

diabetan 2 mg tablets

Glimepiride

Read all this leaflet carefully before you start taking this medicine.

- 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. 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 **diabetan 2 mg tablets** is and what it is used for.
2. Before you take **diabetan 2 mg tablets**.
3. How to take **diabetan 2 mg tablets**.
4. Possible side effects.
5. How to store **diabetan 2 mg tablets**.
6. Further information.

1. WHAT diabetan 2 mg tablets IS AND WHAT IT IS USED FOR

diabetan 2 mg belongs to the group of drugs called Oral Antidiabetics that reduce blood glucose to normal values in patients with adult diabetes.

This medicine is prescribed to treat adult diabetes, when diet, physical exercise and weight loss alone are not adequate.

2. BEFORE YOU TAKE diabetan 2 mg tablets

Do not take diabetan 2 mg:

- If you are allergic to glimepiride, other sulphonylureas or sulphonamides or any of the other ingredients.
- If you suffer type 1 diabetes (juvenile diabetes, which is a defect in insulin production by the pancreas).
- If you suffer diabetic coma (reduced consciousness level due to ketoacidosis).
- If you suffer ketoacidosis (metabolic disorder with increased blood acidity from an accumulation of ketone bodies).
- If you suffer serious kidney or liver disorders. In these cases changing to insulin is required.
- If you are pregnant or breast-feeding (See "Pregnancy" or "Breast-Feeding").

Take special care with diabetan 2 mg:

- If you do not take regular meals, because treatment with **diabetan 2 mg** can excessively reduce blood sugar levels (hypoglycaemia).
- If you cannot take **diabetan 2 mg** regularly, as this may favour the onset of hypoglycaemia.
- If you suffer symptoms of hypoglycaemia (See "Additional advice for the management of hypoglycaemia") despite having taken sugar. If these symptoms are serious or prolonged, you should see a doctor immediately.
- If you suffer from any kidney or liver disease, as this may favour the onset of hypoglycaemia. Your doctor will recommend to you routine monitoring of renal and liver function.
- If you suffer any metabolic disorder (thyroid, parathyroid or steroid hormone disorders), as this may favour the occurrence of hypoglycaemia.
- If are to undergo surgery, as your doctor may temporarily discontinue treatment and replace it with insulin.
- If you have a traffic accident or any infection with fever. Your doctor may prescribe a temporary change of treatment to insulin for you.
- If you take **diabetan 2 mg** together with insulin or other anti-diabetics, as hypoglycaemia may occur (See "Using other medicines").
- Consult your doctor even if you have experienced any of the abovementioned conditions at any time in the past.

diabetan 2 mg must be taken shortly before or during a meal.

Using other medicines:

Tell your doctor or pharmacist if you are using or have recently used any other medicine, even those acquired without medical prescription, as it may be necessary to stop the treatment or adjust the dose of any of them.

If you take **diabetan 2 mg** with the following compounds, hypoglycaemia can occur:

- anti-inflammatories (phenylbutazone, azapropazone and oxyphenbutazone; salicylates and p-amino-salicylic acid).
- anti-diabetics (oral anti-diabetics, insulin, metformin).
- anabolising steroids and male sexual hormones.
- coumarin anticoagulants.
- lipid-lowering agents (fibrates).
- medicines for the treatment of some heart diseases and hypertension.
- some antihypertensives (acting adrenergically).
- anti-cancer drugs (cytotoxicamide, trophosphamide and ipsofosamide).
- antigout drugs (allopurinol, sulphapyrazone and probenecid).
- anti-infectious drugs (chloramphenicol, some long-acting sulphonamides, tetracyclines, quinolone antibiotics, miconazole, fluconazole, parenteral pentoxiphillin at high doses).
- anti-depressant drugs (fluoxetine).
- triquinoline.
- phegluramine.

If you take **diabetan 2 mg** with the following compounds, hypoglycaemia can occur:

- hormones of oestrogen and progestagen type.
- some antihypertensives (saluretics and thiazide diuretics).
- drugs enhancing thyroid function.
- glucocorticoids.
- phenothiazine derivatives (chlorpromazine).
- epinephrine and vasoconstrictive drugs, heart function stimulators, bronchodilators or uterine relaxants.
- nicotinic acid (high doses) and its derivatives.
- laxatives (long-term use).
- barbiturates.
- phenytoin, diazoxide, glucagon, rifampin and acetazolamide.

If you take **diabetan 2 mg** with the following compounds, both hypoglycaemia and hyperglycaemia can occur:

- gastric secretion inhibitors.
- drugs against hypertension, heart ischemia and arrhythmia, clonidine and reserpine. Concomitant administration can mask the warning signs for possible hypoglycaemia.
- alcohol.

If you take **diabetan 2 mg** with oral anticoagulants, their action can increase or decrease.

Pregnancy and breast-feeding:

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine.

If you are pregnant or think you may be, do not take **diabetan 2 mg**. In this case, ask your doctor who will probably prescribe the use of insulin for you.

Lactation

Ask your doctor or pharmacist for advice before taking any medicine.

If you are breast feeding, you must not take **diabetan 2 mg**. In this case, ask your doctor who will probably prescribe the use of insulin for you.

Driving and using machines:

Ask your doctor or pharmacist for advice before taking any medicine.

Tests have been conducted on the effects of **diabetan 2 mg** on the ability to drive and use machines. Take into account that alertness and reaction time can be affected by hypoglycaemia or hyperglycaemia (blood sugar decrease or increase), particularly at the start of or after changing treatment to **diabetan 2 mg** or if administration is not regular, which may affect the ability to drive cars or use machines.

Important information about some of the ingredients of diabetan 2 mg tablets:

This medicinal product contains lactose. If your doctor has informed you that you are intolerant to some sugars, ask before using this medicine.

3. HOW TO TAKE diabetan 2 mg tablets

Follow these instructions unless your doctor has told you otherwise.

Remember to take your medicine.

The basis for satisfactory treatment of diabetes is proper diet, regular physical activity and regular blood and urine tests. The adverse effects as a result of an improper diet cannot be compensated with tablets or insulin.

The dosage is based on the results of the metabolic tests (blood and urine glucose measurements).

The starting dose is 1 mg of **diabetan 2 mg** once a day by oral route. If good glucose control is achieved, this same dose can be used as a maintenance treatment.

If glucose control is not satisfactory, your doctor will tell you to gradually increase the dose up to 2, 3 or 4 mg of **diabetan 2 mg** a day.

Only in very rare cases it is recommended to take over 4 mg of **diabetan 2 mg** a day, the recommended maximum dose being 6 mg of **diabetan 2 mg** a day.

If you experience a hypoglycaemic reaction (See "Additional advice for the management of hypoglycaemia") after the administration of a single dose of 1 mg of **diabetan 2 mg**, tell your doctor as it could probably be controlled with diet alone.

During treatment with **diabetan 2 mg**, the dose you need may be reduced. Therefore, your doctor might need to adjust the daily dose according to your needs and even discontinue treatment.

If you are treated with metformin and do not achieve adequate metabolic control, your doctor may supplement the treatment with **diabetan 2 mg**. For this, he will tell you the necessary dose of **diabetan 2 mg** to be used with metformin.

Your doctor will decide whether you need to supplement the treatment of **diabetan 2 mg** with insulin. In this case he will tell you the dose of insulin you should use together with glimepiride tablets.

If you have the impression that the effect of **diabetan 2 mg** is too strong or too weak, talk to your doctor or pharmacist.

Glimepiride tablets must be swallowed whole, with some fluid.

A daily dose of **diabetan 2 mg** is usually enough. It is recommended to take this dose shortly before or during a large breakfast or, in case you do not take it, shortly before or during the first meal.

Your doctor will indicate to you the duration of your treatment with **diabetan 2 mg**. Do not discontinue treatment earlier, as your blood sugar levels can once again be decompensated.

Use in children:

Glimepiride has not been tested in children.

Use in the elderly:

No controlled studies have been conducted in the elderly.

As biological functions may be reduced, your doctor will adjust the dose with utmost caution and closer monitoring will be required.

If you take more diabetan 2 mg than you should:

It can cause an exaggerated reduction of blood sugar (See "Take special care with **diabetan 2 mg**") that can last from 12 to 72 hours and even recur after initial recovery. The symptoms can appear even 24 hours after administration. If this occurs, visit your doctor or the emergency room of the closest hospital taking this leaflet with you.

If you forget to take diabetan 2 mg:

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, **diabetan 2 mg** can have side effects.

Effects related to metabolism

On rare occasions, hypoglycaemic reactions (blood sugar reduction) can be seen after administration of **diabetan 2 mg**. These reactions usually occur immediately, and can be severe and are not always easy to resolve. The occurrence of these reactions depends, as with any hypoglycaemic therapy, on individual factors such as diet and dosage habits (See "Take special care with **diabetan 2 mg**").

Blood disorders

Rarely, do you suffer from fever, sore throat, skin and mucosal bleeding, worsened pallor and blood test alterations, such as decreased red blood cell and/or white blood cell count, that may suggest blood disorders (thrombocytopenia, leucopenia, erythrocytopenia, granulocytopenia, agranulocytosis, haemolytic anaemia and pancytopenia), that can be detected by the routine tests you will undergo. These disorders generally subside when the treatment is discontinued. Tell your doctor immediately if these symptoms occur.

General and skin allergic reactions

Skin allergic reactions can occur, such as red spots on the skin, itching or wheals with irritation and itching (hives). Isolated cases of allergy to light or blood vessel inflammation (allergic vasculitis) have been reported.

Rarely, allergic reactions can occur with breathlessness, palpitations, anxiety with severe sweating, chest pain or tightening and decreased blood pressure. If you notice any of these symptoms, tell your doctor immediately.

Effects related to the liver

Increased liver enzymes have been observed. In very rare cases, liver function impairment can occur associated with yellow discolouring of the skin and mucosa (jaundice), bile flow may stop or be restricted (cholestasis) and liver inflammation (hepatitis) may occur, which could lead to decreased liver function (liver failure). If you suffer any liver disorders, your doctor will recommend to you routine liver function tests (see "Take special care with **diabetan 2 mg**").

Gastro disorders

Rarely do you experience, vomiting, diarrhoea, bloating or abdominal pain. In this event, inform your doctor as soon as possible.

Effects related to sight

You can experience temporary visual disturbances. In this event, inform your doctor as soon as possible.

If you notice any other side effects not listed in this leaflet, please consult your doctor or pharmacist.

5. HOW TO STORE diabetan 2 mg tablets

Keep out of the reach and sight of children.

Do not store above 25°C.

Do not use **diabetan 2 mg** after the expiry date stated on the carton after "EXP".

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

6. FURTHER INFORMATION

What diabetan 2 mg contains:

The active substance is glimepiride. Each tablet contains 2 mg of glimepiride.

The other ingredients (excipients) are: microcrystalline cellulose, povidone, sodium starch glycolate, lactose monohydrate, magnesium stearate, carmine indigo (E132), and quinoline yellow (E104).

What diabetan 2 mg looks like and contents of the package:

diabetan 2 mg is supplied in tablets. Each package contains 30 tablets.

Marketing Authorisation Holder and Manufacturers:

Laboratorios Cinfa, S.A.
C/Olaz-Chipi, 10 • Polígono Industrial Areta
31620 Huarte-Pamplona (Navarra) - Spain

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ADDITIONAL ADVICE FOR THE MANAGEMENT OF HYPOLYCAEMIA

Symptoms of hypoglycaemia

In the event of hypoglycaemia, you may experience any of these symptoms:

- headache,
- nausea, vomiting,
- sudden increased appetite,
- weakness, sleep disturbances, fatigue,
- lack of concentration, alertness and reaction time,
- depression, confusion,
- disorders and even loss of speech and visual disturbances,
- tremors, feeling of lack of strength or mild paralysis in the extremities or other areas of the body,
- alteration of the senses, dizziness,
- feeling of helplessness, loss of self-control, aggressiveness, delirium,
- seizures,
- drowsiness and loss of consciousness that can progress to coma,
- reduce pulse rate,
- impaired breathing.

In addition, a clinical condition called severe hypoglycaemic attack can occur, that can be similar to a stroke (lack of blood flow in the brain). It is characterised by sweating, damp skin, anxiety, increased pulse rate, increased blood pressure, palpitations, acute chest pain (angina pectoris) and changes in the heart rhythm. The symptoms almost always can be resolved by ingesting sugar immediately. Artificial sweeteners have no effect.

Consult your doctor if you feel you are not able to properly follow the treatment regimen or if hypoglycaemia appears repeatedly, as your blood sugar levels may be not adequately controlled.

Prevention of hypoglycaemia

To prevent the occurrence of hypoglycaemia you should:

- take the amount of **diabetan 2 mg** indicated by your doctor.
- take meals regularly and on schedule, avoiding fasting periods.
- avoid diet changes.
- keep a balance between physical exercise and diet.
- avoid taking alcohol, particularly if meals are irregular.
- ask your doctor before you take any other medicine.