

Package leaflet: Information for the patient

Minodiab® 5 mg Tablets

Glipizide

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. See section 4.

What is in this leaflet

1. What Minodiab is and what it is used for
2. What you need to know before you take Minodiab
3. How to take Minodiab
4. Possible side effects
5. How to store Minodiab
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1. What Minodiab is and what it is used for

This medicine contains glipizide which is one of a group of medicines called sulphonylureas. Minodiab is used to treat diabetes (Type II, non-insulin-dependent diabetes) and helps to lower your blood glucose (sugar) levels, when a change in diet alone is not enough to control the condition.

Diabetics produce too much glucose due to a lack of insulin in the body. This can be controlled by Minodiab, which reduces high blood glucose (sugar) levels by increasing insulin production.

You must talk to a doctor if you do not feel better or if you feel worse after taking this medicine.

2. What you need to know before you take Minodiab

Do not take Minodiab:

- If you are allergic to glipizide, similar antidiabetic medicines or any of the other ingredients of this medicine (listed in section 6).
- If you have insulin-dependent diabetes (also called juvenile or Type I diabetes) which would have probably started in your childhood.
- If you have ketone bodies and sugar in your urine (this may mean you may have diabetic ketoacidosis).
- If you suffer from episodes of unconsciousness (this may mean you may have diabetic coma).
- If you have problems with your kidneys or liver.
- If you are pregnant, planning to become pregnant or breast-feeding.
- If you are currently taking miconazole to treat fungal infections.

Warnings and precautions

Talk to your doctor or pharmacist before using Minodiab:

- If you have been told that you have problems with your adrenal or pituitary glands.

- If you are about to have major surgery, have had a recent injury (trauma) or develop a fever or severe infection. (See Section 3 “If you are going to have an operation” for further information).
- If you suffer from G6PD deficiency (a disease that causes abnormal destruction of your red blood cells).

You should test your blood and urine glucose regularly, particularly if you are elderly, debilitated or malnourished. If the results of the tests are outside the limits recommended by your doctor you should contact them immediately.

Minodiab can cause hypoglycaemia (low blood sugar levels), which is characterised by confusion, faintness, sweating, dizziness, drowsiness, headache, shakiness (tremor) and visual disturbances. (These symptoms may also be unrelated to hypoglycaemia). Low blood sugar levels can be prevented by taking a regular intake of carbohydrates (e.g. bread, or other products containing starch/sugar). You should eat regular meals, and not exercise heavily or for a long period without eating something first.

Other medicines and Minodiab

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

When given with Minodiab, the following medicines may **reduce** your blood sugar levels too much:

- Miconazole, fluconazole or voriconazole (used to treat fungal infections).
- Non-steroidal anti-inflammatory agents (used to treat muscle and joint pain e.g. phenylbutazone).
- Aspirin or aspirin like medicines known as salicylates (usually used as pain killers).
- Beta-blockers (used to treat high blood pressure and certain heart conditions e.g. propranolol).
- Angiotensin converting enzyme (ACE) inhibitors (used to treat high blood pressure e.g. captopril).
- Cimetidine (used to treat stomach and duodenal ulcers and other digestive disorders).
- Sulfonamides or chloramphenicol (used to treat bacterial infections).
- Quinolones (used to treat bacterial infections).
- Monoamine oxidase inhibitors (used to treat depression).
- Probenecid (drugs used to treat gout).
- Coumarin anticoagulants (used to treat blood clots e.g. warfarin).
- Fibrates (used to treat high cholesterol e.g. clofibrate).

The following medicines may **increase** your blood sugar levels too much when given with Minodiab:

- Danazol (a hormone treatment).
- Phenothiazines tranquillisers (used to treat psychiatric conditions e.g. chlorpromazine, thioridazine).
- Corticosteroids (used to treat inflammatory conditions (e.g. prednisolone).
- Sympathomimetic agents, such as nasal decongestants and bronchodilators used to treat asthma (e.g. salbutamol, isoprenaline).
- Hormonal agents, including oral contraceptives (the Pill) and hormone replacement therapy (HRT).
- Thiazides or other diuretics (water tablets e.g. bendroflumethiazide).
- Thyroid products (used to treat patients with a low production of thyroid hormones).

- Phenytoin (used to treat epilepsy).
- Nicotinic acid (used in vitamin supplements and to lower cholesterol and other lipid levels).
- Calcium channel blocking agents (used to treat angina and high blood pressure e.g. nifedipine or verapamil).
- Isoniazid (used to treat tuberculosis).

Minodiab with food, drink and alcohol

As food may delay absorption of the drug, each dose should be taken 30 minutes before food. Try to avoid alcohol. Alcoholic drinks (wine, beer, spirits) can further increase the reduction in blood sugar levels and could cause unconsciousness (hypoglycaemic coma).

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Minodiab should not affect your ability to drive or use machines. However, you should be careful when you have just started taking this medicine or if you don't use it regularly.

Be aware of the symptoms of low blood sugar levels (hypoglycaemia). These are characterised by confusion, faintness, sweating, dizziness, drowsiness, headache shakiness (tremor) and visual disturbances.

If you are affected, do not drive or operate machines.

Minodiab contains lactose monohydrate

Lactose monohydrate is a type of sugar. If you have been told that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Minodiab

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Minodiab should only be taken by mouth. It is important that you take your tablets according to the instructions of your doctor. These will be written on the label of the pack. Do not take more Minodiab than your doctor has recommended.

Your dose will be adapted to your individual requirements. Some patients, whose condition is usually controlled by diet alone, may only require Minodiab for a short time.

The recommended dose is:

Adults

The initial dose is usually 5 mg, taken approximately 30 minutes before breakfast or the midday meal, although this may be lower in some patients.

If you are elderly, have mild diabetes or suffer from liver or kidney problems you may be started on 2.5 mg daily.

If your doctor feels your dose needs to be altered, they will instruct you to adjust the dose in small increments, usually in 2.5 – 5 mg steps.

The maximum recommended daily dose is 20 mg.

The label on the pack will tell you what dose YOU should take and how often to take it. If you are still not sure, ask your doctor or pharmacist.

Do not stop taking the tablets or adjust your dosage without seeing your doctor. Stopping the medicine may make your diabetes worse.

Use in children and adolescents

Minodiab is not recommended for use in children or adolescents.

If you take more Minodiab than you should

- If you accidentally take too many tablets, seek medical advice immediately.
- If you suffer faintness, confusion, drowsiness, headache, dizziness, sweating or shakiness and visual disturbances, these may be symptoms of low blood sugar. You should eat or drink something sugary.
- If you suffer fits or loss of consciousness occur, someone should seek urgent medical assistance for you.

If you forget to take Minodiab

If you miss a dose, it is important that you take your medicine as soon as you remember or feel faint, otherwise your blood sugar will become too high and you may go into a coma (or fall unconscious).

Do not take a double dose to make up for a forgotten dose.

If you stop taking Minodiab

Do not stop taking your tablets or alter the dose you are currently taking without seeing your doctor first. Stopping these tablets may make your diabetes worse.

If you are going to have an operation

If you are going to have major surgery or you have recently suffered a severe illness or infection, diabetic control may be lost. At such times it may be necessary to temporarily stop using Minodiab and take insulin.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The majority are temporary and disappear on reducing the dose or on stopping treatment. Do not stop taking the tablets or adjust your dosage without seeing your doctor.

Reasons for contacting your doctor immediately

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine. Although they are very rare, these symptoms can be serious.

- An allergic reaction such as sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body). Allergic reactions (including very rarely, death) have been reported with drugs similar to Minodiab.

Other side effects that may occur are as follows:

Common: may affect up to 1 in 10 people

hypoglycaemia (not enough sugar in the blood)
feeling sick (nausea)
diarrhoea
pain in the stomach

Uncommon: may affect up to 1 in 100 people

dizziness

drowsiness
shakiness (tremor)
blurred vision
being sick (vomiting)
jaundice (yellowing of the skin and eyes, itching and dark urine)
eczema (inflammation of skin)

Not known: frequency cannot be estimated from the available data

agranulocytosis (deficiency of a type of white blood cells)
leukopenia (reduction in white blood cells count)
thrombocytopenia (reduction in platelet count)
haemolytic anaemia (abnormal breakdown of red blood cells)
pancytopenia (decreased count of all type of blood cells)
porphyria non-acute
redness (erythema)
itching (pruritus)
rash (red, bumpy, or measles-like)
itching, skin redness or inflammation (dermatitis allergic)
pale red, raised, itchy bumps (urticaria)
sensitivity to light
reduction in blood sodium (hyponatraemia)
confusion
headache
visual disturbances, double vision
constipation
inflammation of the liver (hepatitis) and abnormal hepatic functions
malaise (general discomfort)
abnormal laboratory tests

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Minodiab

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister strip and carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Minodiab contains

- The active ingredient is glipizide. Each tablet contains 5 mg glipizide.

- The other ingredients are lactose (see section 2 **Minodiab contains lactose**), microcrystalline cellulose, starch and stearic acid.

What Minodiab looks like and contents of the pack

Minodiab 5 mg tablets are white, biconvex tablets scored on both sides. They are available in packs of 28 or 60 tablets in blister strips. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Pfizer Limited, Ramsgate Road, Sandwich,
Kent, CT13 9NJ, United Kingdom

Manufacturer:

Pharmacia Italia S.p.a., Ascoli Piceno Plant,
Ascoli Piceno, Italy.

Company contact address

For further information on this medicine, please contact Medical Information at Pfizer Limited in Walton Oaks, Tadworth, Surrey, Tel: +44 1304 616161

This leaflet was last revised in 02/2018.

Ref: MG 11_1