NDC 0093-7322-06
ROSIGLITAZONE MALEATE
Tablets
2 mg*

* Each film-coated tablet contains rosiglitazone maleate equivalent to 2 mg rosiglitazone.

USUAL DOSE: See package insert for full prescribing information.

Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).

Store at 20°C to 25°C (68°F to 77°F). [See USP Controlled Room Temperature].

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

PREScriber: Dispense the accompanying Medication Guide to each patient.

Rx only

60 TABLETS
NDC 0093-7323-56
ROSIGLITAZONE MALEATE Tablets
4 mg*

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

Rx only

30 TABLETS

Reference ID: 3248447
Each film-coated tablet contains rosiglitazone maleate equivalent to 4 mg rosiglitazone.

Usual Dosage: See package insert for full prescribing information.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure.

Rx only
Each film-coated tablet contains rosiglitazone maleate equivalent to 8 mg rosiglitazone.

**Usual Dosage:** See package insert for full prescribing information.

**Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).**

**Store at 20° to 25°C (68° to 77°F).** [See USP Controlled Room Temperature (79.1)]]

**KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.** Iss. 12/2012

**Rx only**

**100 TABLETS**

**Reference ID: 3248447**
NDC 0093-7324-56
ROSIGLITAZONE MALEATE Tablets
8 mg*

Pharmacist: Dispense the accompanying Medication Guide to each patient.

Rx only
30 TABLETS

Each film-coated tablet contains rosiglitazone maleate equivalent to 8 mg of rosiglitazone.

Usual Dosage: See package insert for full prescribing information.
ROSIGLITAZONE MALEATE Tablets
8 mg*

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

Rx only

500 TABLETS

Reference ID: 3248447
NDC 0093-7322-06
ROSIGLITAZONE MALEATE Tablets
2 mg*

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

Rx only

60 TABLETS

* Each film-coated tablet contains rosiglitazone maleate equivalent to 2 mg rosiglitazone.

Usual Dosage: See package insert for full prescribing information.

Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Iss. 12/2012

Reference ID: 3248447
NDC 0093-7323-01
ROSIGLITAZONE MALEATE Tablets
4 mg*

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

Rx only

100 TABLETS

Reference ID: 3248447
Each film-coated tablet contains Rosiglitazone maleate equivalent to 4 mg Rosiglitazone.

**Usual Dosage:** See package insert for full prescribing information.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Dispense in a tight, light-resistant container as defined in the USP with a child-resistant closure (as required).

Rx only

PHARMACIST: Dispense the accompanying Medication Guide to each patient.
ROSIGLITAZONE MALEATE Tablets

4 mg*

Each film-coated tablet contains rosiglitazone maleate equivalent to 4 mg rosiglitazone.

Usual Dosage: See package insert for full prescribing information.

Store at 20º to 25ºC (68º to 77ºF) [See USP Controlled Room Temperature].

Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

Rx only

500 TABLETS

Reference ID: 3248447
Each film-coated tablet contains rosiglitazone maleate equivalent to 8 mg rosiglitazone.

**Usual Dosage:** See package insert for full prescribing information. [See USP Controlled Room Temperature].

Dispense in a tight, light-resistant container as defined in the USP with a child-resistant closure (as required).

Iss. 12/2012

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

Rx only

100 TABLETS
Each film-coated tablet contains rosiglitazone maleate equivalent to 8 mg rosiglitazone.

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Disperse in a tight, light-resistant container as defined in the USP with a child-resistant closure (as required).

Rx only

Reference ID: 3248447
Each film-coated tablet contains rosiglitazone maleate equivalent to 8 mg rosiglitazone.

Usual Dosage: See package insert for full prescribing information.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

Rx only

500 TABLETS

Reference ID: 3248447
What are rosiglitazone maleate tablets?

Rosiglitazone maleate tablets are a prescription medicine used to treat certain adults with type 2 diabetes (non-insulin-dependent) diabetes mellitus (high blood sugar) who also take other medications to control their blood sugar.

You must only take rosiglitazone maleate tablets if you have type 2 diabetes. You must not take rosiglitazone maleate tablets if you have type 1 diabetes mellitus or type 2 diabetes with severe kidney problems.
serious side effects including:

- Lightheadedness, especially when you change your position quickly.
- Edema (accumulation of fluid in the body tissues).
- Fluid retention leading to weight gain.
- Extra body fat leading to weight gain.
- Gastrointestinal symptoms such as nausea, vomiting, or diarrhea.
- Overactive bladder or difficulty urinating.
- Edema, or swelling in the legs, ankles, or feet.
- Anemia, which is a low red blood cell count.
- Other side effects may include:
  - Headache
  - Blurred vision
  - Infections
  - Cold symptoms
  - Nasal congestion
  - Allergic reactions
  - Rash
  - Skin reactions
  - White blood cell count decrease
  - Stomach pain
  - Diarrhea
  - Constipation
  - Liver function tests abnormalities
  - Transaminase elevation
  - Increased blood glucose levels
  - Frequent urination
  - Changes in your body fat
  - Changes in your body shape
  - Changes in your vision

You should stop taking rosiglitazone maleate tablets if you develop symptoms of an allergic reaction, such as:

- Rash
- Swelling of the face, lips, tongue, or throat
- Difficulty breathing
- Hives

If you stop taking rosiglitazone maleate tablets and then start another medicine that affects your blood sugar levels, you should monitor your blood sugar levels closely. Consult your healthcare provider if necessary.

If your blood sugar levels are a problem for you, talk with your doctor about other treatments. You can ask your doctor or pharmacist for information about other medicines that can help you with your blood sugar levels. You can also find out more about rosiglitazone maleate tablets by calling 1-888-838-2872, MEDICAL AFFAIRS.

If you take rosiglitazone maleate tablets and your blood sugar levels do not improve, see your doctor or pharmacist for information about other medicines that can help you with your blood sugar levels.

If you would like more information, find out more about rosiglitazone maleate tablets by calling 1-888-838-2872, MEDICAL AFFAIRS.

The most common side effects of taking rosiglitazone maleate tablets are:

- Edema
- Lightheadedness
- Edema, or swelling in the legs, ankles, or feet
- Overactive bladder or difficulty urinating

If you have any concerns about the side effects of rosiglitazone maleate tablets, talk with your healthcare provider.

If you are pregnant, tell your doctor or pharmacist before you take rosiglitazone maleate tablets. It is important not only in the primary treatment of type 2 diabetes, but in the prevention of diabetic complications. In monotherapy trials, a greater therapeutic response was observed in females, with increases in body weight. Over the weight range observed in these studies, no significant decrease in hemoglobin A1c (HbA1c) was reported in females compared to males. Treatment with rosiglitazone is also associated with a greater increase in body weight compared to control therapies (Table 14). In a set of clinical trials, rosiglitazone was associated with a greater increase in body weight compared to control therapies, with a greater incidence of edema and a greater incidence of weight-related treatment withdrawals.

Table 14: Change from baseline in body weight and edema

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Body Weight Change</th>
<th>Edema</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rosiglitazone</td>
<td>2 mg twice daily</td>
<td></td>
</tr>
<tr>
<td>Metformin</td>
<td>2 mg twice daily</td>
<td></td>
</tr>
<tr>
<td>Glyburide</td>
<td>8 mg once daily</td>
<td></td>
</tr>
</tbody>
</table>

In patients inadequately controlled on 2.5 grams/day of metformin, treatment failure (n = 90) during the study period was associated with an increase in body weight and edema. The addition of rosiglitazone maleate to either metformin or sulfonylurea (mean baseline FPG 216 mg/dL and mean baseline HbA1c 7.0%) resulted in a significant improvement in glycemic control in both males and females. In metformin monotherapy, an increase in the glyburide-treated patients was not statistically significant. In sulfonylurea monotherapy, the combination of rosiglitazone 4 mg twice daily and metformin (N = 105) had a statistically significant mean increase in HbA1c of 0.8% compared to placebo plus metformin (N = 105) (p < 0.05). The mean increase in HbA1c was greater in females compared to males.

The combination of rosiglitazone 4 mg twice daily and metformin (N = 105) had a significant increase in the incidence of benign prostatic hyperplasia (BPH) in older (≥ 65 years) men compared to younger (< 65 years) men. The addition of rosiglitazone maleate to either metformin or sulfonylurea (mean baseline HbA1c 7.0%) resulted in a significant improvement in glycemic control in both males and females. In metformin monotherapy, an increase in the glyburide-treated patients was not statistically significant. In sulfonylurea monotherapy, the combination of rosiglitazone 4 mg twice daily and metformin (N = 105) had a statistically significant mean increase in HbA1c of 0.8% compared to placebo plus metformin (N = 105) (p < 0.05). The mean increase in HbA1c was greater in females compared to males.

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**Warning and Precautions (5.1)**

Recent major changes include a warning of increased risk of myocardial infarction.

Because of the potential increased cardiovascular risk of rosiglitazone maleate, the manufacturer's labeling has been updated to reflect the increased risk of heart failure and edema and to include a boxed warning about the risk of edema.

**Contraindications (5.2)**

- Congestive heart failure
- History of cardiac failure

**Warnings and Precautions (5.2)**

- Cardiac failure
- Edema
- Hypoglycemia
- Anemia

**Drug Interactions (5.3)**

- Rosiglitazone maleate tablets should not be used with insulin.

**Postmarketing Experience (5.4)**

- Edema
- Cardiac failure

**Hepatic Impairment (5.5)**

- No dose adjustment is required.

**Use In Specific Patient Populations (5.6)**

- Pregnancy
- Initiation of rosiglitazone maleate tablets in patients with established diabetes

**Adverse Reactions (5.7)**

- Edema
- Cardiac failure
- Anemia

**Drug-Drug Interactions (5.8)**

- Rosiglitazone maleate tablets should not be used with insulin.

**Hepatic Impairment (5.9)**

- No dose adjustment is required.

**Use In Specific Patient Populations (5.10)**

- Pregnancy
- Initiation of rosiglitazone maleate tablets in patients with established diabetes

**Adverse Reactions (5.11)**

- Edema
- Cardiac failure
- Anemia

**Drug-Drug Interactions (5.12)**

- Rosiglitazone maleate tablets should not be used with insulin.

**Hepatic Impairment (5.13)**

- No dose adjustment is required.

**Use In Specific Patient Populations (5.14)**

- Pregnancy
- Initiation of rosiglitazone maleate tablets in patients with established diabetes

**Adverse Reactions (5.15)**

- Edema
- Cardiac failure
- Anemia

**Drug-Drug Interactions (5.16)**

- Rosiglitazone maleate tablets should not be used with insulin.

**Hepatic Impairment (5.17)**

- No dose adjustment is required.

**Use In Specific Patient Populations (5.18)**

- Pregnancy
- Initiation of rosiglitazone maleate tablets in patients with established diabetes

**Adverse Reactions (5.19)**

- Edema
- Cardiac failure
- Anemia

**Drug-Drug Interactions (5.20)**

- Rosiglitazone maleate tablets should not be used with insulin.

**Hepatic Impairment (5.21)**

- No dose adjustment is required.

**Use In Specific Patient Populations (5.22)**

- Pregnancy
- Initiation of rosiglitazone maleate tablets in patients with established diabetes

**Adverse Reactions (5.23)**

- Edema
- Cardiac failure
- Anemia

**Drug-Drug Interactions (5.24)**

- Rosiglitazone maleate tablets should not be used with insulin.
Low blood sugar (hypoglycemia).

Low red blood cell count (anemia).

Rosiglitazone maleate tablets may be

This Medication Guide summarizes important

Your doctor should do blood tests to check your

What is the most important

The maximum recommended daily dose is 8 mg. Dose-ranging trials

HC

A total of 2,315 patients with type 2 diabetes,

The maximum recommended daily dose is 8 mg. Dose-ranging trials

Baseline (mean) 8.3 8.2 8.8 8.5

metformin (mean baseline FPG 216 mg/dL and mean baseline HbA1c

Table 8. Week 24 FPG and HbA1c Change From Baseline Last-

A total of 2,315 patients with type 2 diabetes,

Baseline (mean) 8.6 8.8 8.9 8.9

metformin (mean baseline FPG 216 mg/dL and mean baseline HbA1c

In these trials, the combination of rosiglitazone 4 mg or 8 mg daily

In these trials, the combination of rosiglitazone 4 mg or 8 mg daily

Chemically, rosiglitazone maleate is (±)-5-[[4-[2-(methyl-2-pyridinylamino)

Chemically, rosiglitazone maleate is (±)-5-[[4-[2-(methyl-2-pyridinylamino)

Geriatric

The maximum recommended daily dose is 8 mg. Dose-ranging trials

The maximum recommended daily dose is 8 mg. Dose-ranging trials

There were no meaningful differences in incidence of adverse events

Adverse events may include:

This Medication Guide summarizes important

This Medication Guide summarizes important

In these trials, the combination of rosiglitazone 4 mg or 8 mg daily

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In some premenopausal anovulatory women. As

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This Medication Guide summarizes important

This Medication Guide summarizes important
Rosiglitazone Maleate Tablets

Read this Medication Guide carefully before you start taking rosiglitazone maleate tablets. There may be new information. This information does not take the place of talking with your doctor about your medical condition and your treatment. If you have any questions about rosiglitazone maleate tablets, ask your doctor or pharmacist.

What is the most important information I should know about rosiglitazone maleate tablets?

Rosiglitazone maleate tablets are available only through the AVANDIA Medicines Access Program. Both you and your doctor must enroll in the program so that you can get rosiglitazone maleate tablets. To enroll, you must:

• talk to your doctor
• understand all the risks and benefits of rosiglitazone maleate tablets, and
• enroll in the program.

Rosiglitazone maleate tablets may cause serious side effects, including:

New or worse heart failure

Rosiglitazone maleate tablets 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 rosiglitazone maleate tablets. If you have heart failure with symptoms (such as shortness of breath or swelling), even if these symptoms are not severe, rosiglitazone maleate tablets 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 unusual weight increase
• unusual tiredness

Myocardial Infarction ("Heart Attack"). Rosiglitazone maleate tablets may raise the risk of a heart attack. The risk of having a heart attack may be higher in people who take rosiglitazone maleate tablets with insulin. Most people who take insulin should not also take rosiglitazone maleate tablets.

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 and 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 light-headed

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. Rosiglitazone maleate tablets can have other serious side effects. Be sure to read the section below “What are possible side effects of rosiglitazone maleate tablets?”

What are possible side effects of rosiglitazone maleate tablets?

Rosiglitazone maleate tablets are a prescription medicine 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 maleate tablets or
• unable to control their blood sugar on other diabetes medicines, and after talking with their doctor have decided not to take pioglitazone (ACTOS®).

Rosiglitazone maleate tablets help to control high blood sugar. Rosiglitazone maleate tablets may be used alone or with other diabetes medicines. Rosiglitazone maleate tablets may be used along with insulin to control high blood sugar. Rosiglitazone maleate tablets do not cause your body to make more insulin.

Rosiglitazone maleate tablets are not for people with type 1 diabetes mellitus or to treat a condition called diabetic ketoacidosis.

It is not known if rosiglitazone maleate tablets are safe and effective in children under 18 years old.

Who should not take rosiglitazone maleate tablets?

People with heart failure should not start taking rosiglitazone maleate tablets. See "What should I tell my doctor before taking rosiglitazone maleate tablets?"

What should I tell my doctor before taking rosiglitazone maleate tablets?

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

• have heart problems or heart failure, have type 1 ("juvenile") diabetes or had diabetic ketoacidosis. These conditions should be treated with insulin.

• have a type of diabetes 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 rosiglitazone maleate tablets and then keep taking them. See "What should I do if I am pregnant or planning to become pregnant?"

• have type 1 (“juvenile”) diabetes or had diabetic ketoacidosis.
• have heart failure.

Your doctor should do blood tests to check your liver before you start taking rosiglitazone maleate tablets and then keep taking them. See "What should I do if I am pregnant or planning to become pregnant?"

• are pregnant or plan to become pregnant.

Rosiglitazone maleate tablets should not be used during pregnancy. It is not known if rosiglitazone maleate tablets 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 pregnant woman, the "change of life") who does not have regular monthly periods, rosiglitazone maleate tablets may increase your chances of becoming pregnant. Talk to your doctor about birth control choices while taking rosiglitazone maleate tablets. Tell your doctor right away if you become pregnant while taking rosiglitazone maleate tablets.

• are breast-feeding or planning to breast-feed.

It is not known if rosiglitazone maleate tablets pass into breast milk. You and your doctor should decide if you will breast-feed while taking rosiglitazone maleate tablets with breast feeding.

Tell your doctor about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements.

Rosiglitazone maleate tablets and certain other medicines can affect each other and may lead to serious side effects including high or low blood sugar or heart problems. Specifically 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. Give the medicines to your doctor. Keep a list of 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 rosiglitazone maleate tablets with other medicines.

How should I take rosiglitazone maleate tablets?

Take rosiglitazone maleate tablets exactly as prescribed. Your doctor will tell you how many tablets to take and how often.

The usual daily starting dose is 4 mg a day taken one time each day or 2 mg taken two times each day. Your doctor may need to adjust your dose until your blood sugar is better controlled.

Your doctor will probably start you on a low dose and increase it slowly to the full dose. Your dose may be changed from time to time.

Your doctor will probably start you on a low dose and increase it slowly to the full dose. Your dose may be changed from time to time.

Your doctor will probably start you on a low dose and increase it slowly to the full dose. Your dose may be changed from time to time.
Rosiglitazone maleate tablets may be prescribed alone or with other diabetes medicines. This will depend on how well your blood sugar is controlled.

Take rosiglitazone maleate tablets with or without food.

It can take 2 weeks for rosiglitazone maleate tablets to start lowering 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 rosiglitazone maleate tablets, 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 many rosiglitazone maleate tablets, call your doctor or poison center right away.

Test your blood sugar regularly as your doctor tells you.

Diet and exercise can help your body use blood sugar, or if you have certain medical problems. Call your doctor right away if you have any 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 (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 maleate tablets.

Foot numbness (peripheral neuropathy), 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).

Low blood sugar (hypoglycemia). Light-headedness, dizziness, weakness or hunger may mean that your blood sugar is too low. This can happen if you skip meals. If you use another medicine that lowers blood sugar, or if you have certain medical problems. Call your doctor if low blood sugar is a problem for you.

Dullness (release of egg from an ovary in a woman) leading to pregnancy. Ovulation may happen in premenopausal women who do not have regular monthly periods. Call your doctor right away.

See "What should I tell my doctor before taking rosiglitazone maleate tablets?"

The most common side effects of rosiglitazone maleate tablets reported in clinical trials included cold-like symptoms and headaches.

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

In clinical trials, rosiglitazone maleate tablets at room temperature, 20° to 25°C (68° to 77°F).

Keep rosiglitazone maleate tablets in the container they came in.

Safety, throw away rosiglitazone maleate tablets that are out of date or no longer needed.

Keep rosiglitazone maleate tablets and all medicines out of the reach of children.

General information about rosiglitazone maleate tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use rosiglitazone maleate tablets for a condition for which they were not prescribed. Do not give rosiglitazone maleate tablets to other people, even if they have the same symptoms you have. They may harm them.

This Medication Guide summarizes important information about rosiglitazone maleate tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about rosiglitazone maleate tablets that is written for healthcare professionals. You can also find out more about rosiglitazone maleate tablets by calling Teva Pharmaceuticals at 1-888-838-2972, MEDICAL AFFAIRS.

What are the ingredients in rosiglitazone maleate tablets?

Active Ingredient: rosiglitazone maleate.

Inactive Ingredients: croscarmellose sodium, hypromellose (10, 6cP), iron oxide red, iron oxide yellow, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide, and FD&C Blue #2 (indigo carmine aluminum lake), the 4 mg tablet contains iron oxide black, and the 4 mg and 8 mg tablets contain iron oxide yellow.

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

Rosiglitazone maleate tablets are round and standard-convex and look like this:

- 2 mg – pink with “93” on one side and “7322” on the other.
- 4 mg – orange with “93” on one side and “7324” on the other.
- 8 mg – red brown with “93” on one side and “7326” on the other.

All brand names listed are the registered trademarks of their respective owners and are not trademarks of Teva Pharmaceuticals USA.

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

Manufactured in Israel By:

TEVA PHARMACEUTICAL IND. LTD.
Jerusalem, 91010, Israel

Manufactured For:

TEVA PHARMACEUTICALS USA
Sellersville, PA 18960

Iss. 11/2011
Symptoms of a heart attack can include:
• chest discomfort that feels like pressure or fullness or pain
• discomfort in your arms, back, neck, jaw or stomach
• shortness of breath or trouble breathing, especially when you are not physicaly active or when you are lying down
• nausea or vomiting
• breaking out in a cold sweat
• feeling light-headed

Call your doctor or go to the nearest 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. Rosiglitazone maleate tablets can have other serious side effects. Be sure to read the section above ‘What are the possible side effects of rosiglitazone maleate tablets?’ before you start taking rosiglitazone maleate tablets.

What are the possible side effects of rosiglitazone maleate tablets?

Rosiglitazone maleate tablets can have other serious side effects. Be sure to read the section above ‘What are the possible side effects of rosiglitazone maleate tablets?’ before you start taking rosiglitazone maleate tablets.

What should I do if I am pregnant?

If you are pregnant or plan to become pregnant.

Rosiglitazone maleate tablets may increase your chances of having a baby that is born with the following:
• a small head
• a cleft lip or palate (a split in the back of the eye).

These conditions can be treated with surgery, but the risks and benefits of surgery must be discussed with your doctor.

Tell your doctor about all the medicines you take while taking rosiglitazone maleate tablets. This includes prescription, non-prescription, and herbal medicines.

You may need to adjust your dose while taking rosiglitazone maleate tablets.

Rosiglitazone maleate tablets are not right for everyone.

You should not take rosiglitazone maleate tablets:

• if you are allergic to rosiglitazone maleate tablets or any of the other ingredients in this medicine
• if you have liver problems, or have had liver problems while taking rosiglitazone maleate tablets and during treatment as needed.
• if you have myeloproliferative disease
• if you have or have had a heart attack or stroke
• if you have had liver problems while taking rosiglitazone maleate tablets and during treatment as needed.

Tell your doctor about any medicines you take while taking rosiglitazone maleate tablets. This includes prescription, non-prescription, and herbal medicines.

You may need to adjust your dose while taking rosiglitazone maleate tablets.

Rosiglitazone maleate tablets are not right for everyone.

You should not take rosiglitazone maleate tablets:

• if you are allergic to rosiglitazone maleate tablets or any of the other ingredients in this medicine
• if you have liver problems, or have had liver problems while taking rosiglitazone maleate tablets and during treatment as needed.
• if you have myeloproliferative disease
• if you have had liver problems while taking rosiglitazone maleate tablets and during treatment as needed.

Tell your doctor about any medicines you take while taking rosiglitazone maleate tablets. This includes prescription, non-prescription, and herbal medicines.

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Rosiglitazone maleate tablets may be prescribed alone or with other diabetes medicines. This will depend on how well your blood sugar is controlled.

Take rosiglitazone maleate tablets with or without food.

It can take 2 weeks for rosiglitazone maleate tablets to start lowering 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 rosiglitazone maleate tablets, 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 many rosiglitazone maleate tablets, call your doctor or poison control center.

Test your blood sugar regularly as your doctor tells you.

• 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 rosiglitazone maleate tablets.

• Your doctor should do blood tests to check your liver before you start taking rosiglitazone maleate. Your doctor should do these liver blood tests frequently while you take rosiglitazone maleate. Your doctor should also do regular blood sugar tests (for example, "A1C").

• Test to swelling in the back of the eye while taking rosiglitazone maleate tablets. Tell your doctor right away if you have any eye problems (such as changes in your vision) while taking rosiglitazone maleate tablets.

• Swelling in the hands, upper arm or foot. Talk to your doctor about how to keep your bones healthy.

• Any abnormal swelling in the body, usually in the feet while taking rosiglitazone maleate tablets.

• Low blood sugar (hypoglycemia). Lightheadedness, dizziness, weakness or hunger may mean that your blood sugar is too low. You can have hypoglycemia if you skip meals, if you use another medicine that lowers blood sugar, or if you have certain medical problems. Call your doctor if low blood sugar is a problem for you.

Divalproex (release of egg from an ovary in a woman) leading to pregnancy. Divalproex may happen in premenopausal women who do not have regular monthly periods.

• Tell your doctor if you are a woman and you do not have regular monthly periods.

• Call your doctor or your pharmacist for information about rosiglitazone maleate tablets that is written for healthcare professionals. You can also find out more about rosiglitazone maleate tablets by calling Teva Pharmaceuticals at 1-888-333-2072, MEDICAL AFFAIRS.

• What are the ingredients in rosiglitazone maleate tablets?

Active ingredient: rosiglitazone maleate.

Inactive ingredients: croscarmellose sodium, hypromellose (10, 60%), iron oxide red, iron oxide yellow, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, polyvinylpyrrolidone, hydroxypropyl methylcellulose, FD&C blue #2 (indigo carmine aluminum lake), the 4 mg tablet contains iron oxide black, and the 4 mg and 8 mg tablets contain iron oxide yellow.

Always check to make sure that the medicine you are taking is the correct one. Rosiglitazone maleate tablets are round and standard convex and look like this:

2 mg – pills with "93" on one side and "7322" on the other.
4 mg – orange with "93" on one side and "7323" on the other.
8 mg – red-brown with "93" on one side and "7324" on the other.

All brand names listed are the registered trademarks of their respective owners and are not trademarks of Teva Pharmaceuticals USA.

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

TEVA PHARMACUTICALS USA
Sellersville, PA 18960

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