INFORMATION FOR PATIENTS
Ambien CR® (zolpidem tartrate 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 different types of medicines available to help people sleep better. Sleep problems are usually temporary, requiring treatment for only a short time, usually 1 to 2 days up to 1 to 2 weeks. Some people have chronic sleep problems that may require a larger use of 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
- oversedation (sleepiness)
- dizziness
You may feel that these medicines make you sleepy during the day. How long this feeling depends upon how your body responds to the medicine, which sleep medicine you are taking, and how long a dose your doctor has prescribed. Oversedation is most 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 right 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 soporific effect in you in the next day, use extreme care while doing anything that requires complete alertness, such as driving a car, operating machinery, or piloting an aircraft.
- Take lower doses of medicine while you are being treated with Ambien CR® or any other 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 must be 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.

SIDE EFFECTS
There are some specific 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 asleep. Be sure to talk to your doctor before you use Ambien CR® if you are at risk for this behavior, especially if you have a history of sleepwalking, sleep eating, or sleep terror.
- Inability to get out of bed: If you start feeling sleepy or tired after you take your Ambien CR® dose, you may need to take more days off from work or school.
- Memory problems: Sleep medicine 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. And 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 trying to eat or drive, especially if you have a history of sleepwalking, sleep eating, or sleep terror.
- Tolerance: When sleep medicines are used every night or 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 to 2 days and generally no longer than 7 to 10 nights if your sleep problems continue. Consult your doctor who will determine whether other measures are needed to treat your sleep problems.
- Dependence: Sleep medicines can cause dependence, especially when these medicines are used regularly for a longer time and at high doses. People who increase the dose of sleep medicine more quickly may develop this problem. In contrast, if the dose of already used on a particular medicine or have any questions about the medicine, call your doctor or pharmacist.

INFORMATION FOR PATIENTS
AMBENCR® (zolpidem tartrate extended-release tablets)

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 other 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, nay more severe cases, anxiety, and muscle tremors, vomiting, sweating, shaking, and rarely neuroses may occur. These symptoms are called "rebound insomnia." This is not to say that a person may not 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 to 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 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 include:
- more outgoing or aggressive behavior than normal
- confusion
- strange behavior
- agitation
- hallucinations
- worsening of depression
- suicidal thoughts

How these other effects occur depends on several factors, such as a person's general health and 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 being caused by the medicine or by the problem that was 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 a pregnant woman or if you are planning to become pregnant or if you become pregnant while taking Ambien CR®.

SAFETY IN DRIVING, MECHANICAL MACHINES, OR OPERATING MACHINERY

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 feeling of your body or throat swelling, stop taking Ambien CR or any other sleep medicine until you get medical help.

4. Be sure to tell your doctor all about your medicines, both prescription and over-the-counter, before you start taking Ambien CR.

5. Your doctor will need to tell you about the other medicines you take, including medicines that may cause a sedation of the unborn baby when used during the last weeks of pregnancy. Be sure to tell your doctor if you are a pregnant woman or if you are planning to become pregnant or if you become pregnant while taking Ambien CR®.

6. Be sure to tell your doctor if you are taking any alcohol or drugs that may cause sedation of the unborn baby when used during the last weeks of pregnancy. Be sure to tell your doctor if you are a pregnant woman or if you are planning to become pregnant or if you become pregnant while taking Ambien CR®.

7. Be sure to tell your doctor if you are taking any alcohol or drugs that may cause sedation of the unborn baby when used during the last weeks of pregnancy. Be sure to tell your doctor if you are a pregnant woman or if you are planning to become pregnant or if you become pregnant while taking Ambien CR®.

8. Be sure to tell your doctor if you are taking any alcohol or drugs that may cause sedation of the unborn baby when used during the last weeks of pregnancy. Be sure to tell your doctor if you are a pregnant woman or if you are planning to become pregnant or if you become pregnant while taking Ambien CR®.

9. Be sure to tell your doctor if you are taking any alcohol or drugs that may cause sedation of the unborn baby when used during the last weeks of pregnancy. Be sure to tell your doctor if you are a pregnant woman or if you are planning to become pregnant or if you become pregnant while taking Ambien CR®.

10. Do not take Ambien CR® until you are allowed by your doctor. If you start taking Ambien CR® or any other sleep medicine when Ambien CR® was not taken for an appropriate number of days, the amount of medicine in your body may not be enough to prevent withdrawal symptoms.

11. Do not take Ambien CR® until you are allowed by your doctor. If you start taking Ambien CR® or any other sleep medicine when Ambien CR® was not taken for an appropriate number of days, the amount of medicine in your body may not be enough to prevent withdrawal symptoms.

12. Ambien CR works quickly. You should only take Ambien CR® right before going to bed and are ready to go to sleep.
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 16 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 Type 2 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 diabetes ("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 a day 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; however, 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 cells or anemia. Your blood count may be low. Call your doctor if you have unusual bleeding or bruising.
- 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°F to 86°F (15°C 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 this patient information leaflet. 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 1-888-625-6249 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.

GlaxoSmithKline
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CELEBREX<sup>®</sup>
(celcoxib 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.

The 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 "steroids" and "antiplatelet agents"
- 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
- if you have a heart attack or stroke 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 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)?

**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

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
- skin rash or blisters with fever
- unusual weight gain
- swelling of the 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:

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Trade Name</th>
</tr>
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<tbody>
<tr>
<td>Celecoxib</td>
<td>Celebrex</td>
</tr>
<tr>
<td>Diclofenac</td>
<td>Cataflam, Voltaren, Arthrotec (combined with misoprostol)</td>
</tr>
<tr>
<td>Diflunisal</td>
<td>Dolobid</td>
</tr>
<tr>
<td>Etodolac</td>
<td>Lodine, Lodine XL</td>
</tr>
<tr>
<td>Fenoprofen</td>
<td>Nalfon, Nalfon 210</td>
</tr>
<tr>
<td>Flurbiprofen</td>
<td>Ansaid</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>Motrin, Ibu-Profen, Vicoprofen* (combined with hydrocodone), Combipain (combined with oxycodeone)</td>
</tr>
<tr>
<td>Indomethacin</td>
<td>Indocin, Indocin SR, Indocin-Low, Indocin-Hemagen</td>
</tr>
<tr>
<td>Ketoprofen</td>
<td>Orudis</td>
</tr>
<tr>
<td>Ketorolac</td>
<td>Toradol</td>
</tr>
<tr>
<td>Mefenamic Acid</td>
<td>Ponsel</td>
</tr>
<tr>
<td>Meloxicam</td>
<td>Mobic</td>
</tr>
<tr>
<td>Naproxen</td>
<td>Naprosyn, Anaprox, Anaprox US, EC-Naproxyn, Naprosyn, Naprosyn (extended-release with misoprostol)</td>
</tr>
<tr>
<td>Oxicam</td>
<td>Oxyproz</td>
</tr>
<tr>
<td>Piroxicam</td>
<td>Feldene</td>
</tr>
<tr>
<td>Sulindac</td>
<td>Clinoril</td>
</tr>
<tr>
<td>Tolmetin</td>
<td>Toletin, Toletin DS, Toletin 600</td>
</tr>
</tbody>
</table>

*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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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 glucose, 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 OptiClick (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

LOWER YOUR HIGH CHOLESTEROL
High cholesterol is more than just a number; it's a risk factor that should not be ignored. If your doctor says 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 LIPTOR, 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

POSSIBLE SIDE EFFECTS OF LIPTOR
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 other medicines with LIPTOR.
- Liver problems. Your doctor may do blood tests to check your liver before you start LIPTOR 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 LIPTOR are:
- Diarrhea
- Muscle and joint pain
- Upset stomach
- Changes in some blood tests

WHO IS LIPTOR FOR?
Who can take LIPTOR:
- People who cannot lower their cholesterol enough with diet and exercise
- Adults and children over 10

Who should NOT take LIPTOR:
- Women who are pregnant or may become pregnant. LIPTOR may harm your unborn baby. If you become pregnant while taking LIPTOR, stop LIPTOR and call your doctor right away.
- Women who are breastfeeding. LIPTOR can pass into your breast milk and may harm your baby.
- People with liver problems
- People allergic to anything in LIPTOR

BEFORE YOU START LIPTOR
Tell your doctor:
- About all the medicines you take, including prescription, over-the-counter medications 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 LIPTOR
LIPTOR is a prescription medicine. Along with diet and exercise, it lowers "bad" cholesterol in your blood. It can also raise "good" cholesterol (HDL-C).

LIPTOR can lower the risk of heart attack, stroke, certain types of heart surgery, and best 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.

LIPTOR 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.

HOW TO TAKE LIPTOR
Do:
- Take LIPTOR as prescribed by your doctor.
- Try to eat heart-healthy foods while you take LIPTOR.
- Take LIPTOR 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 LIPTOR to other people. It may harm them even if their 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.liptor.com or call 1-888-LIPTOR

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

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Rx only

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New York, NY 10017 USA
June 2009
What is LOVZA? LOVZA is a prescription medication. LOVZA's active ingredient isLovaza 3-golden bass fish oil. LOVZA is used for the treatment of hypercholesterolemia in adults. Before taking LOVZA, tell your doctor if you have:

- A history of liver disease
- A history of kidney disease
- A history of heart disease

Do not take LOVZA if you:

- Are allergic to any components of LOVZA
- Have had liver or kidney problems

Tell your doctor if you:

- Have any medical conditions
- Are taking any other medications
- Are pregnant or breastfeeding

What should I avoid while taking LOVZA? LOVZA may affect how other medications work. Before taking LOVZA, tell your doctor about all your medications. LOVZA may affect other medications that cause bleeding, such as aspirin, warfarin, and clopidogrel.

What should I consider before having surgery while taking LOVZA? LOVZA may interact with certain medications and cause bleeding. Before having surgery while taking LOVZA, tell your doctor about all your medications.

What are the possible side effects of LOVZA? LOVZA may cause side effects such as:

- Headache
- Dizziness
- Fatigue

What is the most important information I should know about LOVZA? LOVZA is a prescription medication. LOVZA's active ingredient is Lovaza 3-golden bass fish oil. LOVZA is used for the treatment of hypercholesterolemia in adults. Before taking LOVZA, tell your doctor if you have:

- A history of liver disease
- A history of kidney disease
- A history of heart disease

Do not take LOVZA if you:

- Are allergic to any components of LOVZA
- Have had liver or kidney problems

Tell your doctor if you:

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IMPORTANT FACTS

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 take LYRICA if you 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.

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 of 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, weakness or weakness along with feeling sick and fever
- Eyeight 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
- Trouble concentrating
- Blurry vision
- Swelling of hands and feet
- Weight gain
- Dry mouth
- Nausea
- Rash
- Headache
- Insomnia
- If you have diabetes, you should pay extra attention to your skin while taking LYRICA and tell your doctor of any sore 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 sway while taking LYRICA.
- Drink alcohol or use other medicines that make you sleepy, while taking LYRICA.
- Change the dose of or stop LYRICA suddenly.
- Add or stop 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).

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IMPORTANT INFORMATION ABOUT SYMBCORT

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

An 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 healthcare professional. Only your healthcare provider has the training to weigh the risks and benefits of a prescription drug.

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT SYMBCORT?
In patients with asthma, long-acting beta-agonist (LABA), medications, such as formoterol fumarate (one of the medications in SYMBCORT) may increase the chance of death from asthma problems, compared with patients who did not use LABA medications. Talk with your healthcare professional about this risk and the benefits of treating your asthma with SYMBCORT.

SYMBCORT does not relieve sudden symptoms, so you should always have a fast-acting inhaler (short-acting beta-agonist) medication with you. If you do not have this type of inhaler, talk with your healthcare 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 SYMBCORT unless your healthcare professional tells you to do so because your symptoms might get worse.

WHAT IS SYMBCORT?
SYMBCORT is a prescription medicine taken once a day. Each day, a long period of time before exercise and chronic obstructive pulmonary disease (COPD).

SYMBCORT contains two medications:
- Salmeterol is a long-acting beta-agonist (LABA) medication. LABA medications are used in patients with COPD and asthma. LABA medications help to keep the muscles in the bronchi relaxed and keep the airways open.
- Formoterol is a short-acting beta-agonist (SABA) medication. SABA medications work quickly to relax the muscles in the bronchi, helping to open the airways faster and more completely.

SYMBCORT comes in two strengths for asthma: 125 mcg and 250 mcg for COPD:
- 212 mcg for children:
- 212 mcg for adults:
- 212 mcg for children:
- 212 mcg for adults:

WHAT SHOULD I TELL MY HEALTHCARE PROFESSIONAL BEFORE USING SYMBCORT?
Tell your healthcare professional about all of your health conditions, including:
- Heart problems
- High blood pressure
- Ulcers
- Thyroid problems
- Diabetes
- Ulcers
- Osteoporosis
- Anemia
- Allergy to any medications
- Exposure to dust or mold
- Pregnancy or planning to become pregnant because it is not known if SYMBCORT can harm your unborn baby
- Breast-feeding because it is not known if SYMBCORT passes into your milk and can harm your baby. You and your healthcare professional should decide if you will breast-feeding while taking SYMBCORT.

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

SYMBCORT is not for use in children. If you get your medicine in a new bottle, you may not have a new medicine. Just because there are no potential drug interactions.

HOW DO I USE SYMBCORT?
Do not use SYMBCORT unless your healthcare professional has carefully demonstrated how to do it. If you have any questions, ask your pharmacist about SYMBCORT. Ask your healthcare professional if you should take SYMBCORT or not. Every day as prescribed by your healthcare professional.

SYMBCORT contains two medications:
- Salmeterol (a short-acting beta-agonist) does not work as long as formoterol (a long-acting beta-agonist) does. When using LABA and SABA together for the first time, it may take up to 1 month for your healthcare professional to adjust your medicine as needed.

WHO SHOULDN'T TAKE SYMBCORT?
You should not take SYMBCORT if you have asthma or other lung disease that cannot be controlled with another medicine, if you only use a fast-acting inhaler once or a day, and if you have severe asthma or COPD.

To reduce SYMBCORT to treat sudden severe symptoms of asthma or COPD or if you are allergic to any of the ingredients in SYMBCORT.

Contact your healthcare 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 when you are waking.
- You need to use your fast-acting inhaler less than twice per day.
- You need to use your fast-acting inhaler more than once per day.

WHAT MEDICATIONS SHOULD I NOT TAKE WHEN USING SYMBCORT?
- Do not take any medication that contains a long-acting beta-agonist (LABA) or a long-acting beta-agonist (LABA) is used in patients with COPD and asthma. LABA medications help to keep the muscles in the bronchi relaxed and keep the airways open.

WHAT ARE OTHER IMPORTANT SAFETY CONSIDERATIONS WITH SYMBCORT?
- Use your fast-acting inhaler once a day as prescribed by your healthcare professional.
- Do not use SYMBCORT unless your healthcare professional has carefully demonstrated how to do it. If you have any questions, ask your pharmacist about SYMBCORT. Ask your healthcare professional if you should take SYMBCORT or not. Every day as prescribed by your healthcare professional.

WHAT ARE OTHER POSSIBLE SIDE EFFECTS WITH SYMBCORT?
- Severe asthma or COPD:
- Severe chest tightness:
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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 had. 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 1-800-446-0287.

What are the ingredients of UROXATRAL?

Active Ingredient: alfuzosin hydrochloride

Inactive Ingredients: colloidal silicon dioxide (NF), ethylcellulose (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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sanofi-aventis U.S. LLC
Bridgewater, NJ 08807

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