

1178 **MEDICATION GUIDE**
1179 **AVANDARYL® (ah-VAN-duh-riil)**
1180 **(rosiglitazone maleate and glimepiride) Tablets**
1181

1182 Read this Medication Guide carefully before you start taking AVANDARYL and each
1183 time you get a refill. There may be new information. This information does not take
1184 the place of talking with your doctor about your medical condition or your
1185 treatment. If you have any questions about AVANDARYL, ask your doctor or
1186 pharmacist.

1187
1188 **What is the most important information I should know about AVANDARYL?**
1189 **AVANDARYL may cause serious side effects, including:**
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1191 AVANDARYL is available only through the AVANDIA-Rosiglitazone Medicines Access
1192 Program. Both you and your doctor must be enrolled in the program so that you
1193 can get AVANDARYL. To enroll, you must:

- 1194 • talk to your doctor,
- 1195 • understand the risks and benefits of AVANDARYL, and
- 1196 • agree to enroll in the program.

1197
1198 **New or worse heart failure**

- 1199 • Rosiglitazone, one of the two drugs that make up AVANDARYL, can cause your
1200 body to keep extra fluid (fluid retention), which leads to swelling (edema) and
1201 weight gain. Extra body fluid can make some heart problems worse or lead to
1202 heart failure. Heart failure means your heart does not pump blood well enough.
- 1203 • If you have severe heart failure, you cannot start AVANDARYL.
- 1204 • If you have heart failure with symptoms (such as shortness of breath or
1205 swelling), even if these symptoms are not severe, AVANDARYL may not be right
1206 for you.

1207
1208 Call your doctor right away if you have any of the following:

- 1209 • swelling or fluid retention, especially in the ankles or legs
- 1210 • shortness of breath or trouble breathing, especially when you lie down
- 1211 • an unusually fast increase in weight
- 1212 • unusual tiredness

1213
1214 **Myocardial Infarction (“Heart Attack”)**

1215 Rosiglitazone, one of the medicines in AVANDARYL, may raise the risk of heart
1216 attack. The risk of having a heart attack may be higher in people who take

1217 AVANDARYL with insulin. Most people who take insulin should not also take
1218 AVANDARYL.

1219 **Symptoms of a heart attack can include the following:**

- 1220 • chest discomfort in the center of your chest that lasts for more than a few
1221 minutes, or that goes away or comes back
- 1222 • chest discomfort that feels like uncomfortable pressure, squeezing, fullness or
1223 pain
- 1224 • pain or discomfort in your arms, back, neck, jaw or stomach
- 1225 • shortness of breath with or without chest discomfort
- 1226 • breaking out in a cold sweat
- 1227 • nausea or vomiting
- 1228 • feeling lightheaded

1229 **Call your doctor or go to the nearest hospital emergency room right away if**
1230 **you think you are having a heart attack.**

1231
1232 People with diabetes have a greater risk for heart problems. It is important to work
1233 with your doctor to manage other conditions, such as high blood pressure or high
1234 cholesterol.

1235
1236 AVANDARYL can have other serious side effects. Be sure to read the section “What
1237 are possible side effects of AVANDARYL?”.

1238

1239 **What is AVANDARYL?**

1240 AVANDARYL contains 2 prescription medicines to treat diabetes, rosiglitazone
1241 maleate (AVANDIA) and glimepiride (AMARYL). AVANDARYL is used with diet and
1242 exercise to treat certain adults with type 2 (“adult-onset” or “non-insulin
1243 dependent”) diabetes mellitus (“high blood sugar”) who are:

- 1244 • already taking rosiglitazone or rosiglitazone-containing products
- 1245 • unable to control their blood sugar on other diabetes medicines, and after
1246 talking with their doctor have decided not to take pioglitazone (ACTOS) or
1247 pioglitazone-containing products (ACTOPLUS MET, ACTOPLUS MET XR,
1248 DUETACT)

1249

1250 Glimepiride can help your body release more of its own insulin. Rosiglitazone can
1251 help your body respond better to the insulin made in your body and does not cause
1252 your body to make more insulin. These medicines can work together to help control
1253 your blood sugar.

1254

1255 AVANDARYL is not for people with type 1 diabetes mellitus or to treat a condition
1256 called diabetic ketoacidosis.

1257

1258 It is not known if AVANDARYL is safe and effective in children under 18 years old.

1259

1260 **Who should not take AVANDARYL?**

1261 Many people with heart failure should not start taking AVANDARYL (see “What
1262 should I tell my doctor before taking AVANDARYL?”).

1263

1264 **What should I tell my doctor before taking AVANDARYL?**

1265 Before starting AVANDARYL, ask your doctor about what the choices are for
1266 diabetes medicines and what the expected benefits and possible risks are for you in
1267 particular.

1268

1269 Before taking AVANDARYL, tell your doctor about all your medical conditions,
1270 including if you:

- 1271 • **have heart problems or heart failure.**
- 1272 • **have type 1 (“juvenile”) diabetes or had diabetic ketoacidosis.** These
1273 conditions should be treated with insulin and should not be treated with
1274 AVANDARYL.
- 1275 • **have a type of diabetic eye disease called macular edema** (swelling of the
1276 back of the eye).
- 1277 • **have liver problems.** Your doctor should do blood tests to check your liver
1278 before you start taking AVANDARYL and during treatment as needed.
- 1279 • **had liver problems while taking REZULIN[®] (troglitazone), another
1280 medicine for diabetes.**
- 1281 • **have kidney problems.** If people with kidney problems use AVANDARYL, they
1282 may need a lower dose of the medication.
- 1283 • **have glucose 6-phosphate dehydrogenase (G6PD) deficiency.** This
1284 condition runs in families. People with G6PD deficiency who take glimepiride
1285 (one of the medicines in AVANDARYL) may develop hemolytic anemia (fast
1286 breakdown of red blood cells).
- 1287 • **are pregnant or plan to become pregnant.** AVANDARYL should not be used
1288 during pregnancy. It is not known if AVANDARYL can harm your unborn baby.
1289 You and your doctor should talk about the best way to control your diabetes
1290 during pregnancy. If you are a premenopausal woman (before the “change of
1291 life”) who does not have regular monthly periods, AVANDARYL may increase
1292 your chances of becoming pregnant. Talk to your doctor about birth control
1293 choices while taking AVANDARYL. Tell your doctor right away if you become
1294 pregnant while taking AVANDARYL.

1295 • **are breast-feeding or planning to breast-feed.** It is not known if
1296 AVANDARYL passes into breast milk. You should not use AVANDARYL while
1297 breast-feeding.

1298
1299 Tell your doctor about all the medicines you take including prescription and non-
1300 prescription medicines, vitamins or herbal supplements. AVANDARYL and certain
1301 other medicines can affect each other and may lead to serious side effects including
1302 high or low blood sugar, or heart problems. Especially tell your doctor if you take:

- 1303 • **insulin.**
- 1304 • **any medicines for high blood pressure, high cholesterol or heart failure,**
- 1305 **or for prevention of heart disease or stroke.**

1306
1307 Know the medicines you take. Keep a list of all your medicines and show it to your
1308 doctor and pharmacist before you start a new medicine. They will tell you if it is
1309 alright to take AVANDARYL with other medicines.

1310

1311 **How should I take AVANDARYL?**

- 1312 • Take AVANDARYL exactly as prescribed. Your doctor may need to change your
1313 dose until your blood sugar is better controlled.
- 1314 • Take AVANDARYL by mouth one time each day with your first main meal.
- 1315 • It usually takes a few days for AVANDARYL to start lowering your blood sugar. It
1316 may take 2 to 3 months to see the full effect on your blood sugar level.
- 1317 • If you miss a dose of AVANDARYL, take it as soon as you remember unless it is
1318 time to take your next dose. Take your next dose at the usual time. Do not take
1319 double doses to make up for a missed dose.
- 1320 • If you take too much AVANDARYL, call your doctor or poison control center right
1321 away.
- 1322 • Test your blood sugar regularly as your doctor tells you.
- 1323 • Your doctor should do blood tests to check your liver before you start
1324 AVANDARYL and during treatment as needed. Your doctor should also do regular
1325 blood sugar tests (for example, "A1c") to monitor your response to AVANDARYL.
- 1326 • Call your doctor if you get sick, get injured, get an infection, or have surgery.
1327 AVANDARYL may not control your blood sugar levels during these times. Your
1328 doctor may need to stop AVANDARYL for a short time and give you insulin to
1329 control your blood sugar level.
- 1330 • Diet and exercise can help your body use its blood sugar better. It is important
1331 to stay on your recommended diet, lose extra weight, and get regular exercise
1332 while taking AVANDARYL.

1333

- 1334 **What are possible side effects of AVANDARYL?**
- 1335 **AVANDARYL may cause serious side effects, including:**
- 1336 • **New or worse heart failure.** See “What is the most important information I
1337 should know about AVANDARYL?”.
 - 1338 • **Heart attack.** See “What is the most important information I should know
1339 about AVANDARYL?”.
 - 1340 • **Swelling (edema).** AVANDARYL can cause swelling due to fluid retention. See
1341 “What is the most important information I should know about AVANDARYL?”.
 - 1342 • **Low blood sugar (hypoglycemia).** Lightheadedness, dizziness, shakiness or
1343 hunger may mean that your blood sugar is too low. This can happen if you skip
1344 meals, drink alcohol, use another medicine that lowers blood sugar, exercise
1345 (particularly hard or long), or if you have certain medical problems. Call your
1346 doctor if low blood sugar levels are a problem for you.
 - 1347 • **Weight gain.** Rosiglitazone, one of the medicines in AVANDARYL, can cause
1348 weight gain that may be due to fluid retention or extra body fat. Weight gain can
1349 be a serious problem for people with certain conditions including heart problems.
1350 See “What is the most important information I should know about
1351 AVANDARYL?”.
 - 1352 • **Liver problems.** It is important for your liver to be working normally when you
1353 take AVANDARYL. Your doctor should do blood tests to check your liver before
1354 you start taking AVANDARYL and during treatment as needed. Call your doctor
1355 right away if you have unexplained symptoms such as:
 - 1356 • nausea or vomiting
 - 1357 • stomach pain
 - 1358 • unusual or unexplained tiredness
 - 1359 • loss of appetite
 - 1360 • dark urine
 - 1361 • yellowing of your skin or the whites of your eyes.
 - 1362 • **Macular edema** (a diabetic eye disease with swelling in the back of the eye).
1363 Tell your doctor right away if you have any changes in your vision. Your doctor
1364 should check your eyes regularly. Very rarely, some people have had vision
1365 changes due to swelling in the back of the eye while taking rosiglitazone, one of
1366 the medicines in AVANDARYL.
 - 1367 • **Fractures (broken bones)**, usually in the hand, upper arm or foot. Talk to
1368 your doctor for advice on how to keep your bones healthy.
 - 1369 • **Low red blood cell count (anemia).**
 - 1370 • **Ovulation** (release of egg from an ovary in women) leading to pregnancy.
1371 Ovulation may happen in premenopausal women who do not have regular
1372 monthly periods. This can increase the chance of pregnancy. See “What should I
1373 tell my doctor before taking AVANDARYL?”.

1374

1375 The most common side effects with AVANDARYL include cold-like symptoms and
1376 headache.

1377

1378 Call your doctor for medical advice about side effects. You may report side effects
1379 to FDA at 1-800-FDA-1088.

1380

1381 **How should I store AVANDARYL?**

- 1382 • Store AVANDARYL at room temperature, 59° to 86° F (15° to 30° C). Keep
1383 AVANDARYL in the container it comes in. Keep the container closed tightly.
- 1384 • Safely, throw away AVANDARYL that is out of date or no longer needed.

1385

1386 Keep AVANDARYL and all medicines out of the reach of children.

1387

1388 **General information about AVANDARYL**

1389 Medicines are sometimes prescribed for purposes other than those listed in a
1390 Medication Guide. Do not use AVANDARYL for a condition for which it was not
1391 prescribed. Do not give AVANDARYL to other people, even if they have the same
1392 symptoms you have. It may harm them.

1393

1394 This Medication Guide summarizes important information about AVANDARYL. If you
1395 would like more information, talk with your doctor. You can ask your doctor or
1396 pharmacist for information about AVANDARYL that is written for healthcare
1397 professionals. You can also find out more about AVANDARYL by calling 1-888-825-
1398 5249.

1399

1400 **What are the ingredients in AVANDARYL?**

1401 Active Ingredients: Rosiglitazone maleate and glimepiride.

1402 Inactive Ingredients: Hypromellose 2910, lactose monohydrate, macrogol
1403 (polyethylene glycol), magnesium stearate, microcrystalline cellulose, sodium
1404 starch glycolate, titanium dioxide, triacetin, and 1 or more of the following: Yellow,
1405 red, or black iron oxides.

1406

1407 Always check to make sure that the medicine you are taking is the correct one.

1408 AVANDARYL tablets are triangles with rounded corners and look like this:

1409 4 mg/1 mg – yellow with “gsk” on one side and “4/1” on the other.

1410 4 mg/2 mg – orange with “gsk” on one side and “4/2” on the other.

1411 4 mg/4 mg – pink with “gsk” on one side and “4/4” on the other.

1412 8 mg/2 mg – pale pink with “gsk” on one side and “8/2” on the other.

1413 8 mg/4 mg – red with “gsk” on one side and “8/4” on the other.

1414
1415 AVANDARYL and AVANDIA are registered trademarks of GlaxoSmithKline.
1416 The other brands listed are trademarks of their respective owners and are not
1417 trademarks of GlaxoSmithKline. The makers of these brands are not affiliated with
1418 and do not endorse GlaxoSmithKline or its products.

1419
1420 **This Medication Guide has been approved by the U.S. Food and Drug**
1421 **Administration.**

1422



1423
1424 GlaxoSmithKline
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1426
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1428
1429 Month 2011
1430 AVR: XMG