

The medicine is dispensed with
a doctor's prescription only.

Amaryl 1 mg, Amaryl 2 mg, Amaryl 3 mg, Amaryl 4 mg Tablets

SANOFI 

Active ingredient:

Each tablet of Amaryl 1 mg contains Glimepiride 1 mg.
Each tablet of Amaryl 2 mg contains Glimepiride 2 mg.
Each tablet of Amaryl 3 mg contains Glimepiride 3 mg.
Each tablet of Amaryl 4 mg contains Glimepiride 4 mg.
Inactive ingredients - see section 6.

Read this leaflet carefully in its entirety before using the medicine. Save this leaflet, it is possible that you will need to read it again.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

The medicine is not intended for children and adolescents under the age of 18.

If a side effect worsens or if you experience a side effect not mentioned in this leaflet, please refer to a doctor or pharmacist.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for the treatment of type 2 diabetes.

Therapeutic group: The active ingredient belongs to the sulfonylurea group - preparations that increase the amount of insulin released by the pancreas.

2. BEFORE USING THE MEDICINE

Do not use the medicine if

- You are sensitive (allergic) to the active ingredient or any of the additional ingredients contained in the medicine (see section 6).
- You are sensitive to other derivatives of sulfonylurea or sulfonamides. It is possible you will develop an allergy to this medicine too.

Signs of an allergic reaction including skin reactions and severe reactions such as shortness of breath, decreased blood pressure or anaphylactic shock.

- This medicine is not intended for treatment of type 1 diabetes, severe or unstable diabetes, ketosis or acidosis as a complication of diabetes, diabetic coma.

Special warnings regarding use of this medicine

• Amaryl, as with all medicines from the sulfonylurea group, may cause hypoglycemia (low blood sugar levels). This may affect alertness and ability to concentrate and cause risky conditions. Before taking this medicine - talk to the doctor or pharmacist in order to identify this condition and act accordingly.

For your information, signs of hypoglycemia can be concealed or may disappear in patients who are taking medicines from the sympatholytic group, such as beta-blockers, clonidine, guanethidine and reserpine.

• Cases of severe allergic reactions have been reported. The reaction may include the following symptoms: shortness of breath, decreased blood pressure or anaphylactic shock. If you suspect that you are suffering from an allergic reaction, stop treatment with the medicine immediately and refer to a doctor.

• With medicines from the sulfonylurea group, there is a risk of increased incidence of cardiovascular mortality.

Before beginning treatment with Amaryl, tell your doctor if:

- You have a known deficiency of enzyme G6PD. In such a case, use of sulfonylurea-based preparations may cause hemolytic anemia.
- You suffer from weakness and/or malnutrition.
- You suffer from impaired function of the: kidneys, adrenal gland, thyroid, liver.

Tests and follow-up

During the treatment period, the following should be monitored: blood glucose levels, glycosylated hemoglobin (hemoglobin A1c), glucose in urine and tests should be carried out to follow up on blood cell levels and liver functions.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

It is especially important to inform the doctor or pharmacist if you are taking:

a. Medicines that may increase the effect of Amaryl and cause hypoglycemia (decrease in blood sugar levels), such as:

- Medicines to treat diabetes (oral anti-diabetics, pramlintide acetate and insulin).
- Medicines to treat ulcers and gastric acidity (H2 receptor antagonists).
- Medicines to treat pain and inflammation (e.g., propoxyphene, non-steroidal anti-inflammatories, salicylates).
- Medicines to treat fungal and bacterial infections (e.g., miconazole, fluconazole, tetracyclines, quinolones, sulfonamides, chloramphenicol).
- Medicines to treat abnormal blood clotting (e.g., coumarins).
- Muscle-building medicines (anabolic steroids and androgens).
- Hormone replacement therapy for men.
- Anti-depressants (e.g., fluoxetine, medicines from the monoamine oxidase inhibitor group (MAOI)).
- Medicines lowering blood lipid levels (fibrates).
- Medicines for lowering blood pressure (e.g., guanethidine and ACE inhibitors group).
- Medicines to treat abnormal heart beat (e.g., disopyramide).
- Medicines to treat gout (e.g., sulinpyrazone, probenecid).
- Medicines to treat cancer (e.g., cyclophosphamide).
- Medicines used to improve blood flow (pentoxifylline).
- Muscle relaxants (e.g., phenylamidol).

b. Medicines that may reduce the effect of Amaryl and cause an increase in blood glucose levels:

- Medicines that contain female sex hormones (to treat endometriosis - danazol, oral contraceptives, hormone replacement treatment for women).
- Medicines to treat hypertension from the thiazide group and other diuretics.
- Medicines to treat reduced thyroid function (levothyroxine).
- Medicines to treat inflammations and allergies (corticosteroids).
- Medicines to treat mental illness (atypical antipsychotics, phenothiazines).
- Medicines that increase heart rate, asthma treatment, nasal congestion, cough and cold preparations, medicines for treating emergency medical conditions (sympathomimetics).
- Medicines to treat high cholesterol levels (nicotinic acid).
- Medicines to treat constipation (laxatives).
- Medicines to treat epilepsy (phenytoin).
- Medicines to treat epilepsy, nervousness and sleeping problems (barbiturates).
- Medicines to treat high blood pressure or low blood sugar levels (diazoxide).
- Medicines to treat different infections such as tuberculosis (isoniazid and rifampin), and HIV (from the protease inhibitor group).
- Medicines given for treatment of especially low serum glucose levels (glucagon).
- Growth hormones (e.g., somatropin).
- Medicine used to reduce cholesterol associated with bile acids in the intestine (colesevelam). To prevent this interaction, take Amaryl at least 4 hours before taking colesevelam (see section 3).

c. Medicines that may increase or reduce the effect of Amaryl:

- Sympatholytic medicines to treat blood pressure or heart failure (e.g., beta-blockers, clonidine and reserpine). Sympatholytic medicines may mask signs of hypoglycemia. Therefore, have regular check-ups at the doctor if you are taking these medicines.



Use of the medicine and food

Take Amaryl with breakfast or with your first main meal of the day.

Use of the medicine and alcohol consumption

Do not drink wines or alcoholic beverages during treatment with the medicine. Alcohol may increase or weaken the effect of the medicine on reducing blood glucose levels.

Pregnancy, breastfeeding and fertility

If you are pregnant, planning to become pregnant, breastfeeding or planning to breastfeed, consult with the doctor before using medicines.

If you are breastfeeding, monitor the baby for signs of hypoglycemia (e.g., jitters, cyanosis, apnea, hypothermia, excessive sleeping, unwillingness to feed, seizures).

Driving and operating machinery

Do not drive or operate dangerous machinery while taking the medicine because use of this medicine may impair alertness.

Important information about some of the ingredients in the medicine.

The product contains lactose – if you have been told by the doctor that you suffer from sensitivity to some sugars – consult the doctor before taking this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions.

Check with the doctor or pharmacist if you are not sure. The dosage and treatment regimen will be determined by the doctor only.

The usual starting dose is 1 mg or 2 mg once a day.

For elderly patients and patients with kidney failure, the recommended starting dosage is 1 mg per day.

Increasing the dosage of the medicine will only be done following instructions from the attending doctor. The maximum dose is 8 mg per day.

If you are taking colesevelam (for reducing cholesterol by binding the bile acids in the intestine), take Amaryl at least 4 hours before taking colesevelam.

Do not exceed the recommended dosage.

Do not chew the tablet. Swallow the medicine with water.

To ease swallowing, the tablet can be divided into two equal halves along the score line. Take the two halves together, soon after halving the tablet.

Take the tablet with breakfast or the first main meal of the day.

If you accidentally took a higher dosage, you may suffer from hypoglycemia.

Signs of hypoglycemia include: cold sweat, pale skin, persistent headache, increased appetite, tremor. Severe hypoglycemia may cause coma, seizures and neurological disturbances.

If you took an overdose, or if a child 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 forgot to take the medicine

If you forgot to take the medicine at the required time, do not take a double dose. Take the next dose at the scheduled time and consult the doctor.

Be sure to 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 or pharmacist.

If you stop taking the medicine

It is possible that the serum glucose levels are unbalanced and your illness may worsen. Continue taking the medicine until your doctor instructs you to stop treatment.

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

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

4. SIDE EFFECTS

As with any medicine, use of Amaryl may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Stop treatment and refer immediately to a doctor or proceed to a hospital emergency room if you suffer from the following effects:

- Hypoglycemia
- Worsening of allergic skin reactions and worsening of allergic reaction that can be manifested by shortness of breath, a drop in blood pressure or anaphylactic shock.
- Hemolytic anemia in patients with or without a G6PD enzyme deficiency.

Refer to the doctor as soon as possible if you suffer from the following effects:

- Impaired liver function (accompanied by an increase in bile acids and jaundice) and hepatitis that may turn into liver failure.
- Photosensitivity reactions, allergic vasculitis, itching or skin rash.
- Decreased white blood cells, thrombocytopenia: (including severe cases with platelet count less than 10,000/ μ l and thrombocytopenic purpura).
- Low serum sodium levels (hyponatremia).

Additional side effects: dizziness, fatigue or weakness, headache, nausea, weight gain, change in the sense of taste, hair loss.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of 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>

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach 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) appearing on the package. The expiry date refers to the last day of that month.

Storage conditions: Store in the original package in order to protect from moisture, below 30°C.

6. FURTHER INFORMATION

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

Lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, polyvidone 25000, magnesium stearate.

Amaryl 1 mg also contains: red ferric oxide (E172).

Each tablet contains 68.975 mg of lactose.

Amaryl 2 mg also contains: indigo carmine aluminium lake (E132), yellow ferric oxide (E172).

Each tablet contains 137.200 mg of lactose.

Amaryl 3 mg also contains: yellow ferric oxide (E172).

Each tablet contains 136.950 mg of lactose.

Amaryl 4 mg also contains: indigo carmine aluminium lake (E132). Each tablet contains 135.850 mg of lactose.

What does the medicine look like and what are the contents of the package: Amaryl tablets are marketed in packages of 30 tablets.

Amaryl 1 mg: Tablets are pink.

Amaryl 2 mg: Tablets are green.

Amaryl 3 mg: Tablets are light yellow.

Amaryl 4 mg: Tablets are light blue.

License Holder and Importer and its address: sanofi-aventis Israel Ltd., 10 Beni Gaon St., P.O. Box 8090, Netanya 4250499.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, please ask your doctor.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Amaryl 1 mg: 118822993400

Amaryl 2 mg: 118832993200

Amaryl 3 mg: 118842993300

Amaryl 4 mg: 141683191700

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