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MEDICATION GUIDE
AVANDIA® (ah-VAN-dee-a)
(rosiglitazone maleate) Tablets

1003 Read this Medication Guide carefully before you start taking AVANDIA and each
1004 time you get a refill. There may be new information. This information does not take
1005 the place of talking with your doctor about your medical condition or your
1006 treatment. If you have any questions about AVANDIA, ask your doctor or
1007 pharmacist.

1008
1009 **What is the most important information I should know about AVANDIA?**

1010
1011 AVANDIA is available only through the AVANDIA-Rosiglitazone Medicines Access
1012 Program. Both you and your doctor must be enrolled in the program so that you
1013 can get AVANDIA. To enroll, you must:

- 1014 • talk to your doctor,
1015 • understand the risks and benefits of AVANDIA, and
1016 • agree to enroll in the program.

1017
1018 **AVANDIA may cause serious side effects, including:**

1019
1020 **New or worse heart failure**

- 1021 • AVANDIA can cause your body to keep extra fluid (fluid retention), which leads
1022 to swelling (edema) and weight gain. Extra body fluid can make some heart
1023 problems worse or lead to heart failure. Heart failure means your heart does not
1024 pump blood well enough.
1025 • If you have severe heart failure, you cannot start AVANDIA.
1026 • If you have heart failure with symptoms (such as shortness of breath or
1027 swelling), even if these symptoms are not severe, AVANDIA may not be right for
1028 you.

1029
1030 Call your doctor right away if you have any of the following:

- 1031 • swelling or fluid retention, especially in the ankles or legs
1032 • shortness of breath or trouble breathing, especially when you lie down
1033 • an unusually fast increase in weight
1034 • unusual tiredness

1035
1036 **Myocardial Infarction (“Heart Attack”)**

1037 AVANDIA may raise the risk of a heart attack. The risk of having a heart attack may
1038 be higher in people who take AVANDIA with insulin. Most people who take insulin

1039 should not also take AVANDIA.

1040 **Symptoms of a heart attack can include the following:**

- 1041 • chest discomfort in the center of your chest that lasts for more than a few
- 1042 minutes, or that goes away or comes back
- 1043 • chest discomfort that feels like uncomfortable pressure, squeezing, fullness or
- 1044 pain
- 1045 • pain or discomfort in your arms, back, neck, jaw or stomach
- 1046 • shortness of breath with or without chest discomfort
- 1047 • breaking out in a cold sweat
- 1048 • nausea or vomiting
- 1049 • feeling lightheaded

1050 **Call your doctor or go to the nearest hospital emergency room right away if**

1051 **you think you are having a heart attack.**

1052

1053 People with diabetes have a greater risk for heart problems. It is important to work

1054 with your doctor to manage other conditions, such as high blood pressure or high

1055 cholesterol.

1056

1057 AVANDIA can have other serious side effects. Be sure to read the section below

1058 “What are possible side effects of AVANDIA?”.

1059

1060 **What is AVANDIA?**

1061 AVANDIA is a prescription medicine used with diet and exercise to treat certain

1062 adults with type 2 (“adult-onset” or “non-insulin dependent”) diabetes mellitus

1063 (“high blood sugar”) who are:

- 1064 • already taking AVANDIA or
- 1065 • unable to control their blood sugar on other diabetes medicines, and after
- 1066 talking with their doctor have decided not to take pioglitazone (ACTOS)

1067

1068 AVANDIA helps to control high blood sugar. AVANDIA may be used alone or with

1069 other diabetes medicines. AVANDIA can help your body respond better to insulin

1070 made in your body. AVANDIA does not cause your body to make more insulin.

1071

1072 AVANDIA is not for people with type 1 diabetes mellitus or to treat a condition

1073 called diabetic ketoacidosis.

1074

1075 It is not known if AVANDIA is safe and effective in children under 18 years old.

1076

1077 **Who should not take AVANDIA?**

1078 Many people with heart failure should not start taking AVANDIA. See “What should

1079 I tell my doctor before taking AVANDIA?”.

1080

1081 **What should I tell my doctor before taking AVANDIA?**

1082 Before starting AVANDIA, ask your doctor about what the choices are for diabetes
1083 medicines, and what the expected benefits and possible risks are for you in
1084 particular.

1085

1086 Before taking AVANDIA, tell your doctor about all your medical conditions, including
1087 if you:

- 1088 • **have heart problems or heart failure.**
- 1089 • **have type 1 (“juvenile”) diabetes or had diabetic ketoacidosis.** These
1090 conditions should be treated with insulin.
- 1091 • **have a type of diabetic eye disease called macular edema** (swelling of the
1092 back of the eye).
- 1093 • **have liver problems.** Your doctor should do blood tests to check your liver
1094 before you start taking AVANDIA and during treatment as needed.
- 1095 • **had liver problems while taking REZULIN® (troglitazone), another**
1096 **medicine for diabetes.**
- 1097 • **are pregnant or plan to become pregnant.** AVANDIA should not be used
1098 during pregnancy. It is not known if AVANDIA can harm your unborn baby. You
1099 and your doctor should talk about the best way to control your diabetes during
1100 pregnancy. If you are a premenopausal woman (before the “change of life”) who
1101 does not have regular monthly periods, AVANDIA may increase your chances of
1102 becoming pregnant. Talk to your doctor about birth control choices while taking
1103 AVANDIA. Tell your doctor right away if you become pregnant while taking
1104 AVANDIA.
- 1105 • **are breast-feeding or planning to breast-feed.** It is not known if AVANDIA
1106 passes into breast milk. You should not use AVANDIA while breast-feeding.

1107

1108 Tell your doctor about all the medicines you take including prescription and non-
1109 prescription medicines, vitamins or herbal supplements. AVANDIA and certain other
1110 medicines can affect each other and may lead to serious side effects including high
1111 or low blood sugar, or heart problems. Especially tell your doctor if you take:

- 1112 • **insulin.**
- 1113 • **any medicines for high blood pressure, high cholesterol or heart failure,**
1114 **or for prevention of heart disease or stroke.**

1115

1116 Know the medicines you take. Keep a list of your medicines and show it to your
1117 doctor and pharmacist before you start a new medicine. They will tell you if it is
1118 alright to take AVANDIA with other medicines.

1119

1120 **How should I take AVANDIA?**

- 1121 • Take AVANDIA exactly as prescribed. Your doctor will tell you how many tablets
1122 to take and how often. The usual daily starting dose is 4 mg a day taken one
1123 time each day or 2 mg taken two times each day. Your doctor may need to
1124 adjust your dose until your blood sugar is better controlled.
- 1125 • AVANDIA may be prescribed alone or with other diabetes medicines. This will
1126 depend on how well your blood sugar is controlled.
- 1127 • Take AVANDIA with or without food.
- 1128 • It can take 2 weeks for AVANDIA to start lowering blood sugar. It may take 2 to
1129 3 months to see the full effect on your blood sugar level.
- 1130 • If you miss a dose of AVANDIA, take it as soon as you remember, unless it is
1131 time to take your next dose. Take your next dose at the usual time. Do not take
1132 double doses to make up for a missed dose.
- 1133 • If you take too much AVANDIA, call your doctor or poison control center right
1134 away.
- 1135 • Test your blood sugar regularly as your doctor tells you.
- 1136 • Diet and exercise can help your body use its blood sugar better. It is important
1137 to stay on your recommended diet, lose extra weight, and get regular exercise
1138 while taking AVANDIA.
- 1139 • Your doctor should do blood tests to check your liver before you start AVANDIA
1140 and during treatment as needed. Your doctor should also do regular blood sugar
1141 tests (for example, "A1C") to monitor your response to AVANDIA.

1142

1143 **What are possible side effects of AVANDIA?**

1144 **AVANDIA may cause serious side effects including:**

- 1145 • **New or worse heart failure.** See "What is the most important information I
1146 should know about AVANDIA?".
- 1147 • **Heart attack.** See "What is the most important information I should know
1148 about AVANDIA?".
- 1149 • **Swelling (edema).** AVANDIA can cause swelling due to fluid retention. See
1150 "What is the most important information I should know about AVANDIA?".
- 1151 • **Weight gain.** AVANDIA can cause weight gain that may be due to fluid
1152 retention or extra body fat. Weight gain can be a serious problem for people
1153 with certain conditions including heart problems. See "What is the most
1154 important information I should know about AVANDIA?".
- 1155 • **Liver problems.** It is important for your liver to be working normally when you
1156 take AVANDIA. Your doctor should do blood tests to check your liver before you
1157 start taking AVANDIA and during treatment as needed. Call your doctor right
1158 away if you have unexplained symptoms such as:

- 1159 • nausea or vomiting
- 1160 • stomach pain
- 1161 • unusual or unexplained tiredness
- 1162 • loss of appetite
- 1163 • dark urine
- 1164 • yellowing of your skin or the whites of your eyes.
- 1165 • **Macular edema** (a diabetic eye disease with swelling in the back of the eye).
- 1166 Tell your doctor right away if you have any changes in your vision. Your doctor
- 1167 should check your eyes regularly. Very rarely, some people have had vision
- 1168 changes due to swelling in the back of the eye while taking AVANDIA.
- 1169 • **Fractures (broken bones)**, usually in the hand, upper arm or foot. Talk to
- 1170 your doctor for advice on how to keep your bones healthy.
- 1171 • **Low red blood cell count (anemia)**.
- 1172 • **Low blood sugar (hypoglycemia)**. Lightheadedness, dizziness, shakiness or
- 1173 hunger may mean that your blood sugar is too low. This can happen if you skip
- 1174 meals, if you use another medicine that lowers blood sugar, or if you have
- 1175 certain medical problems. Call your doctor if low blood sugar levels are a
- 1176 problem for you.
- 1177 • **Ovulation** (release of egg from an ovary in a woman) leading to pregnancy.
- 1178 Ovulation may happen in premenopausal women who do not have regular
- 1179 monthly periods. This can increase the chance of pregnancy. See “What should I
- 1180 tell my doctor before taking AVANDIA?”.

1181
1182 The most common side effects of AVANDIA reported in clinical trials included cold-
1183 like symptoms and headache.

1184
1185 Call your doctor for medical advice about side effects. You may report side effects
1186 to FDA at 1-800-FDA-1088.

1187 1188 **How should I store AVANDIA?**

- 1189 • Store AVANDIA at room temperature, 59° to 86°F (15° to 30°C). Keep AVANDIA
- 1190 in the container it comes in.
- 1191 • Safely, throw away AVANDIA that is out of date or no longer needed.
- 1192 • Keep AVANDIA and all medicines out of the reach of children.

1193 1194 **General information about AVANDIA**

1195 Medicines are sometimes prescribed for purposes other than those listed in a
1196 Medication Guide. Do not use AVANDIA for a condition for which it was not
1197 prescribed. Do not give AVANDIA to other people, even if they have the same
1198 symptoms you have. It may harm them.

1199
1200 This Medication Guide summarizes important information about AVANDIA. If you
1201 would like more information, talk with your doctor. You can ask your doctor or
1202 pharmacist for information about AVANDIA that is written for healthcare
1203 professionals. You can also find out more about AVANDIA by calling 1-888-825-
1204 5249.

1205
1206 **What are the ingredients in AVANDIA?**

1207 Active Ingredient: Rosiglitazone maleate.

1208 Inactive Ingredients: Hypromellose 2910, lactose monohydrate, magnesium
1209 stearate, microcrystalline cellulose, polyethylene glycol 3000, sodium starch
1210 glycolate, titanium dioxide, triacetin, and 1 or more of the following: Synthetic red
1211 and yellow iron oxides and talc.

1212
1213 Always check to make sure that the medicine you are taking is the correct one.
1214 AVANDIA tablets are triangles with rounded corners and look like this:

1215 2 mg – pink with "SB" on one side and "2" on the other.

1216 4 mg – orange with "SB" on one side and "4" on the other.

1217 8 mg – red-brown with "SB" on one side and "8" on the other.

1218
1219 AVANDIA is a registered trademark of GlaxoSmithKline.

1220 The other brands listed are trademarks of their respective owners and are not
1221 trademarks of GlaxoSmithKline. The makers of these brands are not affiliated with
1222 and do not endorse GlaxoSmithKline or its products.

1223
1224 **This Medication Guide has been approved by the U.S. Food and Drug**
1225 **Administration.**

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1227
1228 GlaxoSmithKline

1229 Research Triangle Park, NC 27709

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