

PACKAGE LEAFLET: INFORMATION FOR THE USER

MANINIL

1.75mg Tablets

3.5mg Tablets

GLIBENCLAMIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

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1. WHAT MANINIL IS AND WHAT IS IT USED FOR

The name of your medicine is MANINIL Tablets. These tablets belong to a group of medicines called sulphonylureas.

MANINIL Tablets are used to lower blood sugar levels and are used in the treatment of late-onset diabetes (type II diabetes mellitus) in patients whose blood sugar is not controlled by diet alone and who are not suitable for insulin injections.

2. BEFORE YOU TAKE MANINIL

You should not take MANINIL Tablets if you:

- are allergic (hypersensitive) to glibenclamide, other sulphonylureas or any of the other ingredients in MANINIL Tablets
- suffer from early onset or type I diabetes (requiring insulin)
- suffer from severe kidney disease
- suffer from liver problems
- are suffering from ketoacidosis (caused by excessively high blood sugars in diabetics)

- are suffering from a severe infection
- are suffering from stress
- are suffering from any condition likely to make controlling your blood sugar difficult
- are due to undergo surgery
- are pregnant
- have reduced consciousness or coma resulting from your diabetes
- have porphyria (a disease of blood proteins affecting the skin, gut and nervous system).
- are elderly (over 70 years of age).

This medicine can cause low blood sugar (hypoglycaemia) particularly in the following situations, so patients should use caution:

Symptoms of low blood sugar include sweating, hunger, increased heart rate, reduced consciousness, coma or seizures.

Low blood sugar may occur:

- in patients whose diabetes is controlled by diet alone
- if you take too high doses of MANINIL Tablets
- if you are malnourished
- if you take meals irregularly or skip meals altogether
- if you increase your physical activity and carbohydrate intake does not match this increase
- if you are unwell
- if your kidney function is decreased
- if you suffer from particular hormone-induced disorders (functional disorders of the pituitary or adrenal glands)
- if you drink alcohol, especially in combination with skipped meals.

Low blood sugar may occur if you are in stress situations (e.g. accidents, surgical operations, fever etc.). During such times you should inform your doctor you are taking MANINIL Tablets, as your doctor may adjust your dose of medicine or may temporarily switch you to insulin therapy.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. The following medicines can affect or be affected by MANINIL Tablets:

- medicines used to reduce pain and inflammation (e.g. aspirin, other non-steroidal anti-inflammatory drugs, azapropazone and phenylbutazone)
- medicines used to treat bacterial infections (e.g. isoniazid, rifamycins, chloramphenicol, co-trimoxazole, sulphonamides and tetracyclines)
- medicines used to treat depression (e.g. monoamine oxidase inhibitors [MAOIs])
- medicines used to treat fungal infections (e.g. miconazole)
- medicines used to treat gout (e.g. allopurinol, sulfapyrazone and probenecid)
- medicines used to treat high blood pressure (e.g. diazoxide, captopril, enalapril and beta-blockers)
- medicines used to treat and prevent malaria (e.g. quinine and quinidine)
- medicines used to thin the blood and prevent clotting (e.g. warfarin and disopyramide)
- medicines used to treat psychosis and other mental illness (e.g. chlorpromazine)
- medicines used to treat stomach ulcers (e.g. cimetidine and ranitidine)
- medicines used in the treatment of cancer (e.g. crisantaspase)
- medicines used to treat water retention and heart failure (e.g. loop and thiazide diuretics)
- medicines used to reduce cholesterol (e.g. clofibrate)
- lithium (used to treat manic depression/bipolar disorder)
- hormone treatments and contraceptives (e.g. testosterone, oestrogens, progesterones, oral contraceptives, anabolic steroids, corticosteroids and ocreotides)
- thyroid hormone (used to treat an underactive thyroid gland)

- ciclosporin, used to prevent organ transplant rejection
- bosentan, used to treat high blood pressure.

Pregnancy and breast-feeding

You should not take this medicine if you are pregnant. Talk to your doctor or pharmacist before taking them if you are breastfeeding a baby.

Driving and using machinery

If your blood sugar is not well controlled then this can affect your vision and/or concentration. If you are affected in any way do not drive or operate machinery.

Important information about some of the ingredients in MANINIL Tablets

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE MANINIL

Always take MANINIL Tablets as your doctor has told you. Your doctor will decide the right dose for you, this will be on the pharmacist's label. This medicine should be swallowed whole.

Adults

- this dose will be adjusted by your doctor according to your response to treatment
- total daily dose rarely exceeds 15mg
- your total daily dose should normally be taken as a single dose taken with or immediately after breakfast or your first main meal

Infirm patients

Such patients may be more at risk of hypoglycaemia, therefore treatment should be started with one 1.75mg tablet daily.

Children

- MANINIL Tablets like any other medicine belonging to its class, is not recommended for use in children. You may be changed to glibenclamide from other drugs. Your doctor will decide the right dose for you. Your urine and blood sugar levels should be tested regularly, particularly when you first start taking MANINIL Tablets.

If you take more MANINIL Tablets than you should

If you (or anybody else, including a child) take more MANINIL Tablets than you should, contact your nearest hospital casualty department or your doctor immediately. Always take the container and this leaflet with you. Signs that could indicate you have taken too many are symptoms of low blood sugar which include sweating, hunger, increased heart rate, reduced consciousness, coma or seizures.

If you forget to take MANINIL Tablets

If you forget a dose, take another as soon as you remember. If it is almost time for your next dose, then do not take the missed dose at all. NEVER take a double dose to make up for the one missed.

4. POSSIBLE SIDE EFFECTS

Like all medicines, MANINIL Tablets can cause side effects, although not everybody gets them.

As can happen with any medicine, a few people may develop an allergic reaction. If you experience any of the following, seek medical help immediately:

- rash, itching and/or difficulty breathing.

Side effects that have been reported with MANINIL Tablets are:

- rash
- sensitivity to light
- jaundice (yellowing of the skin or the whites of the eyes)
- changes in blood cells
- fever
- low blood sugar (hypoglycaemia, refer to section 2 of this leaflet)
- problems with blood salt levels
- heartburn
- weight gain
- diarrhoea
- itching
- skin inflammation
- blistering of the skin, mouth, eyes and genitals
- liver problems
- water retention
- feeling and being sick (nausea/vomiting)
- anorexia
- increased appetite
- metallic taste in mouth

If you experience any side effects or feel that the medicine is affecting you badly tell your doctor or pharmacist immediately.

5. HOW TO STORE MANINIL

Keep out of the reach and sight of children.

- Do not store above 25°C.
- Store in the original package in order to protect from light and moisture.
- MANINIL Tablets should not be taken after the expiry date on the carton; the expiry date refers to the last day of the month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.