

This medicine can be sold with a physician's prescription only.

## Gluben® - 5 mg Tablets

Each tablet contains: Glibenclamide 5 mg

For list of inactive ingredients - see section 6.

**Read this entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about the medicine. If you have any further questions, refer to the physician or pharmacist.

This medicine has been prescribed for the treatment of your illness; do not pass it on to others. It may harm them, even if you think that their medical condition is similar.

The use of this medicine is not recommended in children under 18 years of age.

**1. What is the medicine intended for?**  
Gluben is an oral antidiabetic medicine.

**Therapeutic group:** sulfonylurea group.

**2. Before using the medicine**

**Do not use the medicine if:**

- You are pregnant or breastfeeding.
- You are hypersensitive to the active ingredient or to any one of the additional ingredients that the medicine contains or to another medicine of the sulfonylurea group (medicines for bacterial infections) or sulfonylurea.
- You suffer from insulin dependent diabetes (type 1 diabetes), from severe or unstable diabetes.
- You suffer from or have suffered in the past from diabetic ketoacidosis (a complication of diabetes with some of the following signs: fatigue, nausea (feeling sick), frequent urination and muscle stiffness), diabetic coma.
- You underwent major surgery, you suffer from an infectious disease, severe liver, severe trauma.
- You suffer from a severe impairment of liver, kidney or adrenal cortex function.
- You take Bosentan (for the treatment of pulmonary hypertension).

**Special warnings regarding the use of this medicine**

**Before treatment with Gluben, tell the physician if you suffer from any of the following conditions. In addition, if any of these conditions develop during treatment with the medicine, consult the physician:**

- You suffer or have suffered in the past from impaired function of: heart and / or vascular system, liver, kidney/urinary tract, thyroid gland.
- You suffer from malfunction of the pituitary, adrenal cortex, you suffer from malnutrition.
- You suffer from a deficiency of the glucose-6-phosphate dehydrogenase (G6PD) enzyme (since lowering of the haemoglobin level and breakdown of red blood cells (haemolytic anemia) can occur) or any other serious illness.

- You smoke.
- You are about to undergo surgery, including dental treatment.
- You are recovering from an injury, operation, infections with fever, or from other forms of stress - it may be necessary to temporarily change the treatment.
- You are allergic to any kind of food or medicine.

**Additional Warnings:**

- This medicine may cause particular sensitivity with exposure to the sun manifested by skin rash or over tanning, therefore avoid sun exposure and ensure appropriate protection (long clothes, hat, sunscreen, etc.).
- The use of this medicine is in addition to a diet determined as appropriate, and not as a substitute.
- The efficacy of hypoglycemic medicines in lowering blood sugar levels may reduce over time, due to disease progression or because of a decreased response to the medicine. This is called secondary failure, to distinguish from primary failure, in which the medicine is ineffective when it is given for the first time.
- The use of the medicine is not recommended for children under 18 years of age.

**When taking the medicine, you may suffer from hypoglycaemia (low blood sugar level). The following factors may increase the risk of hypoglycaemia:**

- Undernourishment, irregular meal time, missed or delayed meal or period of fasting
- Changes to your diet
- Taking the medicine at a higher dosage than necessary.
- Having kidneys that do not work properly
- Having severe liver disease
- If you suffer from particular hormone-induced disorders (disorders of the thyroid glands, of the pituitary gland or adrenal cortex)
- Drinking alcohol (especially when you skip a meal)
- Taking certain other medicines (see section 3 "If you are taking or have recently taken other medicines").
- Using other medicines to lower blood sugar levels.
- If you increase the amount of exercise you do and you don't eat enough food or eat food containing less carbohydrate than usual.
- You are elderly, weak or have adrenal or pituitary insufficiency.

**Signs of hypoglycaemia include:**

- Hunger pangs, headache, nausea, vomiting, sluggishness, sleepiness, problems sleeping, restlessness, aggression, problems with concentration, reduced alertness and reaction time, depression, confusion, problems with your speech and sight, slurred speech, shakiness, partial paralysis, dizziness, helplessness.
- The following signs may also occur: sweating, clammy and cold skin, anxiety, fast or increased

heart beat, high blood pressure, awareness of your heart beat, sudden strong chest pain that may radiate to nearby areas (angina pectoris and cardiac arrhythmias). If blood sugar levels continue to drop, you may suffer from considerable confusion (delirium), develop fits, lose self control, breathing may be shallow and your heart beat slowed down, you may fall into unconsciousness. The clinical picture of a severe reduced blood sugar level may resemble that of a stroke.

It may be difficult to recognize the signs of hypoglycaemia in patients suffering from an autonomic neurological disease, the elderly and people taking medicines from the beta-blockers or sympatholytic medicine groups (see section 3 "If you are taking or have recently taken other medicines").

**Treating hypoglycaemia:**

In most cases the signs of reduced blood sugar vanish very quickly when you consume some form of sugar, e.g. sugar cubes, sweet juice, sweetened tea. You should therefore always take some form of sugar with you (e.g. sugar cubes). Remember that artificial sweeteners are not effective. Please contact your doctor or go to the hospital if taking sugar does not help or if the symptoms recur.

**Tell the physician or pharmacist if you are taking or have recently taken any other medicines, including non-prescription drugs and nutrition supplements.**

Especially if you are taking:  
Bosentan (see section "Do not use this medicine if"), Cyclosporine.

The following medicines can increase the blood sugar reducing effect of Gluben. This may lead to the risk of hypoglycaemia (low blood sugar levels):

- Other medicines used for the treatment of diabetes (e.g. insulin, biguanides)
- Sopyramide (e.g. for the treatment of arrhythmias)
- Medicines from the non-steroidal anti-inflammatory group for the treatment of pain and inflammation (Salicylates, Phenylbutazone, Azopropazone, Oxphenbutazone)
- Medicines for the treatment of urinary tract infections (e.g. Sulphonamides), for the treatment of bacterial and fungal infections (Tetracyclines, Chloramphenicol, Flucanazole, Miconazole, Clarithromycin, Quinolones such as Ciprofloxacin)
- Anticoagulants (coumarin derivatives e.g. warfarin)
- Medicines supporting muscle build up (anabolics)
- Medicines used for male sex hormone replacement therapy
- Medicines for the treatment of depression (Fluoxetine, MAO inhibitors)
- Medicines to reduce cholesterol (fibrates such as Clofibrate, Bezafibrate)

- Medicines to lower blood pressure (Angiotensin Converting Enzyme Inhibitors - ACE)
- Medicines for the treatment of gout (Probenecid and Sulfinpyrazone)
- Medicines for the treatment of cancer (Cyclophosphamide, Ifosfamide, Tiofosfamide)
- Medicines to reduce weight (Fenfluramine)
- Medicines to increase circulation when given in a high dose intravenous infusion (pentoxifylline)
- Medicines to treat nasal allergies such as hay fever (triquinolane)
- Medicines called sympatholytics to treat high blood pressure, heart failure, or prostate symptoms

The following medicines can reduce the blood sugar reducing effect of Gluben. This may lead to the risk of hyperglycaemia (high blood sugar levels):

- Medicines that contain female sex hormones (estrogens, progesterone such as oral contraceptives)
- Thiazide type diuretics (e.g. for the treatment of hypertension), other diuretics
- Thyroid gland hormones
- Calcium channel blockers e.g. for the treatment of hypertension
- Medicines for the treatment of allergy and inflammation (corticosteroids)
- Medicines for the treatment of mental disorders (phenothiazine derivatives)

- Medicines used to raise heart beat, to treat asthma or nasal congestion, cough and cold, reduce weight or used in life-threatening emergencies (adrenaline and sympathomimetic medicines)
- Medicines to reduce cholesterol (Nicotinic acid)
- Medicines to treat constipation when they are used long term (laxatives)

- Medicines for the treatment of epilepsy, seizures (Phenytoin)
- Medicines for the treatment of sleeping problems, anxiolytics (Barbiturates)
- Medicines to treat increased pressure in the eye (Acetazolamide (e.g. for the treatment of glaucoma))
- Medicines to treat high blood pressure or lowering blood sugar (Diazoxide)
- Medicines for the treatment of infections, antibiotics (Rifampicin, Isoniazid)
- Medicines for the treatment of very low blood sugar level (Glucagon)
- Colesevelam

The following medicines can increase or decrease the blood sugar reducing effect of Gluben:

- Medicines for the treatment of stomach ulcers such as Cimetidine or Ranitidine (H<sub>2</sub> receptor antagonists)
- Medicines for the treatment of hypertension or heart failure such as beta blockers, Clonidine, Guanethidine and Reserpine. These medicines may also hide the signs of hypoglycaemia. Therefore, special care is required when taking these medicines

Gluben can increase or weaken the effect of medicines inhibiting blood clotting (coumarin derivatives such as warfarin).

**Use of this medicine and food**

Take the medicine immediately before or with the first meal of the day (usually breakfast). If you do not eat in the morning, take the medicine according to the schedule prescribed by the physician. Be sure not to skip meals while using this medicine.

**Use of this medicine and alcohol consumption**  
**Do not drink wine or alcoholic beverages** during the treatment period of this medicine. Alcohol can increase or decrease the blood sugar reducing effect of Gluben unexpectedly.

**Pregnancy and Breastfeeding**

Do not take Gluben if you are pregnant. Inform the physician if you are pregnant, think you might be pregnant or planning to become pregnant. Do not take Gluben while breastfeeding. Gluben may pass into breast milk.  
Consult a physician or pharmacist before taking medicines.

**Driving and using machines**

Your ability to concentrate or react may be reduced if your blood sugar is lowered (hypoglycaemia), or raised (hyperglycaemia) or if you develop visual problems as a result of such conditions.

Bear in mind that you could endanger yourself or others (e.g. when driving a car or using machines). Please ask your doctor whether you can drive a car if you:

- have frequent episodes of hypoglycaemia,
- have fewer or no warning signals of hypoglycaemia

**Important information about some of the ingredients in this medicine:**  
This medicine contains lactose. If you have been told in the past by a physician that you suffer from an intolerance to certain sugars, refer to the physician before beginning treatment with this medicine.

**3. How to use this medicine**

Always use according to the physician's instructions. Check with the physician or pharmacist if you are not sure.  
The dosage and administration will be determined by the physician only.

**Do not exceed the recommended dose.**  
If you are weak or elderly, the initial dosage will generally be lower. There may be a need for dosage adjustment in case of weight change, change in lifestyle or if you are under intense stress. Consult the physician in such situations.

If you feel the dosage of Gluben is too low or too high, do not change the dosage on your own, rather refer to the physician.

Swallow the tablet with at least half of a glass of water. Take the medicine with food (see section "Use of this medicine and food").  
Do not chew / crush. May be halved.

**Tests and Follow Up**

During treatment with this medicine and especially in the elderly, blood and urine sugar levels, sugar hemoglobin levels (HbA1C), liver and kidney function tests should be performed. The physician may refer you to blood tests to monitor blood cell level.

**If you have accidentally taken a higher dosage** there is a risk of hypoglycaemia (signs of hypoglycaemia are detailed in section 2 under "Special warnings regarding the use of this medicine"). Immediately consume a sufficient amount of sugar (e.g. sugar cubes, juice or sweetened tea) and refer to a physician or emergency room at a hospital immediately!

When treating hypoglycaemia in a child who accidentally swallowed the medicine, the quantity of sugar given must be supervised in order to prevent the risk of hyperglycaemia (high blood sugar levels).

Do not be given food or water to a person in a state of unconsciousness. Severe cases of hypoglycaemia, accompanied by a loss of consciousness and coma, are medical emergencies that require immediate medical care and hospitalization. Inform those around you to refer to a physician in these situations. Since a hypoglycemic state may continue for some time, it is very important to monitor the condition of the patient until the danger has passed.

Hospitalization may be required.  
If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.  
**Do not induce vomiting unless explicitly instructed to do so by the physician!**

Use this medicine at set times as determined by the attending physician. **If you forget to take the medicine** at the required time, take a dose as soon as you remember but never take two doses together! If you unsure or concerned, consult the physician.  
Continue with the treatment as recommended by the physician.

Even if there is an improvement in your health, do not stop taking this medicine without consulting the physician.  
**If you stop taking this medicine,** the desired effect of reducing blood sugar levels will not be achieved or the illness will once again worsen. It is essential to follow the diet and other instructions given to you by the physician.

**Do not take medicines in the dark!** Check the label and the dose each time you take a medicine. Wear glasses if you need them.  
If you have any further questions regarding the use of this medicine, consult the physician or pharmacist.

**4. Side Effects**

Like all medicines, the use of Gluben may cause side effects in some users. Do not be alarmed

while reading the list of side effects, you may not suffer from any of them.

**Stop use of this medicine and refer to the physician immediately if the following side effects appear:**

- abnormal liver function including jaundice (yellowing of the skin and eyes), problems with bile flow (cholestasis), inflammation of the liver (hepatitis) or liver failure.
- allergic reaction which may develop into a severe reaction with breathing difficulties, a drop in blood pressure and sometimes even shock.

**Refer to the physician immediately if the following side effects appear:**

- allergy (hypersensitivity) of the skin such as irritation, itching, rash, redness of the skin, hives, increased sensitivity to sunlight. In addition, muscle pain, joint pain, inflammation of blood vessels. Mild allergic reactions may develop into severe reactions with breathing and swallowing difficulties, swelling of the face, throat, lips, tongue, neck (angioedema). In case of a severe allergic reaction, stop using this medicine and refer to the physician immediately.
- dark colored urine.
- severe hypoglycemia including loss of consciousness, seizures or coma.
- decrease in the number of blood cells; platelets (increases the risk of bleeding and bruising), may appear as a skin rash resulting from bleeding from small blood vessels; white blood cells (increases the risk of infections); red blood cells (causes symptoms such as pallor, weakness, shortness of breath) - rare. These effects usually improve after stopping the use of Gluben.

**Additional side effects**  
**Common side effects- effects that appear in 1-10 users out of 100:**  
Gastrointestinal disturbances such as nausea, vomiting, epigastric feeling of fullness, abdominal pain, heartburn, diarrhea. These effects are usually of dosage dependent nature and may disappear when reducing the dosage.

**Rare side effects- effects that appear in 1-10 users out of 10,000:**  
Lower blood sugar level than usual (hypoglycaemia) (see section 2- "Before using the medicine").

**Very rare side effects- effects that appear in less than one user out of 10,000:**  
■ Allergic reaction, abnormal liver function - see details in section "Refer to the physician immediately".

■ Decreased blood sodium levels (shown by blood tests), Hyponatremia (low blood sodium levels) may occur, manifested by symptoms such as: vomiting, semi-consciousness, convulsions.

■ A Disulfiram-like reaction when consuming alcohol, may be manifested by symptoms such as a pounding headache, flushing, nausea, vomiting, sweating, breathing difficulties, confusion, fast pulse, hypotension, dizziness.

**Side effects with unknown frequency (effects whose frequency has not yet been determined):**

- Vision problems, such as blurred vision, changes in visual focus seemingly due to changes in blood sugar levels.
- Increased liver enzymes
- Purpura (expressed as blisters on the skin), hemolytic anemia (fast destruction of red blood cells), aplastic anemia (significant reduction of all blood cells, may be manifested by pallor, weakness, fatigue, bleeding and infections), pancytopenia (simultaneous reduction in a few types of blood cells).

If a side effects appears, if any of the side effects worsens, or if you experience a side effect not mentioned in this leaflet, consult the physician.

**5. How to store the medicine**

**Avoid poisoning!** This medicine and all other medicines must be stored in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician!

Do not use the medicine after the expiry date (Exp. Date) stated on the package. The expiry date refers to the last day of that month.  
**Storage conditions:** Store at temperature below 25°C. Store in the original package.

In case of doubt, consult the pharmacist who dispensed you the medicine. Do not store different medicines in the same package.

**6. Additional information:**

In addition to the active ingredient, this medicine also contains:

Lactose monohydrate, Microcrystalline cellulose, Sodium starch glycolate, Carmellose sodium, Magnesium stearate, Silica colloidal anhydrous.

Each tablet contains approximately 126 mg of lactose.

**What does the medicine look like and what does the package contain?**

White biconvex tablets with a score line on one side.  
Approved package sizes: 10, 28, 30, 50, 100, 1000 tablets. Not all package sizes may be marketed.

This leaflet was checked and approved by the Ministry of Health in: 04/2015.

**Drug registration number at the national medicines registry of the Ministry of Health:** 040 08 20814 00

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