

PATIENT INFORMATION LEAFLET

GLYFORMIN / Metformin Hydrochloride 500 mg TABLETS

PLEASE READ THIS LEAFLET CAREFULLY BEFORE YOU START TAKING THIS MEDICINE
KEEP THIS LEAFLET UNTIL YOU HAVE FINISHED ALL THE PRESCRIBED COURSE OF GLYFORMIN
IF YOU HAVE ANY QUESTIONS CONCERNING YOUR MEDICINE ASK YOUR DOCTOR OR PHARMACIST FOR MORE INFORMATION

What is in your medicine?

The name of this medicine is Glyformin. Each tablet contains 500 mg of Metformin Hydrochloride BP, together with the following ingredients: Lactose, silicon dioxide, gelatin, sodium starch glycollate, magnesium stearate, hydroxypropylmethylcellulose, ethylcellulose, titanium dioxide (E171), and diethyl phthalate.

Glyformin tablets are white, round, bi-convex film-coated tablets, and are available in containers of 28, 30, 50, 56, 60, 84, 100, 250, 500 & 1000 tablets, and in blister packs of 28, 30, 50, 56, 60, 84, 100, 250, 500 & 1000 tablets.

The Manufacturer of Glyformin is either: DDSA Pharmaceuticals Ltd., Chatfield Road, off York Road, London SW11 3SE or: Meridian Healthcare (UK) Ltd., Chatfield Road, off York Road, London SW11 3SE

The Product Licence Holder of Glyformin is Chelonia Healthcare Limited, Boumpoulinas 11, 3rd Floor, Nicosia, P.C. 1060, Cyprus.

Why have you been prescribed Glyformin?

Glyformin belongs to a group of medicines known as anti-diabetics. It is used in diabetes occurring in middle age when diet alone has failed. It is also used in obese diabetic patients who are not well controlled by insulin, but who are dependent on insulin and may therefore occasionally benefit when Glyformin is used together with insulin.

If you are not sure why you have been prescribed Glyformin then please ask your doctor.

Check before you take Glyformin

Before taking this medicine, tell your doctor if you have ever had any unusual or allergic reactions to Metformin Hydrochloride or to any of the other ingredients.

Also tell your doctor or pharmacist if you are allergic to any other substances such as foods, preservatives or dyes.

Because the presence of other medical problems may affect the use of Glyformin, make sure to tell your doctor if you have had any of the following:

- Liver disease
- Kidney disease

- Cardiac failure, or recent coronary thrombosis
- Lung impairment
- Alcoholism (either chronic or acute)
- Severe infection
- Blocking of the blood vessels of the extremities, particularly the legs, known as peripheral vascular disease.
- Dehydration.
- Disturbances in the metabolic state of the blood (lactic acidosis, hypoxaemia).

It is important that you tell your doctor if you are pregnant, likely to become pregnant, or are breast-feeding.

If you develop any new medical problems while using this medicine, check with your doctor or pharmacist.

Use in pregnancy & while breast-feeding

Do not take Glyformin if you are pregnant, breast-feeding or planning a pregnancy.

Can you take Glyformin with other medicines?

It is important that your doctor is aware of any other medication you are taking, whether it is prescribed or bought without a prescription from a pharmacy or elsewhere. Your doctor will be able to identify medicines which you should not take with Glyformin.

Tell your doctor or pharmacist if you are taking any of the following:

- Cimetidine (used to treat stomach ulcers), which can increase blood concentrations of meformin.
- Alcohol, which will increase the blood sugar lowering effects of meformin.
- Anti-coagulants such as warfarin (blood-thinners).
- Sulphonylureas
- Insulin

Patients receiving Glyformin over prolonged periods should have their levels of Vitamin B₁₂ measured yearly, since levels may be altered by this medicine.

Proper use of this medicine

Take this medicine by mouth and only in the doses prescribed by your doctor. Do not take more of it, and do not take it more often or for a longer time than your doctor ordered.

Dosages:

Adults: Usually one 500 mg tablet 3 times a day, to be taken with meals. Should control of diabetes be incomplete, a gradual increase in dosage to a maximum of 3 g daily, in divided doses, taken together with meals may be instituted.

This dosage regimen should not be increased above 3 g.

Children: Not recommended.

Elderly: Metformin Hydrochloride, while indicated in the

elderly, should not be used when renal function is impaired.

If you forget to take your medicine, just carry on with the next dose as normal. Do not take an extra dose to make up for the missed dose. If you are not sure, ask your doctor or pharmacist for advice.

If you feel that this medicine is not working as well after you have taken it for a short time (1-2 weeks) do not increase the dose, instead check with your doctor.

What to do if too many tablets are taken at the same time

If you think you may have taken an overdose of this medicine you must obtain emergency help at once. Go to your doctor or the Accident & Emergency Department of your nearest hospital straight away. Take with you any remaining tablets in the original container so that the medicine can be identified.

What side effects can occur when taking Glyformin?

Although Glyformin is usually well tolerated, gastro-intestinal disturbances may sometimes occur, and although usually minor they can normally be avoided by taking Glyformin with, or after, food.

Storing your medicine

You must keep the medicine in a safe place where children cannot get it. Your medicine could harm them.

Keep your medicine in a dry place and store below 25°C, in securely closed containers.

On the label you will find the words "Expiry Date" followed by some numbers indicating the day, month and year. This is the date when the medicine is no longer fit for use. Do not use the medicine after this date, but return it to your pharmacist.

A reminder

REMEMBER this medicine is for you. Never give it to someone else, even if their symptoms are the same as yours.

This leaflet does not contain the complete information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist who have access to additional information.

This leaflet was prepared in February 2009.