tablets be sure to ask your doctor or pharmacist.

Ambien is used to treat different types of sleep problems, such as:
- trouble falling asleep
- waking up too early in the morning
- waking up often during the night

Some people may have more than one of these problems.
Ambien belongs to a group of medicines known as the "sedative/hypnotics," or simply, sleep medicines. There are many different sleep medicines available to help people sleep better. Sleep problems are usually temporary, requiring treatment for only a short time, usually 1 or 2 days up to 1 or 2 weeks. Some people have chronic sleep problems that may require more prolonged use of sleep medicine. However, you should not use these medicines for long periods without talking with your doctor about the risks and benefits of prolonged use.

SIDE EFFECTS

Most common side effects: All medicines have side effects. Most common side effects of sleep medicines include
- drowsiness
- dizziness
- lightheadedness
- difficulty with coordination

You may find that these medicines make you sleepy during the day. How drowsy you feel depends upon how your body reacts to the medicine, which sleep medicine you are taking, and how large a dose your doctor has prescribed. Daytime drowsiness is best avoided by taking the lowest dose possible that will still help you sleep at night. Your doctor will work with you to find the dose of Ambien that is best for you.
To manage these side effects while you are taking this medicine:
- When you first start taking Ambien or any other sleep medicine until you know whether the medicine will still have some carryover effect in you the next day, use extreme care while doing anything that requires complete alertness such as driving a car, operating machinery, or piloting an aircraft.
- NEVER drink alcohol while you are being treated with Ambien or any sleep medicine. Alcohol can increase the side effects of Ambien or any other sleep medicine.
- Do not take any other medicines without asking your doctor first. This includes medicines you can buy without a prescription. Some medicines can cause drowsiness and are best avoided while taking Ambien.
- Always take the exact dose of Ambien prescribed by your doctor. Never change your dose without talking to your doctor first.

SPECIAL CONCERNS

There are some special problems that may occur while taking sleep medicines.

Memory problems: Sleep medicines may cause a special type of memory loss or "amnesia." When this occurs, a person may not remember what has happened for several hours after taking the medicine. This is usually not a problem since most people fall asleep after taking the medicine.
Memory loss can be a problem, however, when sleep medicines are taken while traveling, such as during an airplane flight and the person wakes up before the effect of the medicine is gone. This has been called "traveler's amnesia."
Memory problems are not common while taking Ambien. In most instances memory problems can be avoided if you take Ambien only when you are able to get a full night's sleep (7 to 8 hours) before you need to be active again. Be sure to talk to your doctor if you think you are having memory problems.

Tolerance: When sleep medicines are used every night for more than a few weeks, they may lose their effectiveness to help you sleep. This is known as "tolerance." Sleep medicines should, in most cases, be used only for short periods of time, such as 1 or 2 days and generally no longer than 1 or 2 weeks. If your sleep problems continue, consult your doctor, who will determine whether other measures are needed to overcome your sleep problems.

Dependence: Sleep medicines can cause dependence, especially when these medicines are used regularly for longer than a few weeks or at high doses. Some people develop a need to continue taking their medicines. This is known as dependence or "addiction."
When people develop dependence, they may have difficulty stopping the sleep medicine. If the medicine is suddenly stopped, the body is not able to function normally and unpleasant symptoms (see *Withdrawal*) may occur. They may find they have to keep taking the medicine either at the prescribed dose or at increasing doses just to avoid withdrawal symptoms.
All people taking sleep medicines have some risk of becoming dependent on the medicine. However, people who have been dependent on alcohol or other drugs in the past may have a higher chance of becoming addicted to sleep medicines. This possibility must be considered before using these medicines for more than a few weeks.
If you have been addicted to alcohol or drugs in the past, it is important to tell your doctor before starting Ambien or any sleep medicine.

Withdrawal: Withdrawal symptoms may occur when sleep medicines are stopped suddenly after being used daily for a long time. In some cases, these symptoms can occur even if the medicine has been used for only a week or two.
In mild cases, withdrawal symptoms may include unpleasant feelings. In more severe cases, abdominal and muscle cramps, vomiting, sweating, shakiness, and rarely seizures may occur. These more severe withdrawal symptoms are very uncommon.
Another problem that may occur when sleep medicines are stopped is known as "rebound insomnia." This means that a person may have more trouble sleeping the first few nights after the medicine is stopped than before starting the medicine. If you should experience rebound insomnia, do not get discouraged. This problem usually goes away on its own after 1 or 2 nights.
If you have been taking Ambien or any other sleep medicine for more than 1 or 2 weeks, do not stop taking it on your own. Always follow your doctor's directions.

Changes in behavior and thinking: Some people using sleep medicines have experienced unusual changes in their thinking and/or behavior. These effects are not common. However, they have included:
- more outgoing or aggressive behavior than normal
- loss of personal identity
- confusion
- strange behavior
- agitation
- hallucinations
- worsening of depression
- suicidal thoughts

How often these effects occur depends on several factors, such as a person's general health, the use of other medicines, and which sleep medicine is being used. Clinical experience with Ambien suggests that it is uncommonly associated with these behavior changes.
It is also important to realize that it is rarely clear whether these behavior changes are caused by the medicine, an illness, or occur on their own. In fact, sleep problems that do not improve may be due to illnesses that were present before the medicine was used. If you or your family notice any changes in your behavior or if you have any unusual or disturbing thoughts, call your doctor immediately.

Pregnancy: Sleep medicines may cause sedation of the unborn baby when used during the last weeks of pregnancy.
Be sure to tell your doctor if you are pregnant, if you are planning to become pregnant, or if you become pregnant while taking Ambien.

SAFE USE OF SLEEPING MEDICINES

To ensure the safe and effective use of Ambien or any other sleep medicine, you should observe the following cautions:
1. Ambien is a prescription medicine and should be used ONLY as directed by your doctor. Follow your doctor's instructions about how to take, when to take, and how long to take Ambien.
2. Never use Ambien or any other sleep medicine for longer than directed by your doctor.
3. If you notice any unusual and/or disturbing thoughts or behavior during treatment with Ambien or any other sleep medicine, contact your doctor.
4. Tell your doctor about any medicines you may be taking, including medicines you may buy without a prescription. You should also tell your doctor if you drink alcohol. DO NOT use alcohol while taking Ambien or any other sleep medicine.
5. Do not take Ambien unless you are able to get a full night's sleep before you must be active again. For example, Ambien should not be taken on an overnight airplane flight of less than 7 to 8 hours since "traveler's amnesia" may occur.
6. Do not increase the prescribed dose of Ambien or any other sleep medicine unless instructed by your doctor.
7. When you first start taking Ambien or any other sleep medicine until you know whether the medicine will still have some carryover effect in you the next day, use extreme care while doing anything that requires complete alertness, such as driving a car, operating machinery, or piloting an aircraft.
8. Be aware that you may have more sleeping problems the first night or two after stopping Ambien or any other sleep medicine.
9. Be sure to tell your doctor if you are pregnant, if you are planning to become pregnant, or if you become pregnant while taking Ambien.
10. As with all prescription medicines, never share Ambien or any other sleep medicine with anyone else. Always store Ambien or any other sleep medicine in the original container out of reach of children.
11. Ambien works very quickly. You should only take Ambien right before going to bed and are ready to go to sleep.

Ambien® ℂ
(zolpidem tartrate)

Printed in USA

INFORMATION FOR PATIENTS
Ambien CR® ©
(zolpidem tartrate extended-release) tablets

AMBIEN CR®
ZOLPIDEM TARTRATE EXTENDED RELEASE ©
6.25 MG & 12.5 MG EXTENDED RELEASE TABLETS

INFORMATION FOR PATIENTS TAKING AMBIEN CR

Your doctor has prescribed Ambien CR to help you sleep. The following information is intended to guide you in the safe use of this medicine. It is not meant to take the place of your doctor's instructions. If you have any questions about Ambien CR tablets be sure to ask your doctor or pharmacist.

Ambien CR is used to treat different types of sleep problems, such as:
- trouble falling asleep
- waking up often during the night

Some people may have more than one of these problems.

Ambien CR belongs to a group of medicines known as the "sedative/hypnotics", or simply, sleep medicines. There are many different sleep medicines available to help people sleep better. Sleep problems are usually temporary, requiring treatment for only a short time, usually 1 or 2 days up to 1 or 2 weeks. Some people have chronic sleep problems that may require more prolonged use of sleep medicine. However, you should not use these medicines for long periods without talking with your doctor about the risks and benefits of prolonged use.

SIDE EFFECTS

Most common side effects:
- headache
- somnolence (sleepiness)
- dizziness

You may find that these medicines make you sleepy during the day. How drowsy you feel depends upon how your body reacts to the medicine, which sleep medicine you are taking, and how large a dose your doctor has prescribed. Daytime drowsiness is best avoided by taking the lowest dose possible that will still help you sleep at night. Your doctor will work with you to find the dose of Ambien CR that is best for you.

To manage these side effects while you are taking this medicine:

- When you first start taking Ambien CR or any other sleep medicine until you know whether the medicine will still have some carryover effect in you the next day, use extreme care while doing anything that requires complete alertness, such as driving a car, operating machinery, or piloting an aircraft.
- NEVER drink alcohol while you are being treated with Ambien CR or any sleep medicine. Alcohol can increase the side effects of Ambien CR or any other sleep medicine.
- Do not take any other medicines without asking your doctor first. This includes medicines you can buy without a prescription. Some medicines can cause drowsiness and are best avoided while taking Ambien CR.
- Always take the exact dose of Ambien CR prescribed by your doctor. Never change your dose without talking to your doctor first.

SPECIAL CONCERNS

There are some special problems that may occur while taking sleep medicines.

"Sleep-Driving" and other complex behaviors: There have been reports of people getting out of bed after taking a sleep medicine and driving their cars while not fully awake, often with no memory of the event. If you experience such an event, it should be reported to your doctor immediately, since "sleep-driving" can be dangerous. This behavior is more likely to occur when Ambien CR is taken with alcohol or other drugs such as those for the treatment of depression or anxiety. Other complex behaviors such as preparing and eating food, making phone calls, or having sex have been reported in people who are not fully awake after taking a sleep medicine. As with "sleep-driving", people usually do not remember these events.

Memory problems: Sleep medicines may cause a special type of memory loss or "amnesia." When this occurs, a person may not remember what has happened for several hours after taking the medicine. This is usually not a problem since most people fall asleep after taking the medicine.

Memory loss can be a problem, however, when sleep medicines are taken while traveling, such as during an airplane flight and the person wakes up before the effect of the medicine is gone. This has been called "traveler's amnesia."

Be sure to talk to your doctor if you think you are having memory problems. Although memory problems are not very common while taking Ambien CR, in most instances, they can be avoided if you take Ambien CR only when you are able to get a full night's sleep (7 to 8 hours) before you need to be active again.

Tolerance: When sleep medicines are used every night for more than a few weeks, they may lose their effectiveness to help you sleep. This is known as "tolerance". Sleep medicines should, in most cases, be used only for short periods of time, such as 1 or 2 days and generally no longer than 1 or 2 weeks. If your sleep problems continue, consult your doctor who will determine whether other measures are needed to overcome your sleep problems.

Dependence: Sleep medicines can cause dependence, especially when these medicines are used regularly for longer than a few weeks or at high doses. Some people develop a need to continue taking their medicines. This is known as dependence or "addiction."

When people develop dependence, they may have difficulty stopping the sleep medicine. If the medicine is suddenly stopped, the body is not able to function normally and unpleasant symptoms may occur (see *Withdrawal*). They may find that they have to keep taking the medicines either at the prescribed dose or at increasing doses just to avoid withdrawal symptoms.

All people taking sleep medicines have some risk of becoming dependent on the medicine. However, people who have been dependent on alcohol or other drugs in the past may have a higher chance of becoming addicted to sleep medicines. This possibility must be considered before using these medicines for more than a few weeks.

If you have been addicted to alcohol or drugs in the past, it is important to tell your doctor before starting Ambien CR or any sleep medicine.

Withdrawal: Withdrawal symptoms may occur when sleep medicines are stopped suddenly after being used daily for a long time. In some cases, these symptoms can occur even if the medicine has been used for only a week or two.

In mild cases, withdrawal symptoms may include unpleasant feelings. In more severe cases, abdominal and muscle cramps, vomiting, sweating, shakiness, and rarely seizures may occur. These more severe withdrawal symptoms are very uncommon.

Another problem that may occur when sleep medicines are stopped is known as "rebound insomnia." This means that a person may have more trouble sleeping the first few nights after the medicine is stopped than before starting the medicine. If you should experience rebound insomnia, do not get discouraged. This problem usually goes away on its own after 1 or 2 nights.

If you have been taking Ambien CR or any other sleep medicine for more than 1 or 2 weeks, do not stop taking it on your own. Always follow your doctor's directions.

Changes in behavior and thinking: Some people using sleep medicines have experienced unusual changes in their thinking and/or behavior. These effects are not common. However, they have included:

- more outgoing or aggressive behavior than normal
- confusion
- strange behavior
- agitation
- hallucinations
- worsening of depression
- suicidal thoughts

How often these effects occur depends on several factors, such as a person's general health, the use of other medicines, and which sleep medicine is being used.

It is also important to realize that it is rarely clear whether these behavior changes are caused by the medicine, an illness, or occur on their own. In fact, sleep problems that do not improve may be due to illnesses that were present before the medicine was used. If you or your family notice any changes in your behavior or if you have any unusual or disturbing thoughts, call your doctor immediately.

Pregnancy: Sleep medicines may cause sedation of the unborn baby when used during the last weeks of pregnancy.

Be sure to tell your doctor if you are pregnant, if you are planning to become pregnant or if you become pregnant while taking Ambien CR.

SAFE USE OF SLEEPING MEDICINES

To ensure the safe and effective use of Ambien CR or any other sleep medicine, you should observe the following cautions:

1. Ambien CR is a prescription medicine and should be used ONLY as directed by your doctor. Follow your doctor's instructions about how to take, when to take, and how long to take Ambien CR. Ambien CR tablets should not be divided, crushed or chewed and must be swallowed whole.
2. Never use Ambien CR or any other sleep medicine for longer than directed by your doctor.
3. If you develop an allergic reaction such as rash, hives, shortness of breath or swelling of your tongue or throat when using Ambien CR or any other sleep medicine, discontinue Ambien CR or other sleep medicine immediately and contact your doctor.
4. If you notice any unusual and/or disturbing thoughts or behavior during treatment with Ambien CR or any other sleep medicine, contact your doctor.
5. Tell your doctor about any medicines you may be taking, including medicines you may buy without a prescription. You should also tell your doctor if you drink alcohol. DO NOT use alcohol while taking Ambien CR or any other sleep medicine.
6. Do not take Ambien CR unless you are able to get a full night's sleep before you must be active again. For example, Ambien CR should not be taken on an overnight airplane flight of less than 7 to 8 hours since "traveler's amnesia" may occur.
7. Do not increase the prescribed dose of Ambien CR or any other sleep medicine unless instructed by your doctor.
8. When you first start taking Ambien CR or any other sleep medicine, until you know whether the medicine will still have some carryover effect in you the next day, use extreme care while doing anything that requires complete alertness, such as driving a car, operating machinery, or piloting an aircraft.
9. Be aware that you may have more sleeping problems the first night after stopping Ambien CR or any other sleep medicine.
10. Be sure to tell your doctor if you are pregnant, if you are planning to become pregnant or if you become pregnant while taking Ambien CR or any other sleep medicine.
11. As with all prescription medicines, never share Ambien CR or any other sleep medicine with anyone else. Always store Ambien CR or any other sleep medicine in the original container that you received it in and store it out of reach of children.
12. Ambien CR works very quickly. You should only take Ambien CR right before going to bed and are ready to go to sleep.

Ambien CR® ©
(zolpidem tartrate extended-release tablets)

AMBCR-APR07-IFP-Ad

Revised April 2007

sanofi-aventis U.S. LLC
Bridgewater, NJ 08807

PATIENT INFORMATION – Rx only

AVANDIA® (ah-VAN-dee-a)

Rosiglitazone Maleate Tablets

Read the Patient Information that comes with AVANDIA before you start taking the medicine and each time you get a refill. There may be new information This information does not take the place of talking with your doctor about your medical condition or your treatment If you have any questions about AVANDIA, ask your doctor or pharmacist.

What is AVANDIA?

AVANDIA is a prescription medicine used with diet and exercise to treat type 2 ("adult-onset" or "non-insulin dependent") diabetes mellitus ("high blood sugar"). AVANDIA may be used alone or with other anti-diabetic medicines. AVANDIA can help your body respond better to insulin made in your body. AVANDIA does not cause your body to make more insulin.

Before you take AVANDIA you should first try to control your diabetes by diet, weight loss, and exercise. In order for AVANDIA to work best, it is very important to exercise, lose excess weight, and follow the diet recommended for your diabetes.

The safety and efficacy of AVANDIA have not been established in children under 18 years of age

What is Type 2 Diabetes?

Type 2 diabetes happens when a person does not make enough insulin or does not respond normally to the insulin their body makes. When this happens, sugar (glucose) builds up in the blood. This can lead to serious medical problems including kidney damage, heart disease, loss of limbs, and blindness. The main goal of treating diabetes is to lower your blood sugar to a normal level. Lowering and controlling blood sugar may help prevent or delay complications of diabetes such as heart disease, kidney disease or blindness. High blood sugar can be lowered by diet and exercise, by certain medicines taken by mouth, and by insulin shots.

Who should not take AVANDIA?

Do not take AVANDIA if you are allergic to any of the ingredients in AVANDIA. The active ingredient is rosiglitazone maleate See the end of this leaflet for a list of all the ingredients in AVANDIA.

Before taking AVANDIA, tell your doctor about all your medical conditions, including if you:

- have heart problems or heart failure. AVANDIA can cause your body to keep extra fluid (fluid retention), which leads to swelling and weight gain. Extra body fluid can make some heart problems worse or lead to heart failure.
- have type 1 ("juvenile") diabetes or had diabetic ketoacidosis These conditions should be treated with insulin
- have liver problems. Your doctor should do blood tests to check your liver before you start taking AVANDIA and during treatment as needed
- had liver problems while taking REZULIN® (troglitazone), another medicine for diabetes
- are pregnant or trying to become pregnant. It is not known if AVANDIA can harm your unborn baby. You and your doctor should talk about the best way to control your high blood sugar during pregnancy
- are a premenopausal woman (before the "change of life") who does not have regular monthly periods. AVANDIA may increase your chances of becoming pregnant Talk to your doctor about birth control choices while taking AVANDIA
- are breastfeeding. It is not known if AVANDIA passes into breast milk You should not use AVANDIA while breastfeeding
- are taking prescription or non-prescription medicines, vitamins or herbal supplements. AVANDIA and certain other medicines can affect each other and lead to serious side effects including high blood sugar or low blood sugar. Keep a list of all the medicines you take. Show this list to your doctor and pharmacist before you start a new medicine. They will tell you if it is okay to take AVANDIA with other medicines.

How should I take AVANDIA?

- Take AVANDIA exactly as prescribed. Your doctor will tell you how many tablets to take and how often. The usual daily starting dose is 4 mg a day taken once a day or 2 mg taken twice a day. Your doctor may need to adjust your dose until your blood sugar is better controlled.
- AVANDIA may be prescribed alone or with other anti-diabetic medicines This will depend on how well your blood sugar is controlled
- Take AVANDIA with or without food.
- It can take 2 weeks for AVANDIA to start lowering blood sugar It may take 2 to 3 months to see the full effect on your blood sugar level
- If you miss a dose of AVANDIA, take your pill as soon as you remember, unless it is time to take your next dose. Take your next dose at the usual time Do not take a double dose to make up for a missed dose
- If you take too much AVANDIA, call your doctor or poison control center right away.
- Test your blood sugar regularly as your doctor tells you
- Diet and exercise can help your body use its blood sugar better. It is important to stay on your recommended diet, lose excess weight, and get regular exercise while taking AVANDIA.
- Your doctor should do blood tests to check your liver before you start AVANDIA and during treatment as needed. Your doctor should also do regular blood sugar tests (for example, "A1C") to monitor your response to AVANDIA.

What are possible side effects of AVANDIA?

- heart failure. AVANDIA can cause your body to keep extra fluid (fluid retention), which leads to swelling and weight gain. Extra body fluid can make some heart problems worse or lead to heart failure.
- swelling (edema) from fluid retention. Call your doctor right away if you have symptoms such as:
  - swelling or fluid retention, especially in the ankles or legs
  - shortness of breath or trouble breathing, especially when you lie down
  - an unusually fast increase in weight
  - unusual tiredness
- low blood sugar (hypoglycemia). Lightheadedness, dizziness, shakiness or hunger may mean that your blood sugar is too low. This can happen if you skip meals, if you use another medicine that lowers blood sugar, or if you have certain medical problems. Call your doctor if low blood sugar levels are a problem for you.
- weight gain. AVANDIA can cause weight gain that may be due to fluid retention or extra body fat. Weight gain can be a serious problem for people with certain conditions including heart problems. Call your doctor if you have an unusually fast increase in weight
- low red blood cell count (anemia)
- ovulation (release of egg from an ovary in a woman) leading to pregnancy. Ovulation may happen in premenopausal women who do not have regular monthly periods. This can increase the chance of pregnancy
- liver problems. It is important for your liver to be working normally when you take AVANDIA. Your doctor should do blood tests to check your liver before you start taking AVANDIA and during treatment as needed. Call your doctor right away if you have unexplained symptoms such as:
  - nausea or vomiting
  - stomach pain
  - unusual or unexplained tiredness
  - loss of appetite
  - dark urine
  - yellowing of your skin or the whites of your eyes

The most common side effects of AVANDIA included cold-like symptoms, injury, and headache.

How should I store AVANDIA?

- Store AVANDIA at room temperature, 59° to 86° F (15° to 30° C). Keep AVANDIA in the container it comes in.
- Safely, throw away AVANDIA that is out of date or no longer needed
- Keep AVANDIA and all medicines out of the reach of children.

General Information about AVANDIA

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use AVANDIA for a condition for which it was not prescribed. Do not give AVANDIA to other people, even if they have the same symptoms you have It may harm them

This leaflet summarizes important information about AVANDIA. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about AVANDIA that is written for healthcare professionals. You can also find out more about AVANDIA by calling 1-888-825-5249 or visiting the website www.avandia.com.

What are the ingredients in AVANDIA?

Active Ingredient: rosiglitazone maleate

Inactive Ingredients: hypromellose 2910, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol 3000, sodium starch glycolate, titanium dioxide, triacetin, and 1 or more of the following: synthetic red and yellow iron oxides and talc

AVANDIA is a registered trademark of GlaxoSmithKline.

REZULIN is a registered trademark of Parke-Davis Pharmaceuticals Ltd

PIL–AV:L13

GlaxoSmithKline

CELEBREX®
(celecoxib capsules)

Medication Guide for Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

(See the end of this Medication Guide for a list of prescription NSAID medicines.)

What is the most important information I should know about medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)?

NSAID medicines may increase the chance of a heart attack or stroke that can lead to death.
This chance increases:
- with longer use of NSAID medicines
- in people who have heart disease

NSAID medicines should never be used right before or after a heart surgery called a "coronary artery bypass graft (CABG)."
NSAID medicines can cause ulcers and bleeding in the stomach and intestines at any time during treatment. Ulcers and bleeding:
- can happen without warning symptoms
- may cause death

The chance of a person getting an ulcer or bleeding increases with:
- taking medicines called "corticosteroids" and "anticoagulants"
- longer use
- smoking
- drinking alcohol
- older age
- having poor health

NSAID medicines should only be used:
- exactly as prescribed
- at the lowest dose possible for your treatment
- for the shortest time needed

What are Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)?
NSAID medicines are used to treat pain and redness, swelling, and heat (inflammation) from medical conditions such as:
- different types of arthritis
- menstrual cramps and other types of short-term pain

Who should not take a Non-Steroidal Anti-Inflammatory Drug (NSAID)?
Do not take an NSAID medicine:
- if you had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAID medicine
- for pain right before or after heart bypass surgery

Tell your healthcare provider:
- about all of your medical conditions
- about all of the medicines you take. NSAIDs and some other medicines can interact with each other and cause serious side effects. **Keep a list of your medicines to show to your healthcare provider and pharmacist**
- if you are pregnant. **NSAID medicines should not be used by pregnant women late in their pregnancy.**
- if you are breastfeeding. **Talk to your doctor.**

What are the possible side effects of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)?

Serious side effects include:	Other side effects include:
• heart attack • stroke • high blood pressure • heart failure from body swelling (fluid retention) • kidney problems including kidney failure • bleeding and ulcers in the stomach and intestine • low red blood cells (anemia) • life-threatening skin reactions • life-threatening allergic reactions • liver problems including liver failure • asthma attacks in people who have asthma	• stomach pain • constipation • diarrhea • gas • heartburn • nausea • vomiting • dizziness

Get emergency help right away if you have any of the following symptoms:
- shortness of breath or trouble breathing
- chest pain
- weakness in one part or side of your body
- slurred speech
- swelling of the face or throat

Stop your NSAID medicine and call your healthcare provider right away if you have any of the following symptoms:
- nausea
- more tired or weaker than usual
- itching
- your skin or eyes look yellow
- stomach pain
- flu-like symptoms
- vomit blood
- there is blood in your bowel movement or it is black and sticky like tar
- skin rash or blisters with fever
- unusual weight gain
- swelling of the arms and legs, hands and feet

These are not all the side effects with NSAID medicines. Talk to your healthcare provider or pharmacist for more information about NSAID medicines.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Other information about Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)
- Aspirin is an NSAID medicine but it does not increase the chance of a heart attack. Aspirin can cause bleeding in the brain, stomach, and intestines. Aspirin can also cause ulcers in the stomach and intestines.
- Some of these NSAID medicines are sold in lower doses without a prescription (over-the-counter). Talk to your healthcare provider before using over-the-counter NSAIDs for more than 10 days.

NSAID medicines that need a prescription

Generic Name	Tradename
Celecoxib	Celebrex
Diclofenac	Cataflam, Voltaren, Arthrotec (combined with misoprostol)
Diflunisal	Dolobid
Etodolac	Lodine, Lodine XL
Fenoprofen	Nalfon, Nalfon 200
Flurbiprofen	Ansaid
Ibuprofen	Motrin, Tab-Profen, Vicoprofen* (combined with hydrocodone), Combunox (combined with oxycodone)
Indomethacin	Indocin, Indocin SR, Indo-Lemmon, Indomethagan
Ketoprofen	Oruvail
Ketorolac	Toradol
Mefenamic Acid	Ponstel
Meloxicam	Mobic
Nabumetone	Relafen
Naproxen	Naprosyn, Anaprox, Anaprox DS, EC-Naproxyn, Naprelan, Naprapac (copackaged with lansoprazole)
Oxaprozin	Daypro
Piroxicam	Feldene
Sulindac	Clinoril
Tolmetin	Tolectin, Tolectin DS, Tolectin 600

*Vicoprofen contains the same dose of ibuprofen as over-the-counter (OTC) NSAIDs, and is usually used for less than 10 days to treat pain. The OTC NSAID label warns that long term continuous use may increase the risk of heart attack or stroke.

This Medication Guide has been approved by the U.S. Food and Drug Administration

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G.D. Searle LLC
Division of Pfizer Inc NY, NY 10017

BRIEF SUMMARY OF PRESCRIBING INFORMATION

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use LANTUS safely and effectively. See full prescribing information for LANTUS.

LANTUS® (insulin glargine [rDNA origin] injection) solution for subcutaneous injection

Initial U.S. Approval: 2000

INDICATIONS AND USAGE

LANTUS is a long- acting human insulin analog indicated to improve glycemic control in adults and children with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus. (1)

Important Limitations of Use:

- Not recommended for treating diabetic ketoacidosis. Use intravenous, short-acting insulin instead.

DOSAGE AND ADMINISTRATION

- The starting dose should be individualized based on the type of diabetes and whether the patient is insulin-naïve (2.1, 2.2, 2.3)
- Administer subcutaneously once daily at any time of day, but at the same time every day. (2.1)
- Rotate injection sites within an injection area (abdomen, thigh, or deltoid) to reduce the risk of lipodystrophy. (2.1)
- Converting from other insulin therapies may require adjustment of timing and dose of LANTUS. Closely monitor glucoses especially upon converting to LANTUS and during the initial weeks thereafter. (2.3)

DOSAGE FORMS AND STRENGTHS

Solution for injection 100 units/mL (U-100) in

- 10 mL vials
- 3 mL cartridge system for use in OptiClik (Insulin Delivery Device)
- 3 mL SoloStar disposable insulin device (3)

CONTRAINDICATIONS

Do not use in patients with hypersensitivity to LANTUS or one of its excipients (4)

WARNINGS AND PRECAUTIONS

- Dose adjustment and monitoring: Monitor blood glucose in all patients treated with insulin. Insulin regimens should be modified cautiously and only under medical supervision (5.1)
- Administration: Do not dilute or mix with any other insulin or solution. Do not administer subcutaneously via an insulin pump or intravenously because severe hypoglycemia can occur (5.2)
- Do not share reusable or disposable insulin devices or needles between patients (5.2)
- Hypoglycemia: Most common adverse reaction of insulin therapy and may be life-threatening (5.3, 6.1)
- Allergic reactions: Severe, life-threatening, generalized allergy, including anaphylaxis, can occur (5.4, 6.1)
- Renal or hepatic impairment: May require a reduction in the LANTUS dose (5.5, 5.6)

ADVERSE REACTIONS

Adverse reactions commonly associated with Lantus are:

- Hypoglycemia, allergic reactions, injection site reaction, lipodystrophy, pruritus, and rash. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact sanofi-aventis at 1-800-633-1610 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*

DRUG INTERACTIONS

- Certain drugs may affect glucose metabolism, requiring insulin dose adjustment and close monitoring of blood glucose. (7)
- The signs of hypoglycemia may be reduced or absent in patients taking anti-adrenergic drugs, (e.g., beta-blockers, clonidine, guanethidine, and reserpine). (7)

USE IN SPECIFIC POPULATIONS

- Pregnancy category C: Use during pregnancy only if the potential benefit justifies the potential risk to the fetus (8.1)
- Pediatric: Has not been studied in children with type 2 diabetes. Has not been studied in children with type 1 diabetes <6 years of age (8.4)

See Full Prescribing Information for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling

Revised: 04/2010

GLA-BCPH-NG-APR10 Rx Only

IMPORTANT FACTS

LIPITOR atorvastatin calcium tablets (LIP-ih-tore)

LOWERING YOUR HIGH CHOLESTEROL

High cholesterol is more than just a number, it's a risk factor that should not be ignored. If your doctor said you have high cholesterol, you may be at an increased risk for heart attack and stroke. But the good news is, you can take steps to lower your cholesterol.

With the help of your doctor and a cholesterol-lowering medicine like LIPITOR, along with diet and exercise, you could be on your way to lowering your cholesterol.

Ready to start eating right and exercising more? Talk to your doctor and visit the American Heart Association at www.americanheart.org.

WHO IS LIPITOR FOR?

Who can take LIPITOR:

- People who cannot lower their cholesterol enough with diet and exercise
- Adults and children over 10

Who should NOT take LIPITOR:

- Women who are pregnant, may be pregnant, or may become pregnant. LIPITOR may harm your unborn baby. If you become pregnant, stop LIPITOR and call your doctor right away.
- Women who are breast-feeding. LIPITOR can pass into your breast milk and may harm your baby.
- People with liver problems
- People allergic to anything in LIPITOR

BEFORE YOU START LIPITOR

Tell your doctor:

- About all medications you take, including prescriptions, over-the-counter medications, vitamins, and herbal supplements
- If you have muscle aches or weakness
- If you drink more than 2 alcoholic drinks a day
- If you have diabetes or kidney problems
- If you have a thyroid problem

ABOUT LIPITOR

LIPITOR is a prescription medicine. Along with diet and exercise, it lowers "bad" cholesterol in your blood. It can also raise "good" cholesterol (HDL-C).

LIPITOR can lower the risk of heart attack, stroke, certain types of heart surgery, and chest pain in patients who have heart disease or risk factors for heart disease such as:

- age, smoking, high blood pressure, low HDL-C, family history of early heart disease

LIPITOR can lower the risk of heart attack or stroke in patients with diabetes and risk factors such as diabetic eye or kidney problems, smoking, or high blood pressure.

POSSIBLE SIDE EFFECTS OF LIPITOR

Serious side effects in a small number of people:

- **Muscle problems** that can lead to kidney problems, including kidney failure. Your chance for muscle problems is higher if you take certain other medicines with LIPITOR.
- **Liver problems.** Your doctor may do blood tests to check your liver before you start LIPITOR and while you are taking it.

Call your doctor right away if you have:

- Unexplained muscle weakness or pain, especially if you have a fever or feel very tired
- Allergic reactions including swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing which may require treatment right away
- Nausea, vomiting, or stomach pain
- Brown or dark-colored urine
- Feeling more tired than usual
- Your skin and the whites of your eyes turn yellow
- Allergic skin reactions

Common side effects of LIPITOR are:

- Diarrhea
- Upset stomach
- Muscle and joint pain
- Changes in some blood tests

HOW TO TAKE LIPITOR

Do:

- Take LIPITOR as prescribed by your doctor.
- Try to eat heart-healthy foods while you take LIPITOR.
- Take LIPITOR at any time of day, with or without food.
- If you miss a dose, take it as soon as you remember. But if it has been more than 12 hours since your missed dose, wait. Take the next dose at your regular time.

Don't:

- Do not change or stop your dose before talking to your doctor.
- Do not start new medicines before talking to your doctor.
- Do not give your LIPITOR to other people. It may harm them even if your problems are the same.
- Do not break the tablet.

NEED MORE INFORMATION?

- Ask your doctor or health care provider.
- Talk to your pharmacist.
- Go to www.lipitor.com or call 1-888-LIPITOR.

Uninsured? Need help paying for Pfizer medicines? Pfizer has programs that can help. Call **1-866-706-2400** or visit **www.PfizerHelpfulAnswers.com**.

Pfizer helpful answers

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Rx only

PATIENT INFORMATION
LOVAZA® (lō-vā-zā)
(omega-3-acid ethyl esters) Capsules

LOVAZA®
omega-3-acid ethyl esters

Read the Patient Information that comes with LOVAZA before you start taking it, and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your condition or treatment.

What is LOVAZA?

LOVAZA is a prescription medicine, called a lipid-regulating medicine, for adults. LOVAZA is made of omega-3 fatty acids from oils of fish, such as salmon and mackerel. Omega-3 fatty acids are substances that your body needs but cannot produce itself.

LOVAZA is used along with a low-fat and low-cholesterol diet to lower very high triglycerides (fats) in your blood. Before taking LOVAZA, talk to your healthcare provider about how you can lower high blood fats by:

- losing weight, if you are overweight
- increasing physical exercise

Treatment with LOVAZA has not been shown to prevent heart attacks or strokes.

LOVAZA has not been studied in children under the age of 18 years.

What should I tell my doctor before taking LOVAZA?

Tell your doctor about all of your medical conditions and all the medicines you take, including prescription and non-prescription medicine, vitamins, and herbal supplements. LOVAZA and certain other medicines can interact causing serious side effects.

Especially tell your doctor if you take medicines:

- To reduce clotting–known as anticoagulants or blood thinners. These include aspirin, warfarin, coumarin and clopidogrel (PLAVIX®)

Tell your doctor if you are allergic to fish and/or shellfish. LOVAZA may not be right for you.

Who should NOT take LOVAZA?

Do not take LOVAZA if you:

- **are allergic to LOVAZA or any of its ingredients.**

What are the possible side effects of LOVAZA?

The most common side effects with LOVAZA are burping, infection, flu symptoms, upset stomach and change in sense of taste.

LOVAZA may affect certain blood tests. It may change:

- One of the tests to check liver function (ALT)
- One of the tests to measure cholesterol levels (LDL-C)

Talk to your doctor if you have side effects that bother you or that will not go away.

These are not all the side effects with LOVAZA. Ask your doctor or pharmacist for a complete list.

LOVAZA is a registered trademark of the GlaxoSmithKline group of companies.

PLAVIX is a registered trademark of Sanofi-Synthelabo.

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Research Triangle Park, NC 27709

September 2009

IMPORTANT FACTS

LYRICA® PREGABALIN © (LEER-i-kah)

IMPORTANT SAFETY INFORMATION ABOUT LYRICA

LYRICA may cause serious, even life threatening, allergic reactions. Stop taking LYRICA and call your doctor right away if you have any signs of a serious allergic reaction:
- Swelling of your face, mouth, lips, gums, tongue, throat or neck
- Have any trouble breathing
- Rash, hives (raised bumps) or blisters

Like other antiepileptic drugs, LYRICA may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.
Call your doctor right away if you have any symptoms, especially if they are new, worse or worry you, including:
- New or worsening depression
- Suicidal thoughts or actions
- Unusual changes in mood or behavior

Do not stop LYRICA without first talking with your doctor.
LYRICA may cause swelling of your hands, legs and feet.
This swelling can be a serious problem with people with heart problems.
LYRICA may cause dizziness or sleepiness.
Do not drive a car, work with machines, or do other dangerous things until you know how LYRICA affects you. Ask your doctor when it is okay to do these things.

ABOUT LYRICA

LYRICA is a prescription medicine used in adults 18 years and older to treat:
- Pain from damaged nerves that happens with diabetes or that follows healing of shingles
- Partial seizures when taken together with other seizure medicines
- Fibromyalgia (pain all over your body)

Who should NOT take LYRICA:
- Anyone who is allergic to anything in LYRICA

BEFORE STARTING LYRICA

Tell your doctor about all your medical conditions, including if you:
- Have had depression, mood problems or suicidal thoughts or behavior
- Have or had kidney problems or dialysis
- Have heart problems, including heart failure
- Have a bleeding problem or a low blood platelet count
- Have abused prescription medicines, street drugs or alcohol in the past
- Have ever had swelling of your face, mouth, tongue, lips, gums, neck, or throat (angioedema)
- Plan to father a child. It is not known if problems seen in animal studies can happen in humans.
- Are pregnant, plan to become pregnant or are breastfeeding. It is not known if LYRICA will harm your unborn baby. You and your doctor should decide whether you should take LYRICA or breast-feed, but not both.

Tell your doctor about all your medicines. Include over-the-counter medicines, vitamins, and herbal supplements.
LYRICA and other medicines may affect each other causing side effects. Especially tell your doctor if you take:
- Angiotensin converting enzyme (ACE) inhibitors. You may have a higher chance for swelling and hives

BEFORE STARTING LYRICA, continued

- Avandia® (rosiglitazone)*, Avandamet® (rosiglitazone and metformin)* or Actos® (pioglitazone)** for diabetes. You may have a higher chance of weight gain or swelling of your hands or feet.
- Narcotic pain medicines (such as oxycodone), tranquilizers or medicines for anxiety (such as lorazepam). You may have a higher chance for dizziness and sleepiness.
- Any medicines that make you sleepy

POSSIBLE SIDE EFFECTS OF LYRICA

LYRICA may cause serious side effects, including:
- See "Important Safety Information About LYRICA."
- Muscle problems, pain, soreness or weakness along with feeling sick and fever
- Eyesight problems including blurry vision
- Weight gain. Weight gain may affect control of diabetes and can be serious for people with heart problems.
- Feeling "high"

If you have any of these symptoms, tell your doctor right away.
The most common side effects of LYRICA are:
- Dizziness
- Blurry vision
- Weight gain
- Sleepiness
- Trouble concentrating
- Swelling of hands and feet
- Dry mouth

If you have diabetes, you should pay extra attention to your skin while taking LYRICA and tell your doctor of any sores or skin problems.

HOW TO TAKE LYRICA

Do:
- Take LYRICA exactly as your doctor tells you. Your doctor will tell you how much to take and when to take it.
- Take LYRICA at the same times each day.
- Take LYRICA with or without food.

Don't:
- Drive a car or use machines if you feel dizzy or sleepy while taking LYRICA.
- Drink alcohol or use other medicines that make you sleepy while taking LYRICA.
- Change the dose or stop LYRICA suddenly. You may have headaches, nausea, diarrhea, or trouble sleeping if you stop taking LYRICA suddenly.
- Start any new medicines without first talking to your doctor.

NEED MORE INFORMATION?

- Ask your doctor or pharmacist. This is only a brief summary of important information.
- Go to www.lyrica.com or call 1-866-459-7422 (1-866-4LYRICA).

Uninsured? Need help paying for Pfizer medicines? Pfizer has programs that can help. Call **1-866-706-2400** or visit www.PfizerHelpfulAnswers.com.

Pfizer helpful answers

PARKE–DAVIS, Division of Pfizer Inc , New York, NY 10017

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Rx only

IMPORTANT INFORMATION ABOUT SYMBICORT

Please read this summary carefully and then ask your doctor about SYMBICORT.

No advertisement can provide all the information needed to determine if a drug is right for you or take the place of careful discussions with your health care professional. Only your health care professional has the training to weigh the risks and benefits of a prescription drug.

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT SYMBICORT?

In patients with asthma, long-acting beta$_2$-agonist (LABA) medicines, such as formoterol (one of the medicines in SYMBICORT), may increase the chance of death from asthma problems. In a large asthma study, more patients who used another LABA medicine died from asthma problems, compared with patients who did not use that LABA medicine. Talk with your health care professional about this risk and the benefits of treating your asthma with SYMBICORT

SYMBICORT does not relieve sudden symptoms, so you should always have a fast-acting inhaler (short-acting beta$_2$-agonist medicine) with you. If you do not have this type of inhaler, talk with your health care professional to have one prescribed for you.

Get emergency medical care if your breathing problems worsen quickly and your fast-acting inhaler does not relieve them.

Do not stop using SYMBICORT unless your health care professional tells you to stop because your symptoms might get worse.

WHAT IS SYMBICORT?

SYMBICORT is an inhaled prescription medicine taken twice a day, every day, over long periods of time to control asthma and chronic obstructive pulmonary disease (COPD).

Asthma

SYMBICORT 80/4.5 mcg or 160/4.5 mcg is used long-term, two times each day, to control symptoms of asthma and prevent symptoms such as wheezing in patients age 12 years and older.

Chronic Obstructive Pulmonary Disease

COPD is a chronic lung disease that includes chronic bronchitis, emphysema, or both. SYMBICORT 160/4.5 mcg is used every day, two times each day, to help improve lung function for better breathing in adults with COPD.

SYMBICORT contains two medicines:

- Budesonide (the same medicine found in PULMICORT FLEXHALER® [budesonide inhalation powder]), an inhaled corticosteroid medicine or ICS. ICS medicines help to decrease inflammation in the lungs. Inflammation in the lungs can lead to asthma symptoms
- Formoterol (the same medicine found in Foradil® Aerolizer®) is a long-acting beta$_2$-agonist medicine, or LABA. LABA medicines are used in patients with COPD and asthma. LABA medicines help the muscles in the airways of your lungs stay relaxed to prevent asthma symptoms, such as wheezing and shortness of breath. These symptoms can happen when the muscles in the airways tighten. This makes it hard to breathe, which, in severe cases, can cause breathing to stop completely if not treated right away

WHO SHOULD NOT TAKE SYMBICORT?

You should not take SYMBICORT if your health care professional decides that your asthma or COPD is well controlled using another medicine, or you only use a fast-acting inhaler once in a while.

Do not use SYMBICORT to treat sudden severe symptoms of asthma or COPD or if you are allergic to any of the ingredients in SYMBICORT

WHAT SHOULD I TELL MY HEALTH CARE PROFESSIONAL BEFORE USING SYMBICORT?

Tell your health care professional about all of your health conditions, including if you

- have heart problems
- have high blood pressure
- have seizures
- have thyroid problems
- have diabetes
- have liver problems
- have osteoporosis
- have an immune system problem
- are allergic to any medications
- are exposed to chicken pox or measles
- are pregnant or planning to become pregnant because it is not known if SYMBICORT may harm your unborn baby
- are breast-feeding because it is not known if SYMBICORT passes into your milk and if it can harm your baby. You and your health care professional should decide if you will be taking SYMBICORT while breast-feeding

Tell your health care professional about ALL the medicines you are taking, including all your prescription and nonprescription medicines, vitamins, and herbal supplements.

SYMBICORT and certain other medicines may interact with each other and can cause serious side effects. Be sure to keep track of ALL the medication you take. You might want to make a list and show it to your health care professional, including your pharmacist, each time you get any new medicine. Just to be sure there are no potential drug interactions

HOW DO I USE SYMBICORT?

Do not use SYMBICORT unless your health care professional has carefully demonstrated how to do so. If you have any questions concerning the use of SYMBICORT, ask your health care professional.

SYMBICORT should be taken twice (2 puffs each time) every day as prescribed by your health care professional.

SYMBICORT comes in two strengths for asthma: 80/4.5 mcg and 160/4.5 mcg. Your health care professional will prescribe the strength that is best for you. SYMBICORT 160/4.5 mcg is the approved dosage for COPD.

- Make sure that you rinse your mouth with water after each dose (two puffs) of SYMBICORT without swallowing and spit the water out
- Do not change or stop any of the medicines you use to control or treat your breathing problems. Your health care professional will adjust your medicines as needed
- Do not spray SYMBICORT in your eyes. If you accidentally get SYMBICORT in your eyes, rinse your eyes with water. If redness or irritation persists, call your health care professional
- Always have a fast-acting inhaler with you. Use it if you have breathing problems between doses of SYMBICORT

Seek emergency medical care if

- your breathing problems worsen quickly and your fast-acting inhaler does not relieve your breathing problems
- you experience any symptoms of a serious allergic reaction to SYMBICORT, such as a rash; hives; swelling of the face, mouth, or tongue; or breathing problems

Contact your health care professional if

- you need to use your fast-acting inhaler more often than usual
- your fast-acting inhaler does not work as well for you at relieving symptoms
- you need to use four or more inhalations of your fast-acting inhaler for 2 or more days in a row
- you use up your entire fast-acting inhaler canister within 8 weeks
- your peak-flow meter results decrease. Your health care professional will tell you the numbers that are right for you
- your asthma symptoms do not improve after using SYMBICORT regularly for 1 week
- you have COPD and notice any symptoms such as increase in mucus or change in mucus color, fever, chills, increased cough, or increased breathing problems because these symptoms may mean you have pneumonia or another lung infection

WHAT MEDICATIONS SHOULD I NOT TAKE WHEN USING SYMBICORT?

While you are using SYMBICORT, do not use other medicines that contain a long-acting beta$_2$-agonist (LABA) for any reason, such as

- Serevent® Diskus® (salmeterol xinafoate inhalation powder)
- Advair Diskus® or Advair® HFA (fluticasone propionate and salmeterol)
- Formoterol-containing products such as Foradil® Aerolizer®, Brovana® or Perforomist®

WHAT ARE OTHER IMPORTANT SAFETY CONSIDERATIONS WITH SYMBICORT?

- Increased risk of pneumonia if you have COPD
- Eye problems, such as glaucoma and cataracts. Regular eye exams should be considered while using SYMBICORT
- Osteoporosis. People at risk for increased bone loss may have a greater risk with SYMBICORT
- Slowed growth in children. As a result, growth should be carefully monitored
- Immune system effects and a higher chance for infections
- Cardiovascular and central nervous system effects of LABAs, such as chest pain, increased blood pressure, fast or irregular heartbeat, tremor, or nervousness

WHAT ARE OTHER POSSIBLE SIDE EFFECTS WITH SYMBICORT?

Adults and children age 12 years and older with asthma

- Headache
- Sore throat
- Oral thrush
- Upper respiratory tract infection

Patients with COPD

- Oral thrush

Long-acting beta$_2$-agonists may increase the risk of asthma-related death. Tell your health care professional about any side effect that bothers you or that does not go away. These are not all the side effects with SYMBICORT. Ask your health care professional for more information.

NOTE: This summary provides important information about SYMBICORT. For more information, please ask your doctor or health care professional about the full Prescribing Information and discuss it with him or her.

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By: AstraZeneca AB, Dunkerque, France Product of France
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Visit www.MySymbicort.com.
Or, call 1-866-SYMBICORT

Symbicort®
(budesonide/formoterol fumarate dihydrate)
Inhalation Aerosol

AstraZeneca

Patient Information
UROXATRAL®
(Alfuzosin hydrochloride extended-release tablets)

Read the Patient Information that comes with UROXATRAL before you start using it and each time you get a refill There may be new information. This leaflet does not take the place of talking with your doctor about your condition or your treatment. You and your doctor should talk about all your medicines, including UROXATRAL, now and at your regular checkups.

What is the most important information I should know about UROXATRAL?

UROXATRAL can cause:

- **a sudden drop in blood pressure, especially when you start treatment. This may lead to fainting, dizziness, or lightheadedness. Do not drive, operate machinery, or do any dangerous activities until you know how UROXATRAL affects you. This is especially important if you already have a problem with low blood pressure or take medicines to treat high blood pressure. If you begin to feel dizzy or lightheaded, lie down with your legs and feet up, and if your symptoms do not improve call your doctor.**

What is UROXATRAL?

UROXATRAL is a prescription medicine that is called an "alpha-blocker". UROXATRAL is used in adult men to treat the symptoms of benign prostatic hyperplasia (BPH) UROXATRAL may help to relax the muscles in the prostate and the bladder which may lessen the symptoms of BPH and improve urine flow.

Before prescribing UROXATRAL, your doctor may examine your prostate gland and do a blood test called a prostate specific antigen (PSA) test to check for prostate cancer. Prostate cancer and BPH can cause the same symptoms Prostate cancer needs a different treatment

UROXATRAL is not for use in women or children

Some medicines called "alpha-blockers" are used to treat high blood pressure UROXATRAL has not been studied for the treatment of high blood pressure.

Who should not take UROXATRAL?

Do not take UROXATRAL if you:

- have liver problems
- are taking antifungal drugs like ketoconazole or HIV drugs called protease inhibitors
- are already taking an alpha-blocker for either high blood pressure or prostate problems
- are a woman
- are a child under the age of 18
- are allergic to UROXATRAL. The active ingredient is alfuzosin hydrochloride See the end of this leaflet for a complete list of ingredients in UROXATRAL

Before taking UROXATRAL, tell your doctor:

- if you have liver problems
- if you have kidney problems
- if you or any family members have a rare heart condition known as congenital prolongation of the QT interval
- about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Some of your other medicines may affect the way you respond or react to UROXATRAL.
- if you have had low blood pressure, especially after taking another medicine. Signs of low blood pressure are fainting, dizziness, and lightheadedness
- if you have a heart problem called angina (pain in your chest, jaw, or arm)

What you need to know while taking UROXATRAL (alfuzosin HCl) tablets

- If you have an eye surgery for cataract (clouding of the eye) planned, tell your ophthalmologist that you are using UROXATRAL or have previously been treated with an alpha-blocker

How do I take UROXATRAL?

- Take UROXATRAL exactly as your doctor prescribes it.
- Take one UROXATRAL tablet after the same meal each day. UROXATRAL should be taken just after eating food Do not take it on an empty stomach.
- Swallow the UROXATRAL tablet whole Do not crush, split, or chew UROXATRAL tablets
- If you take too much UROXATRAL call your local poison control center or emergency room right away

What are the possible side effects of UROXATRAL?

The most common side effects with UROXATRAL are:

- dizziness
- headache
- tiredness

Call your doctor if you get any side effect that bothers you

These are not all the side effects of UROXATRAL For more information ask your doctor or pharmacist

How do I store UROXATRAL?

Store UROXATRAL between 59°F and 86°F (15°C and 30°C)

Protect from light and moisture

Keep UROXATRAL and all medicines out of the reach of children.

General information about UROXATRAL:

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use UROXATRAL for a condition for which it was not prescribed. Do not give UROXATRAL to other people, even if they have the same symptoms you have It may harm them

This leaflet summarizes the most important information about UROXATRAL. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about UROXATRAL that is written for health professionals

You may also visit our website at www UROXATRAL com or call 1-800-446-6267

What are the ingredients of UROXATRAL?

Active Ingredient: alfuzosin hydrochloride

Inactive Ingredients: colloidal silicon dioxide (NF), ethylcellulose (NF), hydrogenated castor oil (NF), hydroxypropyl methylcellulose (USP), magnesium stearate (NF), mannitol (USP), microcrystalline cellulose (NF), povidone (USP), and yellow ferric oxide (NF)

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Rx Only

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