



glibenclamide

5 mg

scored tablet

sanofi aventis

IDENTIFICATION OF THE MEDICINE

Composition

Glibenclamide..... 5 mg for one scored tablet.

Excipients : lactose monohydrate, maize starch, pregelatinized maize starch, talc, anhydrous colloidal silica, magnesium stearate.

Pharmaceutical form and presentation

Scored tablet, box of 30 or 100.

Pharmaco-therapeutic class

SULFONYLUREA - ORAL ANTIDIABETIC (A : gastrointestinal tract and metabolism)

WHEN SHOULD THIS MEDICINE BE USED

This medicine is indicated in case of non-insulin-dependent diabetes, if a diet has failed.

ATTENTION!

WHEN THIS MEDICINE SHOULD NOT BE USED

This medicine SHOULD NOT BE USED in the following cases :

- allergy to glibenclamide,
- diabetes requiring insulin therapy,
- diabetic ketoacidosis, precomatose diabetes,
- severe liver or kidney disease,
- treatment with miconazole (cf. Drug interactions and other interactions),
- porphyria : accumulation of pigments (porphyrin) in the body,
- lactation.

Unless otherwise specified by your doctor, the combination of this medicine with phenylbutazone or danazol is generally inadvisable.

IN CASE OF DOUBT, YOU MUST ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Special warnings

Hypoglycaemia (reduced levels of sugar in the blood) :

During your treatment, you may suffer from hypoglycaemia. If this occurs, it may be necessary for you to enter hospital to restore your sugar levels.

Following an episode of hypoglycaemia, your doctor will monitor you closely for at least 24 hours.

In order to avoid episodes of hypoglycaemia, the following information is important :

- you should always eat regular meals, including breakfast, because of the increased risk of hypoglycaemia if a meal is missed or if your diet contains insufficient or unbalanced levels of sugars ;
- age, kidney failure, liver failure and certain adrenal or pituitary disorders may favor the onset of hypoglycaemia ;
- the onset of hypoglycaemia is promoted by a severe or poorly balanced diet, by strenuous or prolonged physical exertion, by the consumption of alcohol or during combination with other hypoglycaemic drugs (cf. Drugs interactions and other interactions).

Sugar imbalance :

In the event of surgery, trauma, fever or infection, your doctor may stop this treatment and prescribe insulin.

Biological tests :

The levels of glucose in your blood and urine should be monitored regularly.

Precautions for use

Your doctor will explain to you and your family how to avoid hypoglycaemia, how to recognize the early symptoms and how to treat them.

Your doctor will also explain about the conditions under which you may become resistant to glibenclamide therapy ; under these circumstances, other medicine may be prescribed to replace it.

IN CASE OF DOUBT, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Drug interactions and other interactions

IN ORDER TO AVOID POSSIBLE INTERACTIONS WITH OTHER MEDICINE, YOU

MUST ALWAYS INFORM YOUR DOCTOR OR PHARMACIST ABOUT ANY OTHER CURRENT TREATMENT, and particularly :

1. Medicine which may cause hypoglycaemia : miconazole, phenylbutazone, betablockers, fluconazole, angiotensin converting enzyme inhibitors, alcohol.
2. Medicine which may cause hyperglycaemia through lowering of the efficacy of the antidiabetic : danazol, chlorpromazine, glucocorticosteroids, progestogens, salbutamol, terbutaline, ritodrine.

Pregnancy - Lactation

In the event of pregnancy, the treatment of diabetes is always based on insulin.

If you discover that you are pregnant while taking this medicine, your treatment should be discontinued.

Tell your doctor so that your hypoglycaemic treatment may be adapted accordingly.

This medicine is contraindicated during lactation.

Drivers and machine operators

The attention of drivers must be stressed on hypoglycaemia symptoms and on their effect on vigilance.

List of Excipients which must be specified for the safe use of this medicine in certain patients

Lactose.

HOW TO USE THIS MEDICINE

Dosage

The usual dosage is 1/2 to 3 tablets a day.

Method and route of administration

Oral use. The tablets should be swallowed with about half a glass of water, immediately before a meal.

Management of overdose

In all cases, contact a doctor immediately. If you experience mild signs of hypoglycaemia: weakness , sweating, appetite urge, tremor, drowsiness, dizziness, headache or visual disturbances, eat or drink something which contains sugar.

Management in the event of omission of one or several doses

Take a tablet during the next meal.

Do not double the dose.

UNWANTED AND UNPLEASANT EFFECTS

LIKE ANY ACTIVE SUBSTANCE, THIS MEDICINE MAY, IN SOME PATIENTS, HAVE MORE OR LESS UNPLEASANT EFFECTS :

- Hypoglycaemia (lowering of the levels of sugar in the blood, cf. Warnings and overdose).
- Skin symptoms : urticaria, itching, skin rashes,
- Gastrointestinal disorders : nausea, diarrhoea, stomach discomfort, jaundice, hepatitis.
- Porphyria : accumulation of pigments (porphyrin) in the body.
- Abnormal biological tests results, concerning the liver, kidneys or blood.

DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE AND TO REPORT ANY UNWANTED AND UNPLEASANT EFFECT NOT MENTIONED IN THIS LEAFLET.

STORAGE

DO NOT EXCEED THE EXPIRY DATE INDICATED ON THE OUTER PACKAGING.

Special precautions for storage

Do not store above + 25°C.

DATE OF LEAFLET REVISION

November 2009

Packed by

Benta S.A.L., Dbayeh - Lebanon



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Sanofi Aventis - France

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament
- The doctor and the pharmacist are experts in medicine, its benefits and risks
- Do not by yourself interrupt the period of treatment prescribed for you
- Do not repeat the same prescription without consulting your doctor
- Medicament: keep out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists