Rosiglitazone Maleate and Glimepiride Tablets
4 mg*/1 mg

once daily

Each film-coated tablet contains rosiglitazone maleate equivalent to 4 mg rosiglitazone and contains 1 mg glimepiride. USP.

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

Store at 20° to 25°C (68° to 77°F).

Promptly report any adverse events. See package insert for full prescribing information.

Temperate.

Iss. 9/2015

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

By order

30 TABLETS

TEVA
NDC 0093-7643-05
once daily
Rosiglitazone Maleate and Glimepiride Tablets
4 mg*/1 mg
PHARMACIST: Dispense the accompanying Medication Guide to each patient.
Rx only
500 TABLETS
NDC 0093-7644-56
once daily
Rosiglitazone Maleate and Glimepiride Tablets
4 mg*/2 mg

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

Rx only

30 TABLETS
**Rosiglitazone Maleate and Glimepiride Tablets**

4 mg*/2 mg

**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).**

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**

**NDC 0093-7644-05**

once daily
Rosiglitazone Maleate and Glimepiride Tablets

4 mg*/4 mg

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

RX only

30 TABLETS
Rosiglitazone Maleate and Glimepiride Tablets
4 mg*4 mg

NDC 0093-7642-05
once daily

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. 9/2015

PHARMACIST: Dispense the accompanying Medication Guide to each patient.
Rosiglitazone Maleate and Glimepiride Tablets

8 mg*/2 mg

NDC 0093-7700-56

once daily

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

Rx only

30 TABLETS

TEVA PHARMACEUTICALS USA, INC.
North Wales, PA 19454

*Each film-coated tablet contains rosiglitazone maleate equivalent to 8 mg rosiglitazone and contains 2 mg glimepiride. USP.

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

Store at 25° to 30°C (77° to 86°F) [See USP Controlled Room Temperature].

Keep this and all medications out of the reach of children.
Rosiglitazone Maleate and Glimepiride Tablets
8 mg*/2 mg

*Each film-coated tablet contains rosiglitazone maleate equivalent to 8 mg rosiglitazone and contains 2 mg glimepiride, USP.

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°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.

Rx only

500 TABLETS

Pharmacist: Dispense the accompanying Medication Guide to each patient.
NDC 0093-7702-56
once daily
Rosiglitazone Maleate and Glimepiride Tablets
8 mg*/4 mg

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

30 TABLETS

*Each film-coated tablet contains rosiglitazone maleate equivalent to 8 mg rosiglitazone and contains 4 mg glimepiride. USP.

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.
Rosiglitazone Maleate and Glimepiride Tablets
8 mg*/4 mg

Each film-coated tablet contains rosiglitazone maleate equivalent to 8 mg rosiglitazone and contains 4 mg glimepiride, USP.

*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].

Keep this and all medications out of the reach of children.

Rx only

500 TABLETS

Iss. 9/2015
Rosiglitazone maleate and glimepiride tablets combine 2 antidiabetic agents with different mechanisms of action to improve glycemic control in patients with type 2 diabetes. Rosiglitazone is a thiazolidinedione that acts in the cell nucleus to increase the sensitivity of insulin receptors on the surface of tissue cells. Glimepiride is a sulfonylurea that acts in the pancreas to increase the amount of insulin released. These agents have a synergistic effect on glycemic control that is not simply additive, but also demonstrates a more sustained effect. Rosiglitazone maleate and glimepiride tablets are available for oral administration as tablets containing rosiglitazone maleate 15 mg and glimepiride 2 mg, 4 mg, 8 mg, and 12 mg.

### Pharmacokinetics

Rosiglitazone maleate and glimepiride tablets are rapidly absorbed, with peak drug concentrations (Cmax) 2 to 3 hours post-dose. When glimepiride was given with meals, the mean Cmax decreased 20% compared to fasting conditions. The extent of glimepiride absorption is not affected by food. Cmax and AUC (area under the curve) of glimepiride were increased by 32% and 39%, respectively, with the addition of a high-fat meal. Rosiglitazone maleate and glimepiride tablets are metabolized by the liver, and the main metabolites are excreted in the urine.

### Side Effects

Hypoglycemia was reported to be generally mild to moderate in intensity and none of the reported events of hypoglycemia resulted in hospitalization. The most common adverse reactions associated with rosiglitazone maleate and glimepiride tablets are edema, dyspnea, weight gain, and congestive heart failure. These reactions are most often reported in patients with established cardiovascular disease. The incidence of congestive heart failure was significantly greater in patients treated with rosiglitazone compared to placebo. Rosiglitazone increased plasma volume in a dose-dependent manner, which may contribute to edema and CHF. The fluid retention was transient, and returned to baseline during dose reduction. Alternatively, the increased plasma volume may be related to the increased plasma volume observed with treatment with rosiglitazone.

### Drug Interactions

Rosiglitazone: In patients receiving thiazolidinedione therapy, serious adverse events with or without a fatal outcome, potentially related to heart failure, have been reported in several clinical trials. These events have included new or worsening heart failure, edema, and CHF worsening. These events may be related to the increased plasma volume observed with treatment with rosiglitazone.

Glimepiride: Glimepiride is extensively metabolized in the liver and primarily eliminated in the urine. Glimepiride is not renally excreted. Glimepiride tablets are not recommended for patients experiencing an acute coronary event.

### Use in Special Populations

The safety and efficacy of rosiglitazone maleate and glimepiride tablets have not been established in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

### Pregnancy

Rosiglitazone maleate and glimepiride tablets are not recommended for use during pregnancy. Animal reproduction studies have shown decreased litter size, neonatal viability, and postnatal growth in rats treated with rosiglitazone during gestation and lactation. There are no adequate and well-controlled studies in pregnant women. If rosiglitazone maleate and glimepiride tablets are used during pregnancy, or if the mother is exposed to rosiglitazone during pregnancy, the drug should be discontinued.

### Nursing Mothers

It is not known if rosiglitazone maleate or glimepiride is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when rosiglitazone maleate and glimepiride tablets are administered to a nursing mother.

### Pediatrics

The safety and effectiveness of rosiglitazone maleate and glimepiride tablets in pediatric patients have not been established.

### Geriatric Use

No specific age-related differences in pharmacokinetics or pharmacodynamics were observed between elderly and younger patients in clinical trials. However, elderly patients may be more sensitive to hypoglycemia. Therefore, elderly patients should be started on a lower dose of rosiglitazone maleate and glimepiride tablets and titrated more cautiously.

### Administration

These highlights do not include all the information needed to use rosiglitazone maleate and glimepiride tablets safely and effectively. Please consult the full prescribing information for complete details.

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### Table: Changes in Mean Hematologic Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Placebo</th>
<th>Rosiglitazone 15 mg</th>
<th>Rosiglitazone 45 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red Blood Cells (x10^12/L)</td>
<td>4.5</td>
<td>4.7</td>
<td>5.1</td>
</tr>
<tr>
<td>Hemoglobin (g/dL)</td>
<td>13.5</td>
<td>14.2</td>
<td>14.5</td>
</tr>
<tr>
<td>Hematocrit (%)</td>
<td>41</td>
<td>42</td>
<td>43</td>
</tr>
</tbody>
</table>

### Table: Changes in Mean Lipid Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Placebo</th>
<th>Rosiglitazone 15 mg</th>
<th>Rosiglitazone 45 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Cholesterol (mg/dL)</td>
<td>180</td>
<td>190</td>
<td>195</td>
</tr>
<tr>
<td>LDL Cholesterol (mg/dL)</td>
<td>100</td>
<td>110</td>
<td>115</td>
</tr>
<tr>
<td>HDL Cholesterol (mg/dL)</td>
<td>40</td>
<td>45</td>
<td>50</td>
</tr>
<tr>
<td>Triglycerides (mg/dL)</td>
<td>150</td>
<td>170</td>
<td>180</td>
</tr>
</tbody>
</table>

### Table: Changes in Mean Weight (kg)

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean Change (kg)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>-1</td>
<td>-2 to 0</td>
</tr>
<tr>
<td>Rosiglitazone 15 mg</td>
<td>-1</td>
<td>-2 to -0.5</td>
</tr>
<tr>
<td>Rosiglitazone 45 mg</td>
<td>-1.5</td>
<td>-2.5 to -0.5</td>
</tr>
</tbody>
</table>

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### References

3. US Food and Drug Administration. (2016). Rosiglitazone and Glimepiride Tablets. Available at: [FDA website](https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/020913s000lbl.pdf)

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### Additional Information

For more information, please consult the full prescribing information for rosiglitazone maleate and glimepiride tablets. This summary is intended for use by healthcare professionals and is not a substitute for the full prescribing information.
before taking rosiglitazone and glimepiride tablets. To your doctor before taking rosiglitazone maleate and glimepiride tablets:
• have heart problems or heart block
• have had a heart attack in the past
• have had a stroke in the past
• have diabetes with severe complications (eg, retinopathy, nephropathy, or peripheral neuropathy)
• have a kidney disorder
• have liver disease
• have stomach or intestinal problems (eg, stomach ulcers, intestinal blockage)
• have had hormone-replacement therapy (HRT)
• have had breast cancer
• have had cancer of the breast or uterus
• have a history of myasthenia gravis
• are allergic to rosiglitazone maleate or any of the ingredients in rosiglitazone maleate and glimepiride tablets.

Before taking rosiglitazone maleate and glimepiride tablets, tell your doctor:
• if you have been taking other diabetes medicines
• if you have ever had an allergic reaction to rosiglitazone or any ingredients in rosiglitazone maleate and glimepiride tablets
• if you have used medications that interfere with your body's ability to control your blood sugar
• if you have a history of anemia
• if you have a history of heart disease
• if you have a history of kidney disease
• if you have had heart valve surgery
• if you have had a heart valve replacement
• if you have had liver disease
• if you have a history of cancer
• if you have had a history of myasthenia gravis
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• if you have had a history of myasthenia gravis
• if you have had a history of myasthenia gravis
• if you have had a history of myasthe
diabetes mellitus or to treat a condition called diabetic ketoacidosis.

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

- New or worse heart failure
- Rapid or irregular heartbeat
- Swelling or fluid retention, especially in the ankles or legs
- Very rapid heartbeat
- Very weak or fast pulse

If you have severe heart failure, you cannot start rosiglitazone maleate and glimepiride tablets.

Swelling (edema). Rosiglitazone maleate and glimepiride tablets may cause swelling due to fluid retention. See "What is the most important information I should know about rosiglitazone maleate and glimepiride tablets?" for more information.

Rosiglitazone, one of the two drugs that make up rosiglitazone maleate and glimepiride tablets, is a thiazolidinedione (TZD) diabetes medicine. See "What are rosiglitazone maleate and glimepiride tablets?" for more information.

Take rosiglitazone maleate and glimepiride tablets exactly as prescribed. Your doctor may change the dose or stop your medicine if side effects become a problem.

If you miss a dose:

- Take the missed dose as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and take your next dose at the usual time. Do not take double doses to make up for a dose you missed.

If you do not take your medicine:

- Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088. This Medication Guide summarizes important information about rosiglitazone maleate and glimepiride tablets. Do not use rosiglitazone maleate and glimepiride tablets without calling your doctor. You can ask your doctor or pharmacist for information about the strengths of rosiglitazone maleate and glimepiride tablets that are available for you. See "What are the ingredients in rosiglitazone maleate and glimepiride tablets?"

See the full effect on your blood sugar level. It may take 2 to 3 months to see the full effect on your blood sugar level. See "What are possible side effects of rosiglitazone maleate and glimepiride tablets?"

What are possible side effects of rosiglitazone maleate and glimepiride tablets?

Rosiglitazone maleate and glimepiride tablets may cause serious side effects. Call your doctor right away if you have any of the following:

- Inability to urinate
- Fever, chills, or sore throat that does not improve
- Very rapid heartbeat
- Very weak or fast pulse
- Shortness of breath with or without chest discomfort
- New or worse heart failure
- Very rapid heartbeat

If you have any of the following symptoms, call your doctor right away:

- Inability to urinate
- Fever, chills, or sore throat that does not improve
- Very rapid heartbeat
- Very weak or fast pulse

Rosiglitazone maleate and glimepiride tablets may increase your chances of becoming pregnant. Talk to your doctor about other options with your doctor before taking rosiglitazone maleate and glimepiride tablets for treatment of high blood pressure. Rosiglitazone maleate and glimepiride tablets may increase your chances of becoming pregnant. Talk to your doctor about other options with your doctor before taking rosiglitazone maleate and glimepiride tablets for treatment of high blood pressure.

Rosiglitazone maleate and glimepiride tablets may increase your chances of becoming pregnant. Talk to your doctor about other options with your doctor before taking rosiglitazone maleate and glimepiride tablets for treatment of high blood pressure.