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

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

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

947 **AVANDIA may cause serious side effects, including:**

948 **New or worse heart failure**

- 949 • The risk of heart failure may be higher in people who take AVANDIA with insulin.
950 Most people who take insulin should not also take AVANDIA.
- 951 • AVANDIA can cause your body to keep extra fluid (fluid retention), which leads
952 to swelling (edema) and weight gain. Extra body fluid can make some heart
953 problems worse or lead to heart failure. Heart failure means your heart does not
954 pump blood well enough.
- 955 • If you have severe heart failure, you cannot start AVANDIA.
- 956 • If you have heart failure with symptoms (such as shortness of breath or
957 swelling), even if these symptoms are not severe, AVANDIA may not be right for
958 you.

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

- 960 • swelling or fluid retention, especially in the ankles or legs
- 961 • shortness of breath or trouble breathing, especially when you lie down
- 962 • an unusually fast increase in weight
- 963 • unusual tiredness

964 AVANDIA can have other serious side effects. Be sure to read the section below
965 "What are possible side effects of AVANDIA?"

966 **What is AVANDIA?**

967 AVANDIA is a prescription medicine used with diet and exercise to treat adults with
968 type 2 ("adult-onset" or "non-insulin dependent") diabetes mellitus ("high blood
969 sugar").

970 AVANDIA helps to control high blood sugar. AVANDIA may be used alone or with
971 other diabetes medicines. AVANDIA can help your body respond better to insulin
972 made in your body. AVANDIA does not cause your body to make more insulin.

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

974 called diabetic ketoacidosis.

975 It is not known if AVANDIA is safe and effective in children younger than 18 years
976 old.

977 **Who should not take AVANDIA?**

978 Many people with heart failure should not start taking AVANDIA. See “What should
979 I tell my doctor before taking AVANDIA?”

980 **Do not** take AVANDIA if you are allergic to rosiglitazone or any of the ingredients in
981 AVANDIA. See the end of this leaflet for a complete list of ingredients in AVANDIA.

982 Symptoms of a severe allergic reaction with AVANDIA may include:

- 983 • swelling of your face, lips, tongue, or throat
- 984 • problems with breathing or swallowing
- 985 • skin rash or itching
- 986 • raised red areas on your skin (hives)
- 987 • blisters on your skin or in your mouth, nose, or eyes
- 988 • peeling of your skin
- 989 • fainting or feeling dizzy
- 990 • very rapid heartbeat

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

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

995 Before taking AVANDIA, tell your doctor about all of your medical conditions,
996 including if you:

- 997 • **have heart problems or heart failure.**
- 998 • **have type 1 (“juvenile”) diabetes or had diabetic ketoacidosis.** These
999 conditions should be treated with insulin.
- 1000 • **have a type of diabetic eye disease called macular edema** (swelling of the
1001 back of the eye).
- 1002 • **have liver problems.** Your doctor should do blood tests to check your liver
1003 before you start taking AVANDIA and during treatment as needed.
- 1004 • **had liver problems while taking REZULIN™ (troglitazone), another**
1005 **medicine for diabetes.**
- 1006 • **are pregnant or plan to become pregnant.** It is not known if AVANDIA can
1007 harm your unborn baby. You and your doctor should talk about the best way to
1008 control your diabetes during pregnancy. If you are a premenopausal woman
1009 (before the “change of life”) who does not have regular monthly periods,
1010 AVANDIA may increase your chances of becoming pregnant. Talk to your doctor

1011 about birth control choices while taking AVANDIA. Tell your doctor right away if
1012 you become pregnant while taking AVANDIA.

1013 • **are breastfeeding or planning to breastfeed.** It is not known if AVANDIA
1014 passes into breast milk. You and your doctor should decide if you will take
1015 AVANDIA or breastfeed. You should not do both.

1016 Tell your doctor about all of the medicines you take including prescription and non-
1017 prescription medicines, vitamins or herbal supplements. AVANDIA and certain other
1018 medicines can affect each other and may lead to serious side effects including high
1019 or low blood sugar, or heart problems. Especially tell your doctor if you take:

1020 • **insulin.**
1021 • **any medicines for high blood pressure, high cholesterol or heart failure,**
1022 **or for prevention of heart disease or stroke.**

1023 Know the medicines you take. Keep a list of your medicines and show it to your
1024 doctor and pharmacist before you start a new medicine. They will tell you if it is
1025 alright to take AVANDIA with other medicines.

1026 **How should I take AVANDIA?**

1027 • Take AVANDIA exactly as prescribed. Your doctor will tell you how many tablets
1028 to take and how often. The usual daily starting dose is 4 mg a day taken one
1029 time each day or 2 mg taken two times each day. Your doctor may need to
1030 adjust your dose until your blood sugar is better controlled.

1031 • AVANDIA may be prescribed alone or with other diabetes medicines. This will
1032 depend on how well your blood sugar is controlled.

1033 • Take AVANDIA with or without food.

1034 • It can take 2 weeks for AVANDIA to start lowering blood sugar. It may take 2 to
1035 3 months to see the full effect on your blood sugar level.

1036 • If you miss a dose of AVANDIA, take it as soon as you remember, unless it is
1037 time to take your next dose. Take your next dose at the usual time. Do not take
1038 double doses to make up for a missed dose.

1039 • If you take too much AVANDIA, call your doctor or poison control center right
1040 away.

1041 • Test your blood sugar regularly as your doctor tells you.

1042 • Diet and exercise can help your body use its blood sugar better. It is important
1043 to stay on your recommended diet, lose extra weight, and get regular exercise
1044 while taking AVANDIA.

1045 • Your doctor should do blood tests to check your liver before you start AVANDIA
1046 and during treatment as needed. Your doctor should also do regular blood sugar
1047 tests (for example, "A1C") to monitor your response to AVANDIA.

1048 **What are possible side effects of AVANDIA?**

1049 **AVANDIA may cause serious side effects including:**

1050 • **New or worse heart failure.** See “What is the most important information I
1051 should know about AVANDIA?”

1052 • **Heart attack.** AVANDIA may increase the risk of a heart attack. Talk to your
1053 doctor about what this means to you.

1054 **Symptoms of a heart attack can include the following:**

1055 • chest discomfort in the center of your chest that lasts for more than a few
1056 minutes, or that goes away or comes back

1057 • chest discomfort that feels like uncomfortable pressure, squeezing, fullness, or
1058 pain

1059 • pain or discomfort in your arms, back, neck, jaw, or stomach

1060 • shortness of breath with or without chest discomfort

1061 • breaking out in a cold sweat

1062 • nausea or vomiting

1063 • feeling lightheaded

1064 **Call your doctor or go to the nearest hospital emergency room right
1065 away if you think you are having a heart attack.**

1066 • **Swelling (edema).** AVANDIA can cause swelling due to fluid retention. See
1067 “What is the most important information I should know about AVANDIA?”

1068 • **Weight gain.** AVANDIA can cause weight gain that may be due to fluid
1069 retention or extra body fat. Weight gain can be a serious problem for people
1070 with certain conditions including heart problems. See “What is the most
1071 important information I should know about AVANDIA?”

1072 • **Liver problems.** It is important for your liver to be working normally when you
1073 take AVANDIA. Your doctor should do blood tests to check your liver before you
1074 start taking AVANDIA and during treatment as needed. Call your doctor right
1075 away if you have unexplained symptoms such as:

1076 • nausea or vomiting

1077 • stomach pain

1078 • unusual or unexplained tiredness

1079 • loss of appetite

1080 • dark urine

1081 • yellowing of your skin or the whites of your eyes.

1082 • **Macular edema** (a diabetic eye disease with swelling in the back of the eye).

1083 Tell your doctor right away if you have any changes in your vision. Your doctor
1084 should check your eyes regularly. Very rarely, some people have had vision
1085 changes due to swelling in the back of the eye while taking AVANDIA.

1086 • **Fractures (broken bones)**, usually in the hand, upper arm, or foot. Talk to
1087 your doctor for advice on how to keep your bones healthy.

- 1088 • **Low red blood cell count (anemia).**
1089 • **Low blood sugar (hypoglycemia).** Lightheadedness, dizziness, shakiness, or
1090 hunger may mean that your blood sugar is too low. This can happen if you skip
1091 meals, if you use another medicine that lowers blood sugar, or if you have
1092 certain medical problems. Call your doctor if low blood sugar levels are a
1093 problem for you.
1094 • **Ovulation** (release of egg from an ovary in a woman) leading to pregnancy.
1095 Ovulation may happen in premenopausal women who do not have regular
1096 monthly periods. This can increase the chance of pregnancy. See “What should I
1097 tell my doctor before taking AVANDIA?”

1098 The most common side effects of AVANDIA reported in clinical trials included cold-
1099 like symptoms and headache.

1100 Call your doctor for medical advice about side effects. You may report side effects
1101 to FDA at 1-800-FDA-1088.

1102 **How should I store AVANDIA?**

- 1103 • Store AVANDIA at room temperature, 59°F to 86°F (15°C to 30°C). Keep
1104 AVANDIA in the container it comes in.
1105 • Safely, throw away AVANDIA that is out of date or no longer needed.
1106 • Keep AVANDIA and all medicines out of the reach of children.

1107 **General information about AVANDIA**

1108 Medicines are sometimes prescribed for purposes other than those listed in a
1109 Medication Guide. Do not use AVANDIA for a condition for which it was not
1110 prescribed. Do not give AVANDIA to other people, even if they have the same
1111 symptoms you have. It may harm them.

1112 This Medication Guide summarizes important information about AVANDIA. If you
1113 would like more information, talk with your doctor. You can ask your doctor or
1114 pharmacist for information about AVANDIA that is written for healthcare
1115 professionals. You can also find out more about AVANDIA by calling 1-888-825-
1116 5249.

1117 **What are the ingredients in AVANDIA?**

1118 Active Ingredient: rosiglitazone maleate.

1119 Inactive Ingredients: hypromellose 2910, lactose monohydrate, magnesium
1120 stearate, microcrystalline cellulose, polyethylene glycol 3000, sodium starch
1121 glycolate, titanium dioxide, triacetin, and 1 or more of the following: synthetic red
1122 and yellow iron oxides and talc.

1123 Always check to make sure that the medicine you are taking is the correct one.

1124 AVANDIA tablets are triangles with rounded corners and look like this:
1125 2 mg – pink with “GSK” on one side and “2” on the other.
1126 4 mg – orange with “GSK” on one side and “4” on the other.
1127 8 mg – red-brown with “GSK” on one side and “8” on the other.
1128 AVANDIA is a registered trademark of the GSK group of companies.
1129 REZULIN is a trademark of its respective owner and is not a trademark of the GSK
1130 group of companies. The maker of this brand is not affiliated with and does not
1131 endorse the GSK group of companies or its products.
1132 **This Medication Guide has been approved by the U.S. Food and Drug**
1133 **Administration.**



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