

MEDICATION GUIDE
AVANDARYL® (ah-VAN-duh-riil)
(rosiglitazone maleate and glimepiride) Tablets

Read this Medication Guide carefully before you start taking AVANDARYL 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 AVANDARYL, ask your doctor or pharmacist.

What is the most important information I should know about AVANDARYL? AVANDARYL may cause serious side effects, including:

AVANDARYL is available only through the AVANDIA-Rosiglitazone Medicines Access Program. Both you and your doctor must be enrolled in the program so that you can get AVANDARYL. To enroll, you must:

- talk to your doctor,
- understand the risks and benefits of AVANDARYL, and
- agree to enroll in the program.

New or worse heart failure

- Rosiglitazone, one of the two drugs that make up AVANDARYL, can cause your body to keep extra fluid (fluid retention), which leads to swelling (edema) and weight gain. Extra body fluid can make some heart problems worse or lead to heart failure. Heart failure means your heart does not pump blood well enough.
- If you have severe heart failure, you cannot start AVANDARYL.
- If you have heart failure with symptoms (such as shortness of breath or swelling), even if these symptoms are not severe, AVANDARYL may not be right for you.

Call your doctor right away if you have any of the following:

- 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

Myocardial Infarction (“Heart Attack”)

Rosiglitazone, one of the medicines in AVANDARYL, may raise the risk of heart attack. The risk of having a heart attack may be higher in people who take

AVANDARYL with insulin. Most people who take insulin should not also take AVANDARYL.

Symptoms of a heart attack can include the following:

- chest discomfort in the center of your chest that lasts for more than a few minutes, or that goes away or comes back
- chest discomfort that feels like uncomfortable pressure, squeezing, fullness or pain
- pain or discomfort in your arms, back, neck, jaw or stomach
- shortness of breath with or without chest discomfort
- breaking out in a cold sweat
- nausea or vomiting
- feeling lightheaded

Call your doctor or go to the nearest hospital emergency room right away if you think you are having a heart attack.

People with diabetes have a greater risk for heart problems. It is important to work with your doctor to manage other conditions, such as high blood pressure or high cholesterol.

AVANDARYL can have other serious side effects. Be sure to read the section "What are possible side effects of AVANDARYL?".

What is AVANDARYL?

AVANDARYL contains 2 prescription medicines to treat diabetes, rosiglitazone maleate (AVANDIA) and glimepiride (AMARYL). AVANDARYL is used with diet and exercise to treat certain adults with type 2 ("adult-onset" or "non-insulin dependent") diabetes mellitus ("high blood sugar") who are:

- already taking rosiglitazone or rosiglitazone-containing products
- unable to control their blood sugar on other diabetes medicines, and after talking with their doctor have decided not to take pioglitazone (ACTOS) or pioglitazone-containing products (ACTOPLUS MET, ACTOPLUS MET XR, DUETACT)

Glimepiride can help your body release more of its own insulin. Rosiglitazone can help your body respond better to the insulin made in your body and does not cause your body to make more insulin. These medicines can work together to help control your blood sugar.

AVANDARYL is not for people with type 1 diabetes mellitus or to treat a condition called diabetic ketoacidosis.

It is not known if AVANDARYL is safe and effective in children under 18 years old.

Who should not take AVANDARYL?

Many people with heart failure should not start taking AVANDARYL (see “What should I tell my doctor before taking AVANDARYL?”).

What should I tell my doctor before taking AVANDARYL?

Before starting AVANDARYL, ask your doctor about what the choices are for diabetes medicines and what the expected benefits and possible risks are for you in particular.

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

- **have heart problems or heart failure.**
- **have type 1 (“juvenile”) diabetes or had diabetic ketoacidosis.** These conditions should be treated with insulin and should not be treated with AVANDARYL.
- **have a type of diabetic eye disease called macular edema** (swelling of the back of the eye).
- **have liver problems.** Your doctor should do blood tests to check your liver before you start taking AVANDARYL and during treatment as needed.
- **had liver problems while taking REZULIN[®] (troglitazone), another medicine for diabetes.**
- **have kidney problems.** If people with kidney problems use AVANDARYL, they may need a lower dose of the medication.
- **have glucose 6-phosphate dehydrogenase (G6PD) deficiency.** This condition runs in families. People with G6PD deficiency who take glimepiride (one of the medicines in AVANDARYL) may develop hemolytic anemia (fast breakdown of red blood cells).
- **are pregnant or plan to become pregnant.** AVANDARYL should not be used during pregnancy. It is not known if AVANDARYL can harm your unborn baby. You and your doctor should talk about the best way to control your diabetes during pregnancy. If you are a premenopausal woman (before the “change of life”) who does not have regular monthly periods, AVANDARYL may increase your chances of becoming pregnant. Talk to your doctor about birth control choices while taking AVANDARYL. Tell your doctor right away if you become pregnant while taking AVANDARYL.

- **are breast-feeding or planning to breast-feed.** It is not known if AVANDARYL passes into breast milk. You should not use AVANDARYL while breast-feeding.

Tell your doctor about all the medicines you take including prescription and non-prescription medicines, vitamins or herbal supplements. AVANDARYL and certain other medicines can affect each other and may lead to serious side effects including high or low blood sugar, or heart problems. Especially tell your doctor if you take:

- **insulin.**
- **any medicines for high blood pressure, high cholesterol or heart failure, or for prevention of heart disease or stroke.**

Know the medicines you take. Keep a list of all your medicines and show it to your doctor and pharmacist before you start a new medicine. They will tell you if it is alright to take AVANDARYL with other medicines.

How should I take AVANDARYL?

- Take AVANDARYL exactly as prescribed. Your doctor may need to change your dose until your blood sugar is better controlled.
- Take AVANDARYL by mouth one time each day with your first main meal.
- It usually takes a few days for AVANDARYL to start lowering your 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 AVANDARYL, take it 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 double doses to make up for a missed dose.
- If you take too much AVANDARYL, call your doctor or poison control center right away.
- Test your blood sugar regularly as your doctor tells you.
- Your doctor should do blood tests to check your liver before you start AVANDARYL and during treatment as needed. Your doctor should also do regular blood sugar tests (for example, "A1c") to monitor your response to AVANDARYL.
- Call your doctor if you get sick, get injured, get an infection, or have surgery. AVANDARYL may not control your blood sugar levels during these times. Your doctor may need to stop AVANDARYL for a short time and give you insulin to control your blood sugar level.
- Diet and exercise can help your body use its blood sugar better. It is important to stay on your recommended diet, lose extra weight, and get regular exercise while taking AVANDARYL.

What are possible side effects of AVANDARYL?

AVANDARYL may cause serious side effects, including:

- **New or worse heart failure.** See “What is the most important information I should know about AVANDARYL?”.
- **Heart attack.** See “What is the most important information I should know about AVANDARYL?”.
- **Swelling (edema).** AVANDARYL can cause swelling due to fluid retention. See “What is the most important information I should know about AVANDARYL?”.
- **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, drink alcohol, use another medicine that lowers blood sugar, exercise (particularly hard or long), or if you have certain medical problems. Call your doctor if low blood sugar levels are a problem for you.
- **Weight gain.** Rosiglitazone, one of the medicines in AVANDARYL, 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. See “What is the most important information I should know about AVANDARYL?”.
- **Liver problems.** It is important for your liver to be working normally when you take AVANDARYL. Your doctor should do blood tests to check your liver before you start taking AVANDARYL 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.
- **Macular edema** (a diabetic eye disease with swelling in the back of the eye). Tell your doctor right away if you have any changes in your vision. Your doctor should check your eyes regularly. Very rarely, some people have had vision changes due to swelling in the back of the eye while taking rosiglitazone, one of the medicines in AVANDARYL.
- **Fractures (broken bones),** usually in the hand, upper arm or foot. Talk to your doctor for advice on how to keep your bones healthy.
- **Low red blood cell count (anemia).**
- **Ovulation** (release of egg from an ovary in women) leading to pregnancy. Ovulation may happen in premenopausal women who do not have regular monthly periods. This can increase the chance of pregnancy. See “What should I tell my doctor before taking AVANDARYL?”.

The most common side effects with AVANDARYL include cold-like symptoms and headache.

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

How should I store AVANDARYL?

- Store AVANDARYL at room temperature, 59° to 86° F (15° to 30° C). Keep AVANDARYL in the container it comes in. Keep the container closed tightly.
- Safely, throw away AVANDARYL that is out of date or no longer needed.

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

General information about AVANDARYL

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use AVANDARYL for a condition for which it was not prescribed. Do not give AVANDARYL to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes important information about AVANDARYL. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about AVANDARYL that is written for healthcare professionals. You can also find out more about AVANDARYL by calling 1-888-825-5249.

What are the ingredients in AVANDARYL?

Active Ingredients: Rosiglitazone maleate and glimepiride.

Inactive Ingredients: Hypromellose 2910, lactose monohydrate, macrogol (polyethylene glycol), magnesium stearate, microcrystalline cellulose, sodium starch glycolate, titanium dioxide, triacetin, and 1 or more of the following: Yellow, red, or black iron oxides.

Always check to make sure that the medicine you are taking is the correct one.

AVANDARYL tablets are triangles with rounded corners and look like this:

- 4 mg/1 mg – yellow with “gsk” on one side and “4/1” on the other.
- 4 mg/2 mg – orange with “gsk” on one side and “4/2” on the other.
- 4 mg/4 mg – pink with “gsk” on one side and “4/4” on the other.
- 8 mg/2 mg – pale pink with “gsk” on one side and “8/2” on the other.
- 8 mg/4 mg – red with “gsk” on one side and “8/4” on the other.

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



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