

## PATIENT INFORMATION LEAFLET

### GLICLAZIDE TABLETS BP 80 mg (MELANOV 80)

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#### **Read all of 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 only. Do not pass it on to others. It may harm them, even if their signs of illness 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, health care provider><or><pharmacist>.>

#### **Prescription only medicine**

##### **In this leaflet**

- a) What Melanov 80 is and what it is used for
- b) What you need to know before you take Melanov 80
- c) How to take Melanov 80
- d) Possible Side Effects
- e) How to store Melanov 80
- f) Further information

##### **a. What Melanov 80 is and what it is used for**

Melanov 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).

Gliclazide 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.

##### **b. What you need to know before you take Melanov 80**

Do not take Gliclazide 80 mg

- if you are allergic to gliclazide or any of the other ingredients of Gliclazide 80 mg (listed in section 6), 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) or antibiotics (quinolones) (see section **Other medicines and Gliclazide 80mg**),
- if you are breastfeeding (see section **Pregnancy and breastfeeding**).

### **Children and adolescents**

Gliclazide 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 (for instance glucose, lactose, galactose), contact your doctor before taking this medicinal product.

### **Warnings and precautions**

Follow your doctor's advice about diet and treatment. This is to reduce the chances of very low blood sugar (hypoglycaemia). Make sure your doctor knows:

- if you have an operation, a serious injury, fever or infection,
- difficulty in eating,
- if you plan a pregnancy or become pregnant,
- if you are taking any of the medicines listed in **Other medicines and Gliclazide 80mg**.
- Tell your dentist about your treatment.

### Dietary advice

This medicine may cause episodes of low blood sugar (hypoglycaemia). This is more likely if:

- you are on a strict diet,
- your diet is poorly balanced,
- you are taking prolonged or strenuous exercise,
- you drink alcohol,
- you are taking several medicines for high blood sugar (See **Other medicines and Gliclazide 80mg**).

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 heartbeat, 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, for instance 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.

**While taking Gliclazide 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 Gliclazide 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.

Cases of acute porphyria have been described with some other sulfonylurea drugs, in patients who have porphyria (inherited genetic disorders with accumulation in the body of porphyrins or porphyrin precursors).

**Other medicines and Gliclazide 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 (sulfonamides, clarithromycin, quinolones),
- 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),
- painkiller or antirheumatics (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),
- St John's Wort — *Hypericum perforatum* — preparations to treat mild to moderate depressive episodes.

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

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

### **Taking Gliclazide 80 mg with food, drink and alcohol**

Gliclazide 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 breastfeeding**

Gliclazide 80 mg is not recommended for use during pregnancy. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby while taking this medicine, inform your doctor so that he may prescribe a more suitable treatment for you.

You must not take Gliclazide 80 mg while you are breastfeeding.

### **Driving and using machines**

Provided your blood glucose levels are satisfactorily controlled on Gliclazide 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).

### **c. How to take Melanov 80**

#### **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. The recommended daily 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.

Gliclazide 80 mg is for oral use. Take your tablet(s) with a glass of water (and preferably at the same time each day). Swallow your tablets whole. Do not chew them. You must always eat a meal after taking your tablet(s).

If a combination therapy of Gliclazide 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 Gliclazide 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 Gliclazide 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 Gliclazide 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 Gliclazide 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.

### **d. 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 Gliclazide 80 mg is taken with a meal as recommended.
- Skin disorders: Skin reactions such as rash, redness, itching, hives, blisters, angioedema (rapid swelling of tissues such as eyelids, face, lips, mouth, tongue or throat that may result in breathing difficulty) have been reported. Rash may progress to widespread blistering or peeling of the skin. If you develop this, stop taking Gliclazide 80 mg, seek urgent advice from a doctor and tell him that you are taking this medicine.

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 for instance 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 (for instance jaundice) which in most cases disappeared after withdrawal of the sulfonylurea, but may lead to life threatening liver failure in isolated cases.

### **e. How to store Melanov 80**

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.

**f. further information**

**What Melanov 80 contains**

The active substance is gliclazide. Each uncoated tablet contains 80 mg of gliclazide

The other ingredients are: Lactose, Microcrystalline cellulose, Povidone, Maize Starch, Magnesium Stearate, Talc

**What Melanov 80 looks like and contents of the pack**

White, flat, circular, bevel edged uncoated tablets with ML engraved on one surface and a break line on other surface.

Break line is to facilitate breaking for ease of swallowing and not for dividing into equal doses.

Blister pack of 10 tablets

**Name and full physical address of Marketing Authorization Holder and Manufacturing site**

**Marketing Authorization Holder**

**MICRO LABS LIMITED**

31, Race course road

Bangalore-560001

INDIA

**Manufacturer**

**MICRO LABS LIMITED**

No. 92, Sipcot Industrial Complex

Hosur -635 126 (TN)

INDIA

**For any information about this medicinal product, please contact the <local representative of the> supplier**

**Country: Rwanda**

M/s.Wessex

Pharmaceuticals (Rwanda) Ltd

C/o.Phillips Pharmaceuticals (Rwanda) Ltd

Shop No: Gf68, Kigali Modern City Market Commercial Street  
Kigali, Rwanda

**This leaflet was last approved in**

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