

PACKAGE LEAFLET: INFORMATION FOR THE USER

Dialosa 1 mg, 2 mg, 3 mg, 4 mg and 6 mg tablets

Glimepiride

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Dialosa is and what it is used for
2. Before you take Dialosa
3. How to use Dialosa
4. Possible side effects
5. How to store Dialosa
6. Further information

1. WHAT DIALOSA IS AND WHAT IT IS USED FOR

Dialosa lowers blood sugar levels partly by increasing the body's own insulin production and partly by enhancing the effect of the body's own insulin. Dialosa is used for the treatment of type 2 (adult type) diabetes when diet, weight loss and exercise alone do not produce a sufficient result. Dialosa may also be used together with insulin.

2. BEFORE YOU TAKE DIALOSA

Do not use Dialosa

- if you are allergic (hypersensitive) to glimepiride, other medicinal products from the same group (sulphonylureas or sulphonamides) or any of the other ingredients of Dialosa.
- if you have insulin-dependent (type 1) diabetes, hyperglycaemic or hypoglycaemic coma (unconsciousness) and ketoacidosis (increased levels of acids in the body) or severely impaired kidney or liver function.

Take special care with Dialosa:

- Blood and urine sugar levels should be monitored regularly.
The risk of an excessive reduction in blood sugar levels (hypoglycaemia) is increased during the first few weeks of Dialosa therapy.
- In impaired kidney and liver function as well as longer term fasting, the blood sugar reducing effect of Dialosa may be too strong.
- If you are simultaneously using other medicinal or health products (see section Using other medicines).
- Lowering of the haemoglobin level and breakdown of red blood cells (haemolytic anaemia) can occur in patients missing the enzyme glucose-6-phosphate dehydrogenase.

Symptoms of hypoglycaemia may occur if you

- are using other medicines simultaneously,
- take an overdose,
- have irregular meal times,

- have fever,
- have detrimental stress,
- exert yourself physically more than usual,
- are using alcohol.

The symptoms of hypoglycaemia (excessively low blood sugar levels) include hunger, weakness, perspiration, nervousness, tremor, paleness, headache, even convulsions and coma. Such effects usually resolve quickly after taking sugar. Therefore, always keep sugar with you in some form, for example as fructose, fruit juice, chocolate or similar. Please note that artificial sweeteners are not helpful. If taking sugar does not help or if symptoms recur, contact your doctor.

The symptoms of hyperglycemia (excessively high blood sugar levels) include thirst, urinary frequency, dry mouth and dry skin. In such cases please consult your doctor.

In the event of accident, surgery or fever it may be necessary to switch to insulin treatment.

Using 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 effect of Dialosa may be increased or reduced when used simultaneously with certain other medicines. Such medicines include:

- insulin and other oral antidiabetics
- certain long-acting sulphonamides
- metformin
- tetracyclines
- salicylates and p-amino-salicylic acid
- MAO inhibitors
- anabolic steroids and male sex hormones
- quinolone antibiotics
- chloramphenicol
- coumarin anticoagulants
- miconazole, fluconazole
- ACE inhibitors
- fluoxetine
- allopurinol
- oestrogens and gestagens
- saluretics, thiazide diuretics
- thyroid hormones, glucocorticoids
- phenothiazine derivatives, chlorpromazine
- laxatives (in long-term use)
- phenytoin
- glucagon, barbiturates and rifampicin
- acetazolamide

Alcohol may increase or reduce the blood sugar lowering effect of Dialosa.

Always consult your doctor before taking Dialosa simultaneously with other medicines.

Taking Dialosa with food and drink

Dialosa should be taken as a single dose shortly before or during breakfast or the first main meal of the day and swallowed whole with water (at least ½ glass).

Pregnancy and breast-feeding

Dialosa should not be used during pregnancy. If you are planning a pregnancy, ask your doctor about the medication.

It is not known whether glimepiride is excreted in breast milk. Dialosa should not be used during breast-feeding.

Driving and using machines

Your concentration and reactions may be reduced due to too low or too high blood sugar levels or for example due to reduced vision caused by them. This may be dangerous in situations where such skills are important (e.g. driving or using machines). Therefore, together with your doctor consider whether you should drive or use machines.

Important information about some of the ingredients of Dialosa:

Dialosa tablets contain lactose as an inactive substance. If your doctor has told you that you have an intolerance to some sugars, please talk to your doctor before taking this medicine.

The tablets contain some colouring agents (red iron oxide E172, yellow iron oxide E172, indigo carmine aluminium lake E132 or sunset yellow FCF aluminium lake E110) that may cause hypersensitivity reactions.

3. HOW TO USE DIALOSA

Always use Dialosa exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose in adults is 1-4 mg per day depending on blood sugar levels. The maximum daily dose is 6 mg. It is very important not to miss meals during Dialosa therapy. Insulin may be used in addition to Dialosa therapy. In this case, your doctor will determine an insulin dose suitable for you personally.

If you feel that the effect of Dialosa is too strong or too weak, please contact your doctor or pharmacist.

If you use more Dialosa than you should

Always contact your doctor, hospital or the National Poisons Information Centre immediately. Symptoms may appear up to 24 hours after ingestion of Dialosa tablets.

Overdosage symptoms include low blood sugar, nausea, vomiting, abdominal pain, restlessness, tremor, abnormal vision, coordination disorders, sleepiness, unconsciousness (coma) and convulsions. If an overdose is suspected, sugar, fruit juice or similar should be taken immediately. However, food or drink must not be given to a comatose patient.

If you forget to take Dialosa

Do not take a double dose to make-up for forgotten individual doses. Take your next tablet(s) as usual and continue your therapy.

If you stop using Dialosa:

Elevation of blood sugar levels is possible. Do not stop your treatment before you talk to your doctor.

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

4. POSSIBLE SIDE EFFECTS

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

Rare side effects (more than 1/10 000 but fewer than 1/1000 patients):

Changes in blood count (usually reversible after discontinuation of therapy) and reduction in blood sugar levels.

Very rare side effects (fewer than 1/10 000 patients):

Nausea, vomiting, diarrhoea, a feeling of fullness, abdominal pain, reduction in liver function (e.g. cholestasis and jaundice), hepatitis, liver impairment, severe hypersensitivity reactions (dyspnoea, reduced blood pressure, shock), allergic vasculitis, photosensitivity, reduced serum sodium content.

In addition, elevation of liver enzyme levels, hypersensitivity reactions of the skin, such as itching, rash and urticaria as well as cross allergy to sulphonylureas or sulphonamides may occur. Transient visual disturbances may occur, especially at the beginning of the therapy.

If you experience severe or disturbing symptoms, such as jaundice or dyspnoea, contact your doctor immediately.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE DIALOSA

Keep out of the reach and sight of children.

Do not store above 30°C.

Do not use Dialosa after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not use Dialosa if you notice visible changes in the appearance of the medicinal product.

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 to protect the environment.

6. FURTHER INFORMATION

What Dialosa contains

- The active substance is glimepiride.
- The other ingredients are lactose monohydrate, sodium starch glycolate type A, microcrystalline cellulose, povidone K30, magnesium stearate, 1 mg tablets: red iron oxide (E172), 2 mg tablets: yellow iron oxide (E172), indigo carmine aluminium lake (E132), 3 mg tablets: yellow iron oxide (E172), 4 mg tablets: indigo carmine aluminium lake (E132), 6 mg tablets: sunset yellow FCF aluminium lake (E110).

What Dialosa looks like and contents of the pack

1 mg tablets are pink, oblong with a score line on both sides.

2 mg tablets are green, oblong with a score line on both sides.

3 mg tablets are pale yellow, oblong with a score line on both sides.

4 mg tablets are pale blue, oblong with a score line on both sides.

6 mg tablets are pale orange, oblong with a score line on both sides.

Contents of container: 30 tablets (in 10-tablet blister packs).

Marketing Authorisation Holder and Manufacturer

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