

1 **PATIENT INFORMATION**

2 **AVANDARYL™ (ah-VAN-duh-ri)**

3 **Rosiglitazone Maleate and Glimepiride Tablets**

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

8 **What is AVANDARYL?**

9 AVANDARYL is a prescription medicine that contains 2 medicines to treat diabetes,
10 rosiglitazone maleate (AVANDIA) and glimepiride (AMARYL). AVANDARYL is used with
11 diet and exercise to treat type 2 (“adult-onset” or “non-insulin dependent”) diabetes mellitus
12 (“high blood sugar”).

13 Glimepiride can help your body release more of its own insulin. Rosiglitazone can help your
14 body respond better to the insulin made in your body. These medicines can work together to help
15 control your blood sugar.

16 Diet, weight loss, and exercise can help your body use its blood sugar better. In order for
17 AVANDARYL to work best, it is very important to exercise, lose excess weight, and follow the
18 diet recommended for your diabetes.

19 **What is Type 2 Diabetes?**

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

27 **Who should not take AVANDARYL?**

28 Do not take AVANDARYL if you:

- 29 • are allergic to any of the ingredients in AVANDARYL. The active ingredients in
30 AVANDARYL are rosiglitazone maleate and glimepiride. See the end of this leaflet for a list
31 of all ingredients in AVANDARYL.
32 • have had diabetic ketoacidosis. This condition should be treated with insulin.

33 AVANDARYL has not been studied in children under 18 years of age and is not recommended
34 for use in children under 18 years of age.

35 **What should I tell my doctor before starting AVANDARYL?**

36 You and your doctor will decide what treatment is best for you. Tell your doctor about all your
37 medical conditions, including if you:

- 38 • **have heart problems or heart failure.** AVANDARYL can cause your body to keep extra
39 fluid (fluid retention) which leads to swelling and weight gain. Extra body fluid can make
40 some heart problems worse or lead to heart failure.
- 41 • **have type 1 (“juvenile”) diabetes.** You should not take AVANDARYL if you have type 1
42 diabetes.
- 43 • **have a type of diabetic eye disease called macular edema (swelling of the back of the eye).**
- 44 • **have liver problems.** Your doctor should do blood tests to check your liver before you start
45 taking AVANDARYL and during treatment as needed.
- 46 • **had liver problems while taking REZULIN® (troglitazone), another medicine for**
47 **diabetes.**
- 48 • **have kidney problems.** If patients with kidney problems use AVANDARYL, they may need
49 a lower dose of the medication.
- 50 • **are pregnant or trying to become pregnant.** It is not known if AVANDARYL can harm
51 your unborn baby. You and your doctor should talk about the best way to control your high
52 blood sugar during pregnancy. You should not use AVANDARYL if you are pregnant or
53 trying to get pregnant.
- 54 • **are a premenopausal woman (before the “change of life”) who does not have regular**
55 **monthly periods.** AVANDARYL may increase your chances of becoming pregnant. Talk to
56 your doctor about birth control choices while taking AVANDARYL.
- 57 • **are breastfeeding.** It is not known if AVANDARYL passes into breast milk. You should not
58 use AVANDARYL while breastfeeding.

59 Tell your doctor about all the medicines you take, including prescription and non-prescription
60 medicines, vitamins, and herbal supplements. AVANDARYL and certain other medicines can
61 affect each other and lead to serious side effects including high blood sugar or low blood sugar.
62 Keep a list of all the medicines you take. Show this list to your doctor and pharmacist before you
63 start a new medicine. They will tell you if it is okay to take AVANDARYL with other
64 medicines.

65 **How should I take AVANDARYL?**

- 66 • Take AVANDARYL by mouth once a day with your first main meal. Your doctor may need
67 to adjust your dose until your blood sugar is better controlled.
- 68 • It usually takes a few days for AVANDARYL to start lowering your blood sugar. It may take
69 2 to 3 months to see the full effect on your blood sugar level.
- 70 • If you miss a dose of AVANDARYL, take your pill as soon as you remember unless it is
71 time to take your next dose. Take your next dose at the usual time. Do not take a double dose
72 to make up for a missed dose.

- 73 • If you take too much AVANDARYL, call your doctor or poison control center right away.
- 74 Too much AVANDARYL can make your blood sugar level too low.
- 75 • Test your blood sugar regularly as your doctor tells you.
- 76 • Diet and exercise can help your body use its blood sugar better. It is important to stay on
- 77 your recommended diet, lose excess weight, and get regular exercise while taking
- 78 AVANDARYL.
- 79 • Your doctor should do blood tests to check your liver before you start AVANDARYL and
- 80 during treatment as needed. Your doctor should also do regular blood testing [for example,
- 81 blood glucose (“sugar”) or glycosylated HbA1c (“A1c” or HbA1c)] to monitor your response
- 82 to AVANDARYL.
- 83 • Call your doctor if you get sick, injured, or have surgery. AVANDARYL may not control
- 84 your blood sugar levels during these times. Your doctor may need to stop AVANDARYL for
- 85 a short time and give you insulin to control your blood sugar level.
- 86 • Your doctor should check your eyes regularly. Very rarely, some patients have experienced
- 87 vision changes due to swelling in the back of the eye while taking rosiglitazone, one of the
- 88 drugs in AVANDARYL.

89 **What are possible serious side effects of AVANDARYL?**

90 **Talk to your doctor about these side effects:**

- 91 • **heart failure.** AVANDARYL can cause your body to keep extra fluid (fluid retention),
- 92 which leads to swelling and weight gain. Extra body fluid can make some heart problems
- 93 worse or lead to heart failure. See “**swelling (edema) from fluid retention**” section below.
- 94 • **low blood sugar (hypoglycemia).** Lightheadedness, dizziness, shakiness or hunger may
- 95 mean that your blood sugar is too low. This can happen if you skip meals, drink alcohol, use
- 96 another medicine that lowers blood sugar, exercise (particularly hard or long), or if you have
- 97 certain medical problems. Call your doctor if you have low blood sugar.
- 98 • **high blood sugar or loss of control of blood sugar (hyperglycemia).** If you have fever, an
- 99 infection, trauma, or surgery, your doctor may temporarily stop the AVANDARYL and treat
- 100 the high blood sugar with insulin.
- 101 • **swelling (edema) from fluid retention.** See “**heart failure**” section above. Call your doctor
- 102 right away if you have symptoms such as:
- 103 -swelling or fluid retention, especially in the ankles or legs
- 104 -shortness of breath or trouble breathing, especially when you lie down
- 105 -an unusually fast increase in weight
- 106 -unusual tiredness
- 107 • **weight gain.** AVANDARYL can cause weight gain that may be due to fluid retention or
- 108 extra body fat. Weight gain can be a serious problem for people with certain conditions
- 109 including heart problems. Call your doctor if you have an unusually fast increase in weight.
- 110 • **low red blood cell count (anemia).**

- 111 • **ovulation (release of egg from an ovary in women) leading to pregnancy.** Ovulation may
112 happen in premenopausal women who do not have regular monthly periods. This can
113 increase the chance of pregnancy.
- 114 • **liver problems.** It is important for your liver to be working normally when you take
115 AVANDARYL. Your doctor should do blood tests to check your liver before you start taking
116 AVANDARYL and during treatment as needed.
117 Call your doctor right away if you have unexplained symptoms such as:
- 118 -nausea or vomiting
119 -stomach pain
120 -unusual or unexplained tiredness
121 -loss of appetite
122 -dark urine
123 -yellowing of your skin or the whites of your eyes
124

125 The most common side effects with AVANDARYL include cold-like symptoms, injury, and
126 dizziness.

127 **How should I store AVANDARYL?**

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

132 **General information about AVANDARYL**

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

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

142 **What are the ingredients in AVANDARYL?**

143 **Active Ingredients:** rosiglitazone maleate and glimepiride.

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

147 Always check to make sure that the medicine you are taking is the correct one. The dosage
148 strength and appearance of each tablet of AVANDARYL (rosiglitazone maleate and glimepiride)
149 are as follows:

150 4 mg/1 mg – yellow, rounded triangular tablet, “gsk” on one side and “4/1” on the other.

151 4 mg/2 mg – orange, rounded triangular tablet, “gsk” on one side and “4/2” on the other.

152 4 mg/4 mg – pink, rounded triangular tablet, “gsk” on one side and “4/4” on the other.

153 8 mg/2 mg – pale pink, rounded triangular tablet, “gsk” on one side and “8/2” on the other.

154 8 mg/4 mg – red, rounded triangular tablet, “gsk” on one side and “8/4” on the other.

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156 AVANDARYL is a trademark and AVANDIA is a registered trademark of GlaxoSmithKline.

157 AMARYL is a registered trademark of AVENTIS Pharmaceuticals Inc.

158 REZULIN is a registered trademark of Parke-Davis Pharmaceuticals Ltd.

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