

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

GLUCO-RITE 5 mg Tablets

Each tablet contains 5 mg glipizide

Inactive ingredients and allergens in the medicine: see section 2 **Important information about some of the ingredients of Gluco-Rite** and section 6 in the leaflet.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist. Keep this leaflet, you may want to read it again. This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Gluco-Rite is used for control of hyperglycemia (high blood sugar levels) and the accompanying symptoms in patients with type 2 diabetes in addition to a change in diet.

Therapeutic group: Medicine to lower blood sugar level from the sulphonylurea group.

2. BEFORE USING THE MEDICINE

Do not use Gluco-Rite if:

- You are hypersensitive (allergic) to the active ingredient glipizide, to another similar antidiabetic drug or to any of the other ingredients this medicine contains (see section 6).
- You have juvenile diabetes (type 1 diabetes which probably began in your childhood and is an insulin-dependent diabetes).
- Ketone bodies or sugar have appeared in your urine (you may suffer from diabetic ketoacidosis).
- You suffer from episodes of unconsciousness (you may suffer from diabetic coma).
- You suffer from problems with the kidneys or liver.
- You are pregnant, planning to become pregnant or breastfeeding.
- You are currently taking miconazole to treat fungal infections.

Special warnings regarding the use of the medicine

Before starting treatment with Gluco-Rite, tell the doctor if:

- You have been told that you have a problem with the adrenal gland or the pituitary gland.
- You are about to undergo major surgery, have had a recent injury (trauma), or if you develop a fever or severe infection (see in section 3 **"If you are about to undergo surgery"** for further information).
- You suffer from G6PD deficiency (a disease that causes abnormal destruction of your red blood cells).

You should check your blood and urine glucose level regularly, particularly if you are elderly, disabled or malnourished. If the test results are outside the limits recommended by your doctor, you should contact him immediately.

Gluco-Rite can cause hypoglycemia (low blood sugar levels), which is characterized by confusion, fainting, sweating, dizziness, drowsiness, headache, tremor and visual disturbances (these symptoms may also be unrelated to hypoglycemia). Low blood sugar levels can be prevented by regular consumption of carbohydrates (for example, bread or other products containing starch/sugar). It is recommended to eat regular meals, and not exercise heavily or for a long period without eating something first.

Children and adolescents

Safety and efficacy of use in children have not been determined.

Drug interactions

If you are taking or have recently taken other medicines including non-prescription medicines, nutritional supplements and herbal preparations, tell the doctor or pharmacist, especially if you are taking:

The following medicines may **reduce** your blood

sugar levels excessively when given together with Gluco-Rite:

- Miconazole, fluconazole or voriconazole (used to treat fungal infections)
- Non-steroidal anti-inflammatory drugs (NSAIDs) (used to treat muscle and joint pain, such as phenylbutazone)
- Aspirin or aspirin-like medicines known as salicylates (usually used as pain killers)
- Beta-blockers (used to treat high blood pressure and certain heart problems, such as propranolol)
- ACE (angiotensin converting enzyme) inhibitors (used to treat high blood pressure, such as captopril)
- Cimetidine (used to treat stomach and duodenal ulcers and other digestive disorders)
- Sulphonamides or chloramphenicol (used to treat bacterial infections)
- Quinolones (used to treat bacterial infections)
- Monoamine oxidase (MAO) inhibitors (used to treat depression)
- Probenecid (used to treat gout)
- Coumarin anticoagulants (used to treat blood clots, such as warfarin)
- Fibrates (used to treat high cholesterol, such as clofibrate)

The following medicines may **increase** your blood sugar levels excessively when given together with Gluco-Rite:

- Danazol (a hormone treatment)
- Phenothiazine tranquilizers (used to treat psychiatric conditions, such as chlorpromazine, thioridazine)
- Corticosteroids (used to treat inflammatory conditions, such as prednisolone)
- Sympathomimetic substances, such as nasal decongestants and bronchodilators used to treat asthma (such as salbutamol, isoprenaline)
- Hormonal agents, including oral contraceptives (the pill) and hormone replacement therapy (HRT)
- Thiazides or other diuretics (such as bendroflumethiazide)
- Thyroid preparations (used to treat patients with low production levels of thyroid hormones)
- Phenytoin (used to treat epilepsy)
- Nicotinic acid (found in vitamin supplements and used to lower cholesterol and other lipid levels)
- Calcium channel blockers (used to treat angina pectoris and high blood pressure, such as nifedipine or verapamil)
- Isoniazid (used to treat tuberculosis)
- Preparations containing colesvelam: take Gluco-Rite at least 4 hours before taking colesvelam preparations in order to ensure that colesvelam does not impair the absorption of Gluco-Rite.

Use of the medicine and food

Food may delay absorption of the medicine, therefore each dose should be taken 30 minutes before eating.

Try to avoid alcohol. Alcoholic beverages (wine, beer, liquors) can further increase the reduction of blood sugar levels and may cause loss of consciousness (hypoglycemic coma).

Pregnancy, breastfeeding and fertility
Do not use Gluco-Rite if you are pregnant, planning to become pregnant or breastfeeding.

Driving and using machines

Gluco-Rite is not supposed to affect your ability to drive or use machinery. However, you should be cautious when you have just started taking this medicine or if you do not use it regularly. Be aware of the symptoms of low blood sugar levels (hypoglycemia). These are characterized by confusion, fainting, sweating, dizziness, drowsiness, headache, tremor and visual disturbances. If you experience any effect, do not drive or operate machinery.

Important information about some of the ingredients of Gluco-Rite

Gluco-Rite contains lactose, a type of sugar. If you have been told that you have an intolerance to certain sugars, refer to your doctor before taking this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. You should check with the doctor or pharmacist if you are not sure about the dosage and treatment regimen with the medicine.

Do not take more Gluco-Rite than your doctor has recommended. The dosage and treatment regimen

will be determined by the doctor. The usual recommended dosage is:

Adults

The initial dose is usually 5 mg, taken approximately 30 minutes before breakfast or lunch, although initial dose may be lower in some patients. If you are elderly, have mild diabetes or suffer from liver or kidney problems, you may be asked to start with a dose of 2.5 mg daily. If your doctor feels your dose needs to be altered, he will instruct you to adjust the dose in small increments, usually in 2.5-5 mg steps.

The maximum recommended daily dose is 20 mg. Do not stop taking the tablets or adjust your dosage without consulting the doctor. Stopping the medicine may make your diabetes worse.

Your dose will be adapted for you individually, in accordance with your medical condition. Some patients, whose condition is usually controlled by nutrition alone, may require Gluco-Rite for a short time only.

Do not exceed the recommended dose.

Method of administration

Gluco-Rite should only be taken by mouth. The tablet can be halved. There is no information regarding crushing/chewing.

If you have accidentally taken a higher dosage of Gluco-Rite than required

- If you have taken an overdose, or if a child or someone else has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.
- If you suffer from a sense of fainting, confusion, drowsiness, headache, dizziness, sweating or tremor and visual disturbances, these may be symptoms of low blood sugar level. You should eat or drink something that contains sugar.
- If you suffer from convulsive seizures or in cases of loss of consciousness, someone should seek urgent medical assistance for you.

If you forgot to take Gluco-Rite

If you forgot to take this medicine at the required time, it is important to take your medicine as soon as you remember or when you feel weakness; otherwise your blood sugar level will become too high and you may go into a coma (or fall unconscious). **Do not take a double dose to make up for a forgotten dose.** Adhere to the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

If you stop taking the medicine

Do not stop taking the tablets or alter your dosage without consulting the doctor. Stopping treatment with the medicine may worsen your diabetes.

If you are about to undergo surgery

If you are about to undergo major surgery or you have recently suffered from a severe illness or infection, it is possible that diabetic control will be lost. At such times it may be necessary to temporarily stop using Gluco-Rite and take insulin.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have any further questions regarding the use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, the use of Gluco-Rite may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them. Most of them are temporary and disappear upon reducing the dose or stopping treatment. Do not stop taking the tablets or adjust your dosage without seeing your doctor.

Refer to your doctor immediately if you experience any of the following symptoms after taking this medicine. Although they are very rare, these symptoms can be serious:

- An allergic reaction such as sudden wheezing, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially when appearing all over the body). Allergic reactions (including death, very rarely) have been reported with medicines similar to Gluco-Rite.

Common side effects (may affect up to 1 in 10 patients):

Hypoglycemia (low blood sugar level)
Nausea
Diarrhoea
Pain in the stomach

Uncommon side effects (may affect up to 1 in 100 users):

Dizziness
Drowsiness
Tremor
Blurred vision
Vomiting
Jaundice (yellowing of the skin and eyes, itching and dark urine)
Eczema (inflammation of the skin)

Side effects of unknown frequency (frequency has not yet been determined):

Agranulocytosis (deficiency of a type of white blood cells)
Leukopenia (reduction in white blood cells count)
Thrombocytopenia (reduction in platelet count)
Hemolytic anaemia (abnormal breakdown of red blood cells)
Pancytopenia (decreased count of all type of blood cells)
Non-acute porphyria
Redness (erythema)
Itching
Rash (red, bumpy, or measles-like)
Itching, skin redness or inflammation (allergic dermatitis)
Pale red, raised, itchy bumps (urticaria)
Sensitivity to light
Reduction in blood sodium (hyponatremia)
Confusion
Headache
Visual disturbances and double vision
Constipation
Inflammation of the liver (hepatitis) and abnormal hepatic function
Malaise (general discomfort)
Abnormal laboratory test results

If a side effect appears, if any of the side effects gets worse, or when you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects from Drug Treatment" found on the Ministry of Health homepage www.health.gov.il, that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

In addition, you can report to Perrigo via the following address: www.perrigo-pharma.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 25°C.
- 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 to protect the environment.

6. FURTHER INFORMATION

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

- Lactose 200, Microcrystalline cellulose, Maize starch, Stearic acid.
Each tablet contains 154 mg lactose
- What the medicine looks like and the contents of the package:**
Gluco-Rite 5 mg tablets are round and white, marked with an A on one side and on the other side a score line, in a package of 30 tablets in blisters.
- Manufacturer, registration holder and address:**
Perrigo Israel Pharmaceuticals Ltd., POB 16, Yeruham.
- Revised in February 2020.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 13227.27134

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