

Glyferon®

metformin HCl

FIRST LINE TREATMENT OF TYPE 2 DIABETES

ADULTS	
Starting dose	850 mg, two or three times a day
Your doctor may increase the dosage to a maximum of 3000 mg per day (as three divided doses) until your condition is under control.	
CHILDREN OF 10 YEARS AND OVER & ADOLESCENTS	
Starting dose	850 mg once daily
The maximum daily dose is 2000 mg per day taken as 2 or 3 divided doses.	

GLYFERON® has to be used by oral route with or after a meal.
Swallow the tablet with one glass of water.
The tablets may not be crushed or chewed.

DAFRA PHARMA INTERNATIONAL

Headquarters
Slachthuisstraat 30/7
2300 Turnhout – Belgium

Glyferon®

metformin HCl



FIRST LINE TREATMENT OF TYPE 2 DIABETES

Particularly for overweight patients.
When diet and exercise alone are not enough to
control the blood glucose levels.



Setting the standard

www.dafrapharma.com

Glyferon®

metformin HCl



WHAT IS GLYFERON® AND WHAT IT IS USED FOR?

GLYFERON® contains metformin, a medicine to treat diabetes (ATC code: A10BA02). GLYFERON® is used to treat patients with type 2 diabetes (also called non-insulin-dependent diabetes) when diet and exercise alone have not been enough to control the blood glucose levels. It is used particularly in overweight patients. Adults can take GLYFERON® on its own or together with other oral medicines or insulin to treat diabetes. Children of 10 years and above can take GLYFERON® on its own or together with insulin. A reduction of diabetic complications has been shown in type 2 diabetic adult patients treated with metformin hydrochloride as first-line therapy after diet failure.

WHAT YOU NEED TO KNOW BEFORE YOU TAKE GLYFERON®:

Do not take GLYFERON® if you are allergic to metformin hydrochloride or any of the other ingredients. If you have any kind of kidney or liver disease. If you have serious diabetic complications such as loss of consciousness caused by either very high or very low blood sugar levels (diabetic coma) and a lack of insulin which leads to high blood sugar levels, ketones in the urine and certain acids in the blood (ketoacidosis). If you have heart complications such as heart failure (even if the condition is under control) or recently had a heart attack. If you have a history of a buildup of lactic acid in the blood (lactic acidosis), which may be associated with shock and breathing difficulties. If you drink a lot of alcohol. If you have a severe infection or injury. If you suffer from a loss or lack of water in the body (dehydration). If you have

a severe disease of the blood vessels. If any of the above applies to you, please consult your doctor or pharmacist.

WARNINGS AND PRECAUTIONS:

Take special care with GLYFERON if you are to have an x-ray or CT scan (using iodinated contrast media); you should tell your doctor as you may need to stop your medication. If you use GLYFERON® for a longer time: it may reduce your vitamin B12 level, to be annually monitored by your doctor. If if you suffer from kidney problems, particularly if elderly. If any of the above apply to you, please consult your doctor or pharmacist.

Taking other medicines: Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription. They may interfere with the actions of GLYFERON®. You should tell your doctor if you are taking any of the following: medicines to prevent clotting of the blood, for stomach ulcers and indigestion, for high blood pressure, for depression, for inflammatory and allergic conditions, oral contraceptives, for fluid retention, for high cholesterol, for diabetes such as glibenclamide.

Taking with alcohol: If you drink alcohol whilst taking GLYFERON® it may interfere with the actions of the medicine.

Pregnancy and breastfeeding: If you are pregnant, thinking of becoming pregnant or breastfeeding, GLYFERON® should not be taken unless told to do so by your doctor.

Driving or using machinery: GLYFERON® should not affect your ability to drive or

operate machinery. However, you have to be alerted to the risk of hypoglycaemia when GLYFERON® is used in combination with other antidiabetic agents (sulfonylureas, insulin, repaglinide).

HOW TO TAKE GLYFERON®

The doses stated below are guidelines only. You should always take this medicine as prescribed by your doctor. This leaflet describes GLYFERON® tablets containing 850 mg metformin HCl. An other strength of metformin HCl tablets (1000 mg) is available if needed to set the correct dosing. Do not take more than the doctor has told you to. Read and follow the instructions on the pharmacist's label. If you are not sure about anything, please ask your doctor or pharmacist. GLYFERON® has to be used by oral route with or after a meal. Swallow the tablet with one glass of water. The tablets may not be crushed or chewed.

Adults: Usually start with 500 mg or 850 mg, two or three times a day. This medicine may take a few days to 2 weeks to control your condition. Your doctor may increase the dosage to a maximum of 3000 mg per day (as three divided doses) until your condition is under control. **Children of 10 years and over and adolescents:** The usual starting dose is 500 mg or 850 mg once daily. After 10 to 15 days the dose should be adjusted on the basis of blood glucose measurements. A slow increase of dose may improve gastro-intestinal tolerability. The maximum daily dose is 2000 mg per day taken as 2 or 3 divided doses. **Elderly:** The control of renal functions is necessary. Your doctor will monitor your condition if you have kidney problems. The GLYFERON® dose should be adjusted according to renal function. If you have taken more GLYFERON® than you should, please contact your doctor or seek emergency medical attention.

If you forgot to take GLYFERON®, do not take a double dose to make up for a forgotten dose.

POSSIBLE SIDE EFFECTS:

GLYFERON® is usually well tolerated. However, like most medicines it can cause undesirable side effects in some patients.

Serious side effects: Some people can

develop a condition known as lactic acidosis whilst taking metformin. Lactic acidosis is caused by a buildup of lactic acid in the blood (produced when glucose is turned into energy without oxygen). Possible symptoms of lactic acidosis: unexplained weight loss, feeling sick (nausea), being sick (vomiting), general feeling of being unwell, pain in the belly region, increased breathing rate. If you have or think you may have lactic acidosis, you should go to the hospital immediately as it is a medical emergency. **Very common side effects:** Feeling sick (nausea), being sick (vomiting), diarrhea, weight loss. These side effects may be avoided by taking your medicine with or after a meal. If you have any of these side effects it is important to continue taking your medicine as they normally disappear after a short time. **Other side effects:** Changes in taste (common), decreased vitamin B12 absorption (rare). If any of these side effects get serious or you notice any not listed, please tell your doctor or pharmacist.

HOW TO STORE GLYFERON®

Keep out of the reach and sight of children. Store in the original package below 30°C. Do not use this medicine if the expiry date printed on the pack or bottle (Exp.) has passed. Any unused product or waste material should be disposed of in accordance with local requirements.

WHAT GLYFERON® CONTAINS:

the active substance is 850 mg or 1000 mg metformin HCl. Other excipients of the tablet are: sodium starch glycolate, povidone, colloidal silica, maize starch, magnesium stearate; Excipients of coating: hypromellose, macrogol 6000, propylene glycol, talc, titanium dioxide. What GLYFERON® looks like: Blister pack of 30 film-coated tablets with a leaflet in a carton box.

**GLYFERON® is sold with prescription only.
DO NOT USE WITHOUT CONSULTING YOUR
PHYSICIAN.**