

Metformin Hydrochloride

DESCRIPTION:

Gliafor® (metformin hydrochloride) is an oral antihyperglycemic agent used in the management of type 2 diabetes mellitus.

Inactive Ingredients: Povidone, magnesium stearate, hypromellose.

PHARMACOLOGY:

Gliafor® improves glucose tolerance in subjects with type 2 diabetes, lowering basal and postprandial plasma glucose. **Gliafor®** decreases hepatic glucose production, decreases intestinal absorption of glucose, and improves insulin sensitivity by increasing peripheral glucose uptake and utilization. With **Gliafor®** therapy, insulin secretion remains unchanged, while fasting insulin levels and day-long plasma insulin response may actually decrease.

INDICATIONS:

As an adjunct to adequate dietary management, **Gliafor®** is an oral antidiabetic agent (biguanide) intended for the treatment of adult diabetes. In some cases, it may be used in association with insulin.

A reduction of diabetic complications has been shown in overweight type 2 diabetic patients treated with metformin as first-line therapy after diet therapy.

CONTRAINDICATIONS:

Gliafor® is contraindicated in the following cases:

- Known hypersensitivity to metformin hydrochloride or any of the product ingredients,
- Severe destabilization of diabetes (ketoacidosis),
- Renal insufficiency, even if moderate (impairment of kidney function with increased blood creatinine levels),
- Infectious diseases (respiratory tract infection, urinary tract infection),
- During the two days following an X-ray examination involving the use of iodinated contrast media (for example, intravenous urography, angiography),
- Heart failure, respiratory insufficiency,
- Hepatic insufficiency (impaired liver function),
- Excessive consumption of alcoholic beverages,
- During breast-feeding.

SIDE EFFECTS:

As with all medications, **Gliafor®** film-coated tablets, can cause undesirable effects. Gastrointestinal discomfort (nausea, vomiting, and diarrhea) may occur at the beginning of treatment, especially if **Gliafor®** tablets are not taken with meals. These symptoms are usually temporary, lasting about 10 days, and can be reduced by taking the tablets during or at the end of meals. If the symptoms persist, the patient should stop taking the treatment and consult the doctor. Vomiting, abdominal pain accompanied by muscle cramps and/or general feeling of malaise with severe fatigue occurring during therapy may be signs of a serious destabilization of diabetes (diabetic ketoacidosis or lactic acidosis) requiring specific treatment. If this occurs, the patient should immediately stop taking the treatment and consult his doctor promptly.

WARNINGS AND PRECAUTIONS:

Special warnings:

Vomiting, abdominal pain accompanied by muscle cramps and/or general feeling of malaise with severe fatigue occurring during therapy may be signs of a serious destabilization of diabetes (diabetic ketoacidosis or lactic acidosis) requiring specific treatment. If this occurs, the patient should immediately stop taking the treatment and consult his doctor promptly.

Precautions for use:

The doctor will prescribe periodic laboratory tests (to determine the patient's blood creatinine levels) in order to check his kidney function, which must be adequate since oral antidiabetic agents are excreted mainly by the kidneys. Certain illnesses or medications (corticosteroids and certain diuretics, ritodrine, salbutamol, terbutaline and ACE inhibitors) may cause more or less severe destabilization of diabetes. The patient should inform his doctor of any other treatment he is receiving and of any infectious illnesses such as influenza, respiratory or urinary tract infections. If the patient is scheduled to undergo X-ray examinations involving the use of iodized contrast media, such as intravenous urography or angiography, his doctor will ask him to discontinue treatment with **Gliafor®** prior to or at the time of the test and

will not resume treatment until 48 hours after the test, after ensuring that his kidneys are functioning normally.

If the patient is hospitalized for tests, a surgical procedure, or for any other reason, the patient should advise his doctor that he is taking **Gliafor®**. The patient should avoid consumption of alcoholic beverages.

Pregnancy and lactation: During pregnancy, treatment of diabetes is based upon insulin therapy. If she discovers that she is pregnant while taking **Gliafor®**, the treatment will be replaced by insulin. The doctor should be informed in order to make the necessary changes to the treatment. The doctor should be informed if she wishes to become pregnant. This drug is contraindicated during breast-feeding. The doctor should always be asked for advice before taking any medication in case of pregnancy or breast-feeding.

Effects on the ability to drive and use of machines: When used alone, metformin does not cause hypoglycemia. Therefore, there is no particular risk when driving or using machines. However, in association with other antidiabetic agents (sulphonylurea, hypoglycemic agents, insulin, repaglinide), it is important to be aware of the onset of hypoglycemia, and of its effects on concentration.

DRUG INTERACTIONS:

The doctor or pharmacist should be informed if the patient is taking or have recently taken another drug, i.e. corticosteroids, antihypertensive agents of the ACE inhibitor class (angiotensin-converting enzyme inhibitors), diuretics, ritodrine, salbutamol or terbutaline, iodized media or medications containing alcohol, even if an over-the-counter medication is involved.

DOSAGE AND ADMINISTRATION:

Dosage: The dosage of **Gliafor®** is determined by the doctor on an individual basis according to the results of laboratory blood glucose measurement. In general, the average dosage is 2 tablets per day (taken with or after meals).

Method and route of administration: Oral route.

Frequency and time at which the drug should be taken: the tablets should be swallowed without chewing during or at the end of meals. For example, for a dosage of two tablets daily, 1 tablet is taken with breakfast and 1 tablet with the evening meal.

IN ALL CASES THE PATIENT SHOULD STRICTLY COMPLY WITH HIS DOCTOR'S PRESCRIPTION.

Duration of treatment: **Gliafor®** must be taken daily without interruption, except if specifically indicated by his doctor.

If the patient has forgotten to take one or more doses, he should take the next dose at the usual time and the dose should not be doubled.

If the patient has taken more **Gliafor®** than indicated, he should consult the doctor or pharmacist immediately.

GENERAL RECOMMENDATIONS:

This drug has been prescribed by the doctor for the treatment of diabetes, a disease characterized by hyperglycemia, i.e. an excess of glucose in the blood. Glucose appears in the urine only when it exceeds a certain level in the blood.

There are two types of diabetes:

- The most common type can be treated by medications taken by the oral route (oral antidiabetics),
- The other type requires the administration of insulin injections.

It is essential that medical tests be performed to determine the type of diabetes, as insulin injections and oral antidiabetics cannot be freely interchanged. Important: in all cases, patients with diabetes should strictly adhere to the diet recommended by their doctor.

PRESENTATIONS:

Gliafor® 500 Tablets: Packs of 50 film coated tablets. Each tablet contains 500 mg Metformin Hydrochloride.

Gliafor® 850 Tablets: Packs of 30 film coated tablets. Each tablet contains 850 mg Metformin Hydrochloride.

Gliafor® 1000 Tablets: Packs of 30 film coated tablets. Each tablet contains 1000 mg Metformin Hydrochloride.

STORAGE CONDITIONS:

Store below 30°C.

This is a medicament.

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold you the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and its risks.
- Do not, by yourself, interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.