GLUMETZA (glimepiride) tablets,

Full Prescribing Information: Contents*

HIGHLIGHTS OF PRESCRIBING INFORMATION

INDICATIONS AND USAGE

GLUMETZA is a biguanide indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. (1.1)

Starting dose is 500 mg daily with evening meal (2.1)

WARNINGS AND PRECAUTIONS

3.3 Severe renal impairment

Obtain an eGFR at least annually in all patients taking GLUMETZA. In patients at increased risk for the development of renal impairment, monitor renal function at least annually. If renal function falls below 60 mL/min/1.73 m2; in patients with a history of hepatic impairment, alcoholism, or heart failure; or in patients receiving more than one medication that could affect renal function, consider more frequent monitoring of these patients. (3.3)

3.4 Alcohol intake

Drinking alcohol can increase the hypoglycemic effect of a biguanide such as GLUMETZA, and patients should be cautioned against alcohol intake while receiving GLUMETZA. (3.4)

5.1 Metformin-associated lactic acidosis

Metformin hydrochloride is dialyzable, with a clearance of up to 1.6 mL/kg/hour. If metformin-associated lactic acidosis is suspected, general supportive measures should be instituted promptly. (5.1)

5.4 Pregnancy

Metformin was not teratogenic in rats and rabbits at doses up to 600 mg/kg/day, which represent 3 and 6 times the maximum recommended human daily dose, respectively. However, because animal reproduction studies are not always predictive of human response, and because there is a risk of fetal harm when using any prescribed medicine during pregnancy, GLUMETZA should not be used during pregnancy except in cases of life-threatening situations. (5.4)

7.1 Pregnancy

Consider the benefits of the drug in therapy of a pregnant woman outweighing the potential hazards to the fetus. When such drugs are withdrawn from a patient receiving GLUMETZA, the patient should be observed carefully for hypoglycemia. (7.1)

7.2 Lactation

It is not known if GLUMETZA passes into human milk. The potential for hypoglycemia in the nursing infant due toGLUMETZA is unknown. Consider the benefits of the drug in therapy of a nursing woman outweighing the potential hazards to the infant. If the patient elects to use GLUMETZA while she is nursing, she should be advised of the potential risk to the infant. (7.2)

7.3 Children

Safety and effectiveness in children have not been established. (7.3)

DRUG INTERACTIONS

5.2 Concomitant use of GLUMETZA with specific drugs may increase the risk of metformin-associated lactic acidosis. Consider the benefits of the drug in therapy of a patient receiving GLUMETZA outweighing the potential hazards of the concomitant use of these drugs. (5.2)

7.5 Human milk

It is not known if GLUMETZA passes into human milk. The potential for hypoglycemia in the nursing infant due to GLUMETZA is unknown. Consider the benefits of the drug in therapy of a nursing woman outweighing the potential hazards to the infant. If the patient elects to use GLUMETZA while she is nursing, she should be advised of the potential risk to the infant. (7.5)

ADVERSE REACTIONS

12.1 Treatment-emergent adverse reactions reported by >5% of patients for the combined GLUMETZA and placebo treatment groups in clinical trials of immediate-release GLUMETZA are shown in Table 1. (12.1)

13.1 List of ingredients in GLUMETZA

GLUMETZA tablets contain glimepiride USP, an antihyperglycemic agent of the sulfonylurea class, and the following inactive ingredients: lactose monohydrate, pregelatinized starch, hydroxypropyl methylcellulose, hypromellose, calcium stearate, magnesium stearate, and polyethylene glycol 6000. (13.1)

14.1 How is GLUMETZA supplied?

GLUMETZA is supplied as white, round, scored tablets, containing 2.5 mg, 5 mg, 10 mg, or 15 mg of glimepiride USP (glimepiride monohydrochloride), in bottles of 100, 1000, and 5000. (14.1)

15.1 How should I store GLUMETZA?

Store at 25°C (77°F) excursions permitted between 15°C to 30°C (59°F to 86°F). (15.1)

16.1 How can you get more information?

For more information, contact Patheon, LLC, at 1-844-832-1650. (16.1)

16.2 Patient Information

For patient information, please see Patient Information. (16.2)

17.1 What is the most important information I should know about GLUMETZA?

Serious side effects can happen in people taking GLUMETZA, including:

• Lactic acidosis (3.4)

See "What are the possible side effects of GLUMETZA?" for a description of the possible side effects of GLUMETZA. (17.1)

Table 1:

Treatment-emergent adverse reactions reported by >5% of patients for the combined GLUMETZA and placebo treatment groups in clinical trials of immediate-release GLUMETZA are shown in Table 1. (12.1)

[Table 1: Treatment-emergent adverse reactions reported by >5% of patients for the combined GLUMETZA and placebo treatment groups in clinical trials of immediate-release GLUMETZA is shown here.]

Table 1: Treatment-emergent adverse reactions reported by >5% of patients for the combined GLUMETZA and placebo treatment groups in clinical trials of immediate-release GLUMETZA are shown in Table 1. (12.1)

12.2 Treatment-emergent adverse reactions reported by >5% of patients for the combined GLUMETZA and placebo treatment groups in clinical trials of immediate-release GLUMETZA are shown in Table 1. (12.2)

13.2 List of ingredients in GLUMETZA

GLUMETZA tablets contain glimepiride USP, an antihyperglycemic agent of the sulfonylurea class, and the following inactive ingredients: lactose monohydrate, pregelatinized starch, hydroxypropyl methylcellulose, hypromellose, calcium stearate, magnesium stearate, and polyethylene glycol 6000. (13.2)

14.2 How should I store GLUMETZA?

Store at 25°C (77°F) excursions permitted between 15°C to 30°C (59°F to 86°F). (14.2)

15.2 How can you get more information?

For more information, contact Patheon, LLC, at 1-844-832-1650. (15.2)

16.3 Patient Information

For patient information, please see Patient Information. (16.3)

17.2 What should I tell my doctor before taking GLUMETZA?

Before you take GLUMETZA, tell your doctor if:

• you have type 1 diabetes (3.4)

• you have type 2 diabetes (3.4)
**GLUMETZA**

**What is GLUMETZA?**

GLUMETZA is a prescription medicine used to treat type 2 diabetes in adults. GLUMETZA helps control blood sugar levels when used with lifestyle changes like diet and exercise.

**How should I take GLUMETZA?**

- **Missed Doses:** Take a missed dose as soon as you remember it. If it is almost time for your next dose, skip the missed dose and take your next dose at the regular time. Do not take two doses at the same time.
- **If Taking GLUMETZA with Food:** GLUMETZA can be taken with or without food. Taking it with a meal can help reduce the risk of side effects like nausea, vomiting, and diarrhea.
- **Taking Other Medications:** Talk to your healthcare provider about which medications you can take with GLUMETZA. You can take other medications at the same time you take GLUMETZA, unless your healthcare provider tells you not to.

**What else should I know about GLUMETZA?**

- **Do not take GLUMETZA if you have:**
  - Low blood sugar (hypoglycemia). GLUMETZA can cause serious side effects if you have low blood sugar.
  - Liver disease.
  - Renal impairment.
- **Tell your doctor if you have:**
  - Diabetes.
  - Liver or kidney problems.
  - Allergy to GLUMETZA or any ingredients in GLUMETZA.
  - Heart or blood vessel disease.
  - A history of low blood sugar (hypoglycemia), although it may occur when GLUMETZA is used in conjunction with insulin.
- **Tell your doctor if you are:**
  - Breastfeeding.
  - Pregnant or trying to get pregnant.
  - Planning to donate blood.

**Patients and Caregivers:**

- **Common side effects of GLUMETZA include:**
  - Nausea.
  - Vomiting.
  - Headache.
  - Diarrhea.
  - Constipation.

**Common side effects of GLUMETZA include:**

- **Diarrhea.
  - Nausea.
  - Headache.
  - Vomiting.
  - Constipation.

**GLUMETZA can cause serious side effects if you have:**

- **Liver disease:**
  - Severe liver problems or death.
- **Low blood sugar (hypoglycemia):**
  - Severe, prolonged symptoms of low blood sugar (hypoglycemia).

**Other important information:**

- **Tell your doctor if these symptoms return, as they may be serious:**
  - Headache.
  - Diarrhea.
  - Nausea.
  - Diarrhea.

**GLUMETZA is not for everyone:**

- **Do not take GLUMETZA if you have low blood sugar (hypoglycemia).**
- **Do not take GLUMETZA if you have liver disease.**
- **Do not take GLUMETZA if you are allergic to GLUMETZA.**

**What are the ingredients in GLUMETZA?**

- **Inactive Ingredients:**
  - Sodium starch glycolate, magnesium stearate, hydroxypropyl cellulose, polyethylene glycol 400, and titanium dioxide.

**Warnings and Precautions (5.1):**

- **Carbonic anhydrase inhibitors may cause metabolic acidosis:**
  - Use GLUMETZA with caution in patients taking these medications.

**Drug Interactions (7):**

- **Sucralfate may decrease the effectiveness of GLUMETZA:**
  - Use GLUMETZA with caution in patients taking these medications.

**Possible side effects of GLUMETZA include:**

- **Diabetes:**
  - Severe, prolonged symptoms of low blood sugar (hypoglycemia).
- **Liver disease:**
  - Severe liver problems or death.
- **Low blood sugar (hypoglycemia):**
  - Severe, prolonged symptoms of low blood sugar (hypoglycemia).

**How should I store GLUMETZA?**

- Store GLUMETZA at 68° to 77°F (20° to 25°C).
- Keep GLUMETZA out of the reach of children.
- Do not refrigerate or freeze GLUMETZA.

**What are the ingredients in GLUMETZA?**

- **Active Ingredients:**
  - Metformin hydrochloride 500 mg

**Clinical trials information:**

- **GLUMETZA has been studied in many clinical trials:**

**Pharmacokinetics:**

- **Absorption:**
  - Absorption of GLUMETZA is complete.

**Absorption:**

- **Absorption:**
  - Absorption of GLUMETZA is complete.

**Metabolism:**

- **Metabolism:**
  - Steady state plasma concentrations of metformin are generally reached within 24-48 hours and are generally maintained within this range throughout the dosing interval.

**Excretion:**

- **Excretion:**
  - Metformin, steady state plasma concentrations of metformin are reached within 24-48 hours and are generally maintained within this range throughout the dosing interval.

**Food Effects:**

- **Food Effects:**
  - Taking GLUMETZA with food may reduce the risk of side effects like nausea, vomiting, and diarrhea.

**Clinical Trials with Metformin ER (M-ER) Tablets and Metformin Immediate-Release (M-IR) Tablets in the Treatment of Type 2 Diabetes Mellitus:**

- **GLUMETZA was compared to immediate-release metformin in clinical trials:**

**Safety and Efficacy:**

- **Safety and Efficacy:**
  - GLUMETZA showed similar safety and efficacy compared to immediate-release metformin in clinical trials.

**Patient Counseling Information:**

- **Do not take GLUMETZA with alcohol:**
  - Alcohol may increase the risk of lactic acidosis and severe hypoglycemia.

**Other important information:**

- **Tell your doctor if you have:**
  - Low blood sugar (hypoglycemia).
  - Liver disease.
  - Renal impairment.

**What are the risks of taking GLUMETZA?**

- **Diabetes:**
  - Severe, prolonged symptoms of low blood sugar (hypoglycemia).

**How to treat low blood sugar:**

- **What to eat:**
  - Glucose tablets, gelatin capsules, or other readily available sources of simple glucose.

**Additional information:**

- **For more information:**
  - Talk to your doctor or call 1-800-FDA-1088.

**CLINICAL PHARMACOLOGY:**

- **Absorption:**
  - Absorption of GLUMETZA is complete.

**Metabolism:**

- **Metabolism:**
  - Steady state plasma concentrations of metformin are reached within 24-48 hours and are generally maintained within this range throughout the dosing interval.

**Excretion:**

- **Excretion:**
  - Metformin, steady state plasma concentrations of metformin are reached within 24-48 hours and are generally maintained within this range throughout the dosing interval.

**Clinical Trials Comparison with GLUMETZA:**

- **Comparison with GLUMETZA:**
  - GLUMETZA showed similar safety and efficacy compared to immediate-release metformin in clinical trials.

**PATIENT COUNSELING INFORMATION:**

- **Do not take GLUMETZA with alcohol:**
  - Alcohol may increase the risk of lactic acidosis and severe hypoglycemia.

**Other important information:**

- **Tell your doctor if you have:**
  - Low blood sugar (hypoglycemia).
  - Liver disease.
  - Renal impairment.

**What are the risks of taking GLUMETZA?**

- **Diabetes:**
  - Severe, prolonged symptoms of low blood sugar (hypoglycemia).

**How to treat low blood sugar:**

- **What to eat:**
  - Glucose tablets, gelatin capsules, or other readily available sources of simple glucose.

**Additional information:**

- **For more information:**
  - Talk to your doctor or call 1-800-FDA-1088.

**CLINICAL PHARMACOLOGY:**

- **Absorption:**
  - Absorption of GLUMETZA is complete.

**Metabolism:**

- **Metabolism:**
  - Steady state plasma concentrations of metformin are reached within 24-48 hours and are generally maintained within this range throughout the dosing interval.

**Excretion:**

- **Excretion:**
  - Metformin, steady state plasma concentrations of metformin are reached within 24-48 hours and are generally maintained within this range throughout the dosing interval.

**Clinical Trials Comparison with GLUMETZA:**

- **Comparison with GLUMETZA:**
  - GLUMETZA showed similar safety and efficacy compared to immediate-release metformin in clinical trials.

**PATIENT COUNSELING INFORMATION:**

- **Do not take GLUMETZA with alcohol:**
  - Alcohol may increase the risk of lactic acidosis and severe hypoglycemia.

**Other important information:**

- **Tell your doctor if you have:**
  - Low blood sugar (hypoglycemia).
  - Liver disease.
  - Renal impairment.

**What are the risks of taking GLUMETZA?**

- **Diabetes:**
  - Severe, prolonged symptoms of low blood sugar (hypoglycemia).

**How to treat low blood sugar:**

- **What to eat:**
  - Glucose tablets, gelatin capsules, or other readily available sources of simple glucose.

**Additional information:**

- **For more information:**
  - Talk to your doctor or call 1-800-FDA-1088.

**CLINICAL PHARMACOLOGY:**

- **Absorption:**
  - Absorption of GLUMETZA is complete.

**Metabolism:**

- **Metabolism:**
  - Steady state plasma concentrations of metformin are reached within 24-48 hours and are generally maintained within this range throughout the dosing interval.

**Excretion:**

- **Excretion:**
  - Metformin, steady state plasma concentrations of metformin are reached within 24-48 hours and are generally maintained within this range throughout the dosing interval.

**Clinical Trials Comparison with GLUMETZA:**

- **Comparison with GLUMETZA:**
  - GLUMETZA showed similar safety and efficacy compared to immediate-release metformin in clinical trials.

**PATIENT COUNSELING INFORMATION:**

- **Do not take GLUMETZA with alcohol:**
  - Alcohol may increase the risk of lactic acidosis and severe hypoglycemia.

**Other important information:**

- **Tell your doctor if you have:**
  - Low blood sugar (hypoglycemia).
  - Liver disease.
  - Renal impairment.

**What are the risks of taking GLUMETZA?**

- **Diabetes:**
  - Severe, prolonged symptoms of low blood sugar (hypoglycemia).

**How to treat low blood sugar:**

- **What to eat:**
  - Glucose tablets, gelatin capsules, or other readily available sources of simple glucose.

**Additional information:**

- **For more information:**
  - Talk to your doctor or call 1-800-FDA-1088.