

PACKAGE LEAFLET: INFORMATION FOR THE USER

DIPRIAN

80 mg Tablets

GLICLAZIDE

• 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?

1. What Diprian 80 mg is and what it is used for
2. What you need to know before you take Diprian 80 mg
3. How to take Diprian 80 mg
4. Possible side effects
5. How to store Diprian 80 mg

1. WHAT DIPRIAN 80 MG IS AND WHAT IT IS USED FOR

Diprian 80 mg contains the active substance gliclazide, one of a group of medicines called sulfonylureas. It is an oral hypoglycaemic medicine (blood sugar lowering drug). Diprian 80 mg is used to keep blood sugar at the correct level in adults with non-insulin dependent diabetes when it is not controlled by diet, physical exercise and weight loss alone.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DIPRIAN 80 MG

Do not take Diprian 80 mg

- if you are allergic to gliclazide or any of the other ingredients of Diprian 80 mg, to other medicines of the same group (sulfonylureas), to other related medicines (hypoglycaemic sulfonamides),
- if you have insulin-dependent diabetes (type 1),
- if you have ketone bodies and sugar in your urine (this may mean you have keto-acidosis), a diabetic pre-coma or coma,
- if you have severe kidney or liver disease,
- if you are taking miconazole (a treatment for fungal infections) (see Taking other medicines),
- if you are breast-feeding (see Pregnancy and breast-feeding).

Diprian 80 mg is not recommended for use in children.

If you have been told by your doctor that you have an intolerance to some sugars (e.g. glucose, lactose, galactose), contact your doctor before taking this medicinal product.

Warnings and precautions

Talk to your doctor before taking Diprian 80mg. You should observe the treatment plan prescribed by your doctor to achieve proper blood sugar levels. This means, apart from regular tablet intake, you observe the dietary regimen, have physical exercise and, where necessary, reduce weight.

During gliclazide treatment regular monitoring of your blood (and possibly urine) sugar level and also your glycated haemoglobin (HbA1c) is necessary.

In the first few weeks of treatment the risk of having reduced blood sugar levels (hypoglycaemia) may be increased. So particularly close medical monitoring is necessary.

Low blood sugar (Hypoglycaemia) may occur:

- if you take meals irregularly or skip meals altogether, if you are fasting,
- if you are malnourished,
- if you change your diet,
- if you increase your physical activity and carbohydrate intake does not match this increase,
- if you drink alcohol, especially in combination with skipped meals,
- if you take other medicines or natural remedies at the same time,
- if you take too high doses of gliclazide,
- if you suffer from particular hormone-induced disorders (functional disorders of the thyroid gland, of the pituitary gland or adrenal cortex),
- if your kidney function or liver function is severely decreased.

If you have low blood sugar you may have the following symptoms: headache, intense hunger, nausea, vomiting, weariness, sleep disorders, restlessness, aggressiveness, poor concentration, reduced alertness and reaction time, depression, confusion, speech or visual disorders, tremor, sensory disturbances, dizziness, and helplessness.

The following signs and symptoms may also occur: sweating, clammy skin, anxiety, fast or irregular heart beat, high blood pressure, sudden strong pain in the chest that may radiate into nearby areas (angina pectoris).

If blood sugar levels continue to drop you may suffer from considerable confusion (delirium), develop convulsions, lose self-control, your breathing may be shallow and your heart beat slowed down, you may become unconscious. In most cases the symptoms of low blood sugar vanish very quickly when you consume some form of sugar, e.g. glucose tablets, sugar cubes, sweet juice, sweetened tea. You should therefore always carry some form of sugar with you (glucose tablets, sugar cubes). Remember that artificial sweeteners are not effective.

Please contact your doctor or the nearest hospital if taking sugar does not help or if the symptoms recur.

Symptoms of low blood sugar may be absent, less obvious or develop very slowly or you are not aware in time that your blood sugar level has dropped. This may happen if you are an elderly patient taking certain medicines (e.g. those acting on the central nervous system and beta blockers).

If you are in stress-situations (e.g. accidents, surgical operations, fever etc.) your doctor may temporarily switch you to insulin therapy.

Symptoms of high blood sugar (hyperglycaemia) may occur when gliclazide has not yet sufficiently reduced the blood sugar, when you have not complied with the treatment plan prescribed by your doctor or in special stress situations. These may include thirst, frequent urination, dry mouth, dry itchy skin, skin infections and reduced performance.

While taking Diprian 80 mg you should:

- follow a regular diet: it is important to eat regular meals, including breakfast and never to miss or delay a meal,
- take your medicine regularly (see How to take Diprian 80 mg),
- check your blood glucose regularly as recommended by your doctor.

If you have a family history of or know you have the hereditary condition glucose-6-phosphate dehydrogenase (G6PD) deficiency (abnormality of red blood cells), contact your doctor before taking this medicinal product.

Other medicines and Diprian 80 mg

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. The blood sugar lowering effect of gliclazide may be strengthened and signs of low blood sugar levels may occur when one of the following medicines is taken:

- other medicines used to treat high blood sugar (oral antidiabetics, GLP-1 receptor inhibitors or insulin),
- antibiotics (e.g. sulfonamides, clarithromycin),
- medicines to treat high blood pressure or heart failure (beta blockers, ACE-inhibitors such as captopril or enalapril),
- medicines to treat fungal infections (miconazole, fluconazole),
- medicines to treat ulcers in the stomach or duodenum (H2 receptor antagonists),
- medicines to treat depression (monoamine oxidase inhibitors),
- painkillers or anti-rheumatics (phenylbutazone, ibuprofen),
- medicines containing alcohol.

The blood glucose lowering effect of gliclazide may be weakened and raised blood sugar levels may occur when one of the following medicines is taken:

- medicines to treat disorders of the central nervous system (chlorpromazine),
- medicines reducing inflammation (corticosteroids),
- medicines to treat asthma or used during labour (intravenous salbutamol, ritodrine and terbutaline),
- medicines to treat breast disorders, heavy menstrual bleeding and endometriosis (danazol).

Diprian 80 mg may increase the effects of medicines which reduce blood clotting (e.g. warfarin).

Consult your doctor before you start taking another medicinal product. If you go into hospital tell the medical staff you are taking Diprian 80 mg.

Diprian 80 mg with food, drink and alcohol

Diprian 80 mg can be taken with food and non-alcoholic drinks. Drinking alcohol is not recommended as it can alter the control of your diabetes.

Pregnancy and breast-feeding

Diprian 80 mg is not recommended for use during pregnancy. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

You must not take Diprian 80 mg while you are breast-feeding.

Driving and using machines

Provided your blood glucose levels are satisfactorily controlled on Diprian 80 mg, your ability to drive or use machines should not be affected. However, if your blood glucose levels become too low, this could adversely affect your concentration, and therefore your ability to perform these tasks.

Ask your doctor whether you can drive a car if you:

- have frequent episodes of low blood sugar (hypoglycaemia),
- have few or no warning signals of low blood sugar (hypoglycaemia).

3. HOW TO TAKE DIPRIAN 80 MG

Dose

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

Change in external factors (e.g. weight reduction, change in life style, stress) or improvements in the blood sugar control may require changed gliclazide doses.

The recommended dose is from one half to four tablets. This depends on the response to treatment. When the total daily dose exceeds two tablets, it should be divided into two equal doses taken morning and evening.

Diprian 80mg is for oral use. Take your tablet(s) with a glass of water before a meal.

If a combination therapy of Diprian 80 mg with metformin, an alpha glucosidase inhibitor, a thiazolidinedione, a dipeptidyl peptidase-4 inhibitor, a GLP-1 receptor agonist or insulin is initiated your doctor will determine the

proper dose of each medicine individually for you. If you notice that your blood sugar levels are high although you are taking the medicine as prescribed, you should contact your doctor or pharmacist.

If you take more Diprian 80 mg than you should

If you take too many tablets, contact your doctor or the nearest hospital Accident & Emergency department immediately.

The signs of overdose are those of low blood sugar (hypoglycaemia) described in Section 2.

The symptoms can be helped by taking sugar (4 to 6 lumps) or sugary drinks straight away, followed by a substantial snack or meal. If the patient is unconscious, immediately inform a doctor and call the emergency services.

If you forget to take Diprian 80 mg

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of Diprian 80 mg, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Diprian 80 mg

As the treatment for diabetes is usually life long, you should discuss with your doctor before stopping this medicinal product. Stopping could cause high blood sugar (hyperglycaemia) which increases the risk of developing complications of diabetes.

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.

Low blood sugar (Hypoglycaemia)

The most commonly observed side effect is low blood sugar (hypoglycaemia). For symptoms and signs see Section Warnings and Precautions.

If left untreated these symptoms could progress to drowsiness, loss of consciousness or possibly coma. If an episode of low blood sugar is severe or prolonged, even if it is temporarily controlled by eating sugar, you should seek immediate medical attention.

Other side effects

Digestive disorders: Abdominal pain, nausea, vomiting, indigestion, diarrhoea and constipation. These effects are reduced when Diprian 80 mg is taken with a meal as recommended.

Skin disorders: Skin reactions such as rash, redness, itching, hives, angioedema (rapid swelling of tissues such as eyelids, face, lips, mouth, tongue or throat that may result in breathing difficulty) have been reported. The rash may progress to widespread blistering or peeling of the skin. Exceptionally, signs of severe hypersensitivity reactions (DRESS) have been reported: initially as flu-like symptoms and a rash on the face then an extended rash with a high temperature.

Blood disorders: Decrease in the number of cells in the blood (e.g. platelets, red and white blood cells) which may cause paleness, prolonged bleeding, bruising, sore throat and fever. These symptoms usually stop when the treatment is discontinued.

Liver disorders: There have been isolated reports of abnormal liver function which can cause yellow skin and eyes. If you get this, see your doctor immediately. The symptoms generally disappear if the drug is stopped. Your doctor will decide whether to stop your treatment.

Eye disorders: Your vision may be affected for a short time, especially at the start of treatment. This effect is due to changes in blood sugar levels.

As for other sulfonylureas, the following adverse events have been observed: cases of severe changes in the number of blood cells and allergic inflammation of the wall of blood vessels, reduction in blood sodium

(hyponatraemia), symptoms of liver impairment (e.g. jaundice) which in most cases disappeared after withdrawal of the sulfonylurea, but may lead to life threatening liver failure in isolated cases.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE DIPRIAN 80 MG

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 carton and the blister strip after Exp. The expiry date refers to the last day of that month.

Store in the original package.

This medicinal product 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.

This leaflet was last revised in 09/2015