GLUCOPHAGE® 850mg

metformin

GLUCOPHAGE 850mg, film-coated tablets

Please read this leaflet carefully in full before taking this medication

Qualitative composition/Quantitative composition

Film-coated tablets containing 850mg of metformin (INN) hydrochloride (equivalent to 663mg of metformin base).

Excipients

Polyvidone K 30, magnesium stearate, Opadry clear YS-1-7472, q.s. one film-coated tablet of 899,3mg

Pharmaceutical form

Film-coated tablets.
Pack of 30 tablets = 25,5g of metformin HCl per pack

Pharmaco-therapeutic category

ORAL ANTIDIABETIC AGENT

Therapeutic indications

As an adjunct to adequate dietary management, GLUCOPHAGE 850mg 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.

Contra-indications

This drug MUST NEVER BE USED in the following cases:
- Known hypersensitivity to metformin hydrochloride or any of the product ingredients,
- severe destabilisation 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),
- persistent diarrhea, recurrent vomiting,
- excessive consumption of alcoholic beverages,
- during breast-feeding,

Special warnings

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

Precautions for use

Your doctor will prescribe periodic laboratory tests (to determine your blood creatinine levels) in order to check your 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 destabilisation of diabetes. You should inform your doctor of any other treatment you are receiving and of any infectious illnesses such as influenza, respiratory tract infection or urinary tract infection.
If you are scheduled to undergo X-ray examinations involving the use of iodised contrast media, such as intravenous urography or angiography, your doctor will ask you to discontinue treatment with Glucophage prior to or at the time of the test and will not resume treatment until 48 hours after the test, after ensuring that your kidneys are functioning normally. If you are hospitalised for tests, a surgical procedure, or for any other reason, advise your doctor that you are taking Glucophage. Avoid consumption of alcoholic beverages.

Pregnancy – Breast-feeding

During pregnancy, treatment of diabetes is based on insulin therapy. If you discover that you are pregnant while taking Glucophage, your treatment will be replaced by insulin. Inform your doctor so that he may make the necessary changes to your treatment. Inform your doctor if you wish to become pregnant.
This drug is contra-indicated during breast-feeding. As a general rule, if you are pregnant or breast-feeding you should always ask your doctor for advice before taking a medication.

Effect on ability to drive and use machines

When used alone, Glucophage does not cause hypoglycemia. Consequently, 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.

Intake or use of other medications

Inform your doctor or your pharmacist if you are 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, iodised contrast media or medications containing alcohol, even if an over-the-counter medication is involved.

Dosage

The dosage of Glucophage 850mg is determined by your 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

Swallow the tablets without chewing during or at the end of meals. For example, for a dosage of two tablets daily, take 1 tablet with breakfast and 1 tablet with your evening meal.
IN ALL CASES YOU SHOULD STRICTLY COMPLY WITH YOUR DOCTOR'S PRESCRIPTION.

Duration of treatment

Glucophage must be taken daily without interruption, except if specifically indicated by your doctor.
If you have forgotten to take a GLUCOPHAGE 850mg film-coated tablet: Take the next dose at the usual time. Do not double the dose of Glucophage 850mg film-coated tablets.
If you have taken more GLUCOPHAGE 850mg film-coated tablets than indicated: Consult your doctor or pharmacist immediately.

Undesirable effects

As with all medications, GLUCOPHAGE 850mg film-coated tablets, can cause undesirable effects. Gastrointestinal discomfort (nausea, vomiting, diarrhea) may occur at the beginning of treatment, especially if Glucophage 850mg tablets are not taken with meals. These symptoms are generally transient, lasting about 10 days, and can be reduced by taking the tablets with or after meals. Should symptoms persist, **stop taking the treatment** and consult your doctor. Vomiting, abdominal pain accompanied by muscle cramps and/or a general feeling of malaise with severe fatigue occurring during therapy may be signs of serious destabilisation of your diabetes (diabetic ketoacidosis or lactic acidosis) requiring specific treatment. If this occurs you should stop taking Glucophage immediately and consult your doctor promptly.
REPORT ANY UNDESIRABLE OR DISTRESSING EFFECT WHICH HAS NOT BEEN MENTIONED IN THIS PACKAGE INSERT TO YOUR DOCTOR OR PHARMACIST.

Storage

Store below 25°C in a dry place. Do not use after the expiry date shown on the outer packaging.

KEEP OUT OF THE REACH OF CHILDREN

GENERAL RECOMMENDATIONS

This drug has been prescribed by your doctor for the treatment of diabetes, a disease characterised 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.

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