

Patient Information

Read the package insert carefully before taking the drug. This medication has been prescribed for you personally, and you should not give it to other persons. Even if they have the same disease symptoms as you, the drug could harm them. Keep the package insert. You may wish to read it again later.

Melix® Tablets

What is Melix and when is it used?

Melix contains the active ingredient, Glibenclamide, which has a blood sugar lowering effect (by affecting insulin secretion) and, for that reason, is used for the treatment of diabetes (diabetes mellitus) in patients whose pancreas in fact is still producing insulin but in an insufficient quantity (adult onset diabetes or type 2 diabetes). Despite diet, sufficient physical activity and weight loss the blood sugar balance is disturbed in these patients. Melix may only be used if ordered by a physician and under strict monitoring by the physician.

What should I keep in mind in addition?

No diabetes can be treated appropriately if the patient does not stick precisely to the diet plan prescribed by the physician or by the dietary counselling service. The treatment of diabetes is based on proper nutrition. It is incorrect to think that taking a product that lowers blood sugar allows you to pay less attention to your diet. In case of overweight the quantity of food must be restricted in order to reduce weight.

When should Melix not be used?

Melix should not be taken in the following cases:
patients with diabetes, whose pancreas no longer produces any insulin, especially in children and adolescents (type 1 diabetes);
if you have unstable diabetes with frequent and severe decompensation (in particular, a blood sugar increase with acetone odour on the breath, ketone bodies in the urine or disturbances of consciousness up to and including coma);
if there is a blood sugar increase (hyperglycemia) triggered by stress (infection, operation);
if you have severe liver or kidney disease;
if you have an allergy to Glibenclamide or other ingredients of the tablet;
during pregnancy or when nursing.
Your physician will advise you how to proceed in these cases.

When is caution indicated for the intake of Melix?

There is the risk of too great a decrease in the blood sugar (hypoglycemia), in particular, before a balance has achieved (at the beginning of treatment or when changing from another drug to Melix), as well as when someone has forgotten to take a tablet or has an irregular food intake. Your reaction ability and safety when driving a car or operating machinery could be affected by it.
A series of other medications as well as alcohol can increase or decrease the blood sugar reducing effect of Melix if taken at the same time: involved in particular are certain antibiotics and medications against fungal infections and diseases as well as pain medications and antirheumatics, hormones (in particular contraceptives and drugs for the treatment of menopausal complaints or thyroid disorders), antidepressants, diuretics, drugs for heartburn (antacids), various substances to promote blood circulation in circulatory disorders or when there is increased fat content of the blood.
Certain blood pressure-lowering drugs can make it difficult to perceive a drop in blood sugar.

Inform your physician or pharmacist if you have

- other medical problems,
- allergies,
- are taking any other medications (including over-the-counter medications) or using them externally.

May Melix be taken during pregnancy or while nursing?

In principle, Melix should not be taken during pregnancy, because adverse effects on the unborn child cannot be excluded, for example, stimulation of the pancreas. Substances like Glibenclamide can be transmitted in breast milk, which is why Melix should also not be taken while nursing. The attending physician should be informed early enough if you would like to become pregnant. If a pregnancy should occur during treatment with Melix, the physician must be notified immediately. He will assist you during further treatment of your diabetes.

How do you use Melix?

The physician will determine the correct dosage for you based on regular checks for sugar in your blood and urine, with treatment generally being initiated with a low dose of ½ tablet of Melix per day.
With a daily dose up to two tablets, the tablets are taken in the morning, as a rule, before breakfast. Under physician moni-

ring the daily dose can be increased to up to three (in exceptional cases, up to four) tablets of Melix as needed. The third tablet must then be taken before the evening meal (or the third at midday and the fourth in the evening). The tablets should be taken unchewed with plenty of liquid (at least 1/2 to 1 glass of water). The schedule determined by the physician must be adhered to without fail. If a tablet is forgotten, the omission cannot be corrected after the fact, and the next tablet must then be taken on time as planned.

Do not change the prescribed dosage of your own accord. If you think that the effects of the medication are too weak or too strong, then consult your physician or pharmacist.

What side-effects can Melix have?

Taking Melix can cause the following side-effects:

It can frequently lead to a – often dangerous – decrease in blood sugar (hypoglycemia), either due to too high a dosage, or because a meal was omitted; either due to unaccustomed physical activity or because of an interaction with another drug.

The following warning signs often occur before hypoglycemia: profuse sweating, intense appetite, trembling, palpitations of the heart, headache, disturbances of consciousness, irritability, aggressivity, confusion, drowsiness, sleep disturbances. Severe untreated hypoglycemia can lead to difficulties with speech and vision, paralysis, disturbances of consciousness and loss of consciousness.

Immediately take 2-4 cubes of sugar or glucose as soon as such symptoms appear. Notify your physician if the symptoms do not immediately subside. Hypoglycemia can not be treated with artificial sweeteners.

At the beginning of treatment temporary visual disturbances may occur. Specific digestive disorders (e.g., nausea, vomiting, stomach pain, diarrhoea) as well as allergic reactions (e.g., skin rash, itching; in rare cases, shortness of breath and shock), as well as excessive sensitivity to light sometimes occur, but usually disappear of their own accord. Specific changes in the blood count (e.g., decrease in the number of platelets, red or white blood cells) and of liver function (such as jaundice, liver inflammation and bile flow stoppage) are rare, but can be dangerous. Inflammations of the veins are extremely rare. Please inform your physician if you notice one or more of these side-effects.

What should also be taken into consideration?

Achieving a satisfactory blood sugar balance requires adhering to the therapy plan prescribed by the physician, physical activity and the diet plan. Consuming alcoholic beverages should be avoided during treatment with Melix. Blood sugar checks must be done regularly. If another illness occurs during treatment with Melix, especially if this is associated with vomiting or loss of appetite, the attending physician must be informed immediately. If you are admitted to a hospital or become ill abroad the physician you see must be informed about the existing diabetes.

The medication should be stored in the original package, at room temperature (15-25°C), out of the reach of children.

The medication may only be used until the date marked on the container with "EXP".

Further information can be obtained from your physician or pharmacist. They have access to more detailed product information.

What is contained in Melix?

Each Melix scored tablet contains 5 mg of Glibenclamide as well as inactive materials.

44714 (Swissmedic)

Where can you obtain Melix? Which packages are available?

In pharmacies with a physician's prescription.
Original packages of 30 and 100 tablets.

Holder of the authorisation

Lagap SA, CH-6943 VEZIA

This package insert was last reviewed by the Drug Authority (Swissmedic) in December 2006.

This is a Medicament

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

Keep medicament out of the reach of children!

Council Of Arab Health Ministers Union of Arab Pharmacists Information Updated:

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