

Glargen® 100 IU/ml

Insulin glargine

Solution for injection in a vial

Read all of this leaflet carefully before you take this medicine.

- Keep this leaflet, you may need to read it again.
- If you have any further questions, if you are in doubt, ask your doctor or pharmacist for more information.
- This medicine has been prescribed for you only. Don't pass it on to others, even if the symptoms are the same, it may harm them.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

1. What is Glargen solution for injection and in which case is it used?
2. What you need to know before you take Glargen solution for injection?
3. How to take Glargen, solution for injection?
4. Possible side effects?
5. How to store Glargen, solution for injection?
6. Additional information.

1. WHAT IS GLARGEN, SOLUTION FOR INJECTION AND IN WHICH CASE IS IT USED?

Glargen is a solution for injection containing insulin glargine. Insulin glargine is a modified insulin, comparable to human insulin. Glargen is used to treat diabetes mellitus in adults, adolescents, and children from 2 years of age.

In this disease, the body does not make enough insulin to control the level of sugar in the blood (blood sugar). Insulin glargine lowers blood sugar levels for a long time and regularly.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE GLARGEN, SOLUTION FOR INJECTION?

Never take Glargen

If you are allergic to insulin glargine or any of the other components of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist, or nurse before using Glargen. Carefully follow your doctor's instructions regarding dosage, monitoring (blood and urine tests), diet and physical activity (work and exercise).

If your blood sugar is too low (hypoglycemia), follow your doctor's advice in case of hypoglycemia.

*Travel

Before leaving on a trip, consult your doctor to inform you of the following:

- availability of your insulin in the country you are going to,
- supply of insulin, syringes, etc.,
- keeping your insulin properly while traveling,
- schedule of meals and insulin injections during the trip,
- possible effects of time zone change,
- possible new risks to your health in the visited countries,
- what to do in emergency situations when you are feeling unwell or sick.

*Illnesses and injuries

In the following situations, the management of your diabetes may require a great deal of care (for example, adjusting the dose of insulin, blood, and urine tests):

- if you are ill or have a serious injury, your blood sugar levels may rise (hyperglycemia) or drop (hypoglycemia).
- if you do not eat enough food, your blood sugar levels may drop (hypoglycemia).

In most cases you will need a doctor. Be sure to contact a doctor promptly.

If you have type 1 diabetes (insulin-dependent diabetes), do not stop your insulin, and continue to take enough carbohydrates. Always tell the people who take care of or treat you that you need insulin.

Some patients with long-standing type 2 diabetes and heart disease or who have had a previous stroke, treated with pioglitazone and insulin, have developed heart failure. If you have any signs of heart failure such as unusual shortness of breath or rapid weight gain or localized swelling (edema), tell your doctor as soon as possible.

Other medicines and Glargen

Some medicines cause changes in blood sugar levels (decrease, increase in blood sugar levels, or both depending on the situation). In each case, it may be necessary to adjust your insulin dose to prevent blood sugar levels that are too low or too high. Be careful when starting or stopping other treatment.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Ask your doctor before taking any medicine to find out what effect it may have on your blood sugar and, if so, what action to take.

Medicines that can cause your blood sugar levels to drop (hypoglycemia) include:

- all other medicines used to treat diabetes,
- converting enzyme inhibitors (ACEIs) (used to treat certain heart conditions or high blood pressure),
- disopyramide (used to treat certain heart conditions),
- fluoxetine (used to treat depression),
- fibrates (used to lower high levels of lipids in the blood),
- monoamine oxidase inhibitors (MAOIs) (used to treat depression),
- pentoxifylline, propoxyphene, salicylates (such as aspirin, used to relieve pain and lower fever),
- sulfonamide antibiotics.

Medicines that can cause your blood sugar levels to rise (hyperglycemia) include:

- corticosteroids (such as 'cortisone', used to treat inflammation),
- danazol (medicine that acts on ovulation),
- diazoxide (used to treat high blood pressure),
- diuretics (used to treat high blood pressure or excessive fluid retention),
- glucagon (pancreatic hormone used to treat severe hypoglycemia),
- isoniazid (used to treat tuberculosis),
- estrogens and progestones (such as birth control pills),
- phenothiazine derivatives (used to treat psychiatric illnesses),
- somatropin (growth hormone),
- sympathomimetic medicines (such as epinephrine [adrenaline], salbutamol, terbutaline, used to treat asthma),
- thyroid hormones (used to treat dysfunction of the thyroid gland),
- atypical antipsychotic medications (such as olanzapine and clozapine),
- protease inhibitors (used to treat HIV).

Your blood sugar may increase or decrease if you take:

- beta-blockers (used to treat high blood pressure),
- clonidine (used to treat high blood pressure),
- lithium salts (used to treat psychiatric illnesses),
- pentamidine (used to treat certain infections caused by parasites) can cause low blood sugar sometimes followed by high blood sugar.

Beta-blockers like other sympatholytic medicines (such as clonidine, guanethidine, and reserpine), can alleviate or completely eliminate the warning symptoms that help you recognize hypoglycemia.

If in doubt about the identity of the medications you are using, consult your doctor or pharmacist.

Glargen with alcohol

Your blood sugar may increase or decrease if you drink alcohol.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning pregnancy, ask your doctor or pharmacist for advice before taking this medicine.

Inform your doctor if you want to become pregnant or if you are already pregnant. It may be necessary to change your insulin doses during pregnancy and after childbirth. Particular careful control of your diabetes and prevention of hypoglycemia are essential for the good health of your baby.

If you are breastfeeding, consult your doctor as adjustments to your insulin doses and diet may be necessary.

Driving and using machines

Your ability to concentrate or react may be impaired if:

- you have hypoglycemia (low blood sugar),
- you have hyperglycemia (high level of sugar in the blood),
- you have vision problems.

You should think about this in any situation where you could put your life or the lives of others in danger (such as driving a car or using machines). You should ask your doctor for advice on your ability to drive if:

- you have frequent episodes of hypoglycemia,
- the warning symptoms that help you recognize low blood sugar are reduced or absent.

3. HOW TO TAKE GLARGEN, SOLUTION FOR INJECTION?

Dosage

Always use this medicine exactly as your doctor has told you.

Check with your doctor or pharmacist if in doubt.

Depending on your lifestyle, your glycaemic (glucose) test results and your previous insulin use, your doctor:

- determines the daily dose of Glargen needed and when to inject,
- tells you when to check your blood sugar and if you need urine tests,
- tells you under what circumstances you should increase or decrease the dose of Glargen.

Glargen is a long-acting insulin. If necessary, your doctor will prescribe you to combine it with a rapid-acting insulin or hypoglycemic tablets.

Many factors can affect your blood sugar. You must know them. This will allow you to react correctly to changes in your blood sugar and prevent it from getting too high or too low.

Use in children and adolescents

Glargen can be used in adolescents and children from 2 years old.

The use of Glargen in children under 2 years of age has not been evaluated.

Frequency of administration

A daily injection of Glargen, at the same time of the day, is necessary. In children, only administration in the evening has been studied.

Method of administration

Glargen should be injected under the skin. NEVER inject Glargen into a vein as this will change its effect and may cause hypoglycemia.

Your doctor will show you which area of the skin to inject Glargen. Each time you inject insulin, you must change the injection site in each skin area.

How to handle vials

Inspect the vial before using it. Use only if the solution is clear, colorless, has the fluidity of water and does not contain visible particles.

Do not shake or mix it before use. Make sure that the insulin is not contaminated by alcohol, other disinfectants, or any other substance.

Do not mix Glargen with any other insulin or any other medicine. Do not dilute the product. Mixing or diluting it could indeed modify the effect of Glargen.

Always use a new vial if you notice that your blood sugar control is suddenly getting worse. This may be due to a partial loss of effectiveness of this insulin. If you think you have a problem with Glargen, talk to your doctor or pharmacist.

If you have taken more Glargen than you should

If you have injected too much Glargen your blood sugar level may become too low (hypoglycemia). Check it frequently. Usually, to prevent hypoglycemia, you need to eat more and monitor your blood sugar.

If you forget to take Glargen

If you forget a dose of Glargen or if you have not injected enough insulin, your blood sugar level may become too high (hyperglycemia). Check it frequently.

Do not take a double dose to make up for the dose you forgot to take.

If you stop taking Glargen

This can lead to severe hyperglycemia (very high blood sugar) and ketoacidosis (acid build-up in the blood when the body breaks down fat instead of sugar).

Do not stop Glargen without talking to your doctor, who will tell you what to do.

Insulin errors

You should always check the insulin label before each injection to avoid errors between Glargen and other insulins.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse for more information.

4. POSSIBLE SIDE EFFECTS?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Hypoglycemia (low blood sugar) can be very serious. If your blood sugar drops too much, you may pass out (become unconscious). Severe hypoglycemia can cause brain damage and can be life-threatening. If you have symptoms of low blood sugar, take the necessary steps to immediately raise your blood sugar.

If you have the following symptoms, contact your doctor

immediately:

Widespread skin reactions (rash and itching all over the body), severe swelling of the skin or mucous membranes (angioedema), shortness of breath, low blood pressure with rapid heartbeat and profuse sweating could represent symptoms of **severe allergic reactions to insulins which could be life-threatening.**

Very common side effects (may affect more than 1 in 10 people)

- **Hypoglycemia**

As with all insulin therapy, the most common side effect is hypoglycemia.

Hypoglycemia (low blood sugar) means that you are not having enough sugar in the blood. For more information on the side effects of hypoglycemia or hyperglycemia, see the box at the end of this leaflet.

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

- **Changes in the skin at the injection site**

If you inject your insulin too often in the same area of the skin, the fatty tissue under the skin at that area may become either thinner (lipoatrophy) or thicker (lipodystrophy).

Thickening of fatty tissue occurs in 1-2% of patients, while thinning is rare. Insulin injected in such a location may not work properly. To prevent such skin changes, you must change the injection site each time.

- **Skin and allergic reactions**

In 3 to 4% of patients, injection site reactions (eg redness, unusually severe pain during injection, itching, hives, swelling or inflammation occur).

These reactions can also spread around the injection site. Most minor reactions to insulins usually disappear within a few days to a few weeks.

- **Rare side effects (may affect up to 1 in 1,000 people)**
- **Severe allergic reactions to insulins**

Associated symptoms may include widespread skin reactions (rash and itching all over the body), severe swelling of the skin or mucous membranes (angioedema), shortness of breath, low blood pressure with rapid heartbeat and profuse sweating. These symptoms could be those of **severe allergic reactions to insulins which could be life-threatening.**

- **Ocular reactions**

A significant change (improvement or worsening) in blood sugar control may temporarily affect your vision. If you have proliferative retinopathy (an eye disease associated with diabetes), episodes of severe hypoglycemia may cause temporary loss of vision.

- **General disorders**

In rare cases, treatment with insulin can cause temporary water retention in the body, with swelling of the calves and ankles.

Very rare side effects (may affect up to 1 in 10,000 people)

In very rare cases, dysgeusia (taste disturbance) and myalgia (muscle pain) may occur.

Other side effects of not known (frequency cannot be estimated from the available data)

Treatment with insulin can cause the body to form antibodies to insulin (substances that work against insulin). In rare cases, your insulin dose may need to be changed.

Use in children and adolescents

In general, the side effects reported in children and adolescents of 18 years and younger are the same as those seen in adults.

Complaints of injection site reactions (injection site pain, injection site reaction) and skin reactions (rash, itching) are reported relatively more frequently in children and adolescents of 18 years of age or younger than in adults.

In children under 2 years of age, there are no safety data from clinical studies.

If you get any side effects talk to your doctor, pharmacist, or nurse.

This also applies to any side effects that are not mentioned in this leaflet.

5. HOW TO STORE GLARGEN SOLUTION FOR INJECTION?

Keep this medicine out of the sight and reach of children.

Unopened vials:

Store in the refrigerator (between 2 ° C and 8 ° C)

Do not freeze

Keep the vial in the outer carton away from light.

Opened vials:

After first use, the bottle can be stored for up to 4 weeks at a temperature not exceeding 25 ° C.

6. ADDITIONAL INFORMATION

What Glargen contains

	Glargen
Active ingredient	
Insulin glargine.....	100 IU/ml
Excipients	
metacresol, Glycerol, Zinc chloride, Sodium hydroxide, hydrochloric acid, Water for injections	

What does Glargen, solution for injection in a vial look like and content of the outer packaging?

Glargen is in the form of a solution for injection in vials:

- box of 1 vial of a solution for injection of 10 ml
- box of 1 vial of a solution for injection of 3 ml.

Marketing authorisation holder and manufacturer

Les Laboratoires MEDIS - S.A.
 Road of Tunis - KM 7 - BP 206 8000 Nabeul - Tunisia
 Tel: (216) 31 338 420 ; Fax: (216) 31 338 421
 M.A.N.®

GLARGEN 100 IU/mL; Solution for injection, box of 1 vial of 3 mL; 9234041
 GLARGEN 100 IU/mL; Solution for injection, box of 1 vial of 10 mL; 9234042

Table C

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HYPERGLYCAEMIA AND HYPOGLYCAEMIA

Always carry some sugar (at least 20 grams) with you.

Carry some information with you to show you are diabetic.

HYPERGLYCAEMIA (high blood sugar levels)

If your blood sugar is too high (hyperglycemia), you may not have injected enough insulin. Why does hyperglycemia occur?

Examples include:

- you have not injected your insulin or not injected enough, or if it has become less effective, for example through incorrect storage,
- you are doing less exercise than usual, you are under stress (emotional distress, excitement), or you have an injury, operation, infection or fever,
- you are taking or have taken certain other medicines.

Warning symptoms of hyperglycemia

Thirst, increased need to urinate, tiredness, dry skin, reddening of the face, loss of appetite, low blood pressure, fast heart beat, and glucose and ketone bodies in urine. Stomach pain, fast and deep breathing, sleepiness or even loss of consciousness may be signs of a serious condition (ketoacidosis) resulting from lack of insulin.

What should you do if you experience hyperglycemia?

Test your blood sugar level and your urine for ketones as soon as any of the above symptoms occur. Severe hyperglycemia or ketoacidosis must always be treated by a doctor, normally in a hospital.

HYPOGLYCAEMIA (low blood sugar levels)

If your blood sugar level falls too much you may become unconscious. Serious hypoglycemia may cause a heart attack or brain damage and may be life-threatening. You normally should be able to recognise when your blood sugar is falling too much so that you can take the right actions.

Why does hypoglycemia occur ?

Examples include:

- you inject too much insulin,
- you miss meals or delay them,
- you do not eat enough, or eat food containing less carbohydrate than normal (sugar and substances similar to sugar are called carbohydrates; however, artificial sweeteners are NOT carbohydrates),
- you lose carbohydrates due to vomiting or diarrhoea,
- you drink alcohol, particularly if you are not eating much,
- you are doing more exercise than usual or a different type of physical activity,
- you are recovering from an injury or operation or other stress,
- you are recovering from an illness or from fever,
- you are taking or have stopped taking certain other medicines.

Hypoglycemia is also more likely to occur if

- you have just begun insulin treatment or changed to another insulin preparation, (when changing from your previous basal insulin to Glargen for hyperglycemia, if it occurs, may be more likely to occur in the morning than at night)
- your blood sugar levels are almost normal or are unstable,
- you change the area of skin where you inject insulin (for example from the thigh to the upper arm),
- you suffer from severe kidney or liver disease, or some other disease such as hypothyroidism.

Warning symptoms of hypoglycemia

-In your body

Examples of symptoms that tell you that your blood sugar level is falling too much or too fast: sweating, clammy skin, anxiety, fast heart beat, high blood pressure, palpitations and irregular heartbeat. These symptoms often develop before the symptoms of a low sugar level in the brain.

-In your brain

Examples of symptoms that indicate a low sugar level in the brain: headaches, intense hunger, nausea, vomiting, tiredness, sleepiness, sleep disturbances, restlessness, aggressive behaviour, lapses in concentration, impaired reactions, depression, confusion, speech disturbances (sometimes total loss of speech), visual disorders, trembling, paralysis, tingling sensations (paraesthesia), numbness and tingling sensations in the area of the mouth, dizziness, loss of self-control, inability to look after yourself, convulsions, loss of consciousness.

The first symptoms which alert you to hypoglycemia ("warning symptoms") may change, be weaker or may be missing altogether if

- you are elderly, if you have had diabetes for a long time or if you suffer from a certain type of nervous disease (diabetic autonomic neuropathy),
- you have recently suffered hypoglycemia (for example the day before) or if it develops slowly,
- you have almost normal or, at least, greatly improved blood sugar levels,
- you have recently changed from an animal insulin to a human insulin such as Glargen,
- you are taking or have taken certain other medicines.

In such a case, you may develop severe hypoglycemia (and even faint) before you are aware of the problem. Be familiar with your warning symptoms. If necessary, more frequent blood sugar testing can help to identify mild hypoglycaemic episodes that may otherwise be overlooked. If you are not confident about recognising your warning symptoms, avoid situations (such as driving a car) in which you or others would be put at risk by hypoglycemia.

What should you do if you experience hypoglycemia?

1. Do not inject insulin. Immediately take about 10 to 20 g sugar, such as glucose, sugar cubes or a sugar-sweetened beverage. Caution: Artificial sweeteners and foods with artificial sweeteners (such as diet drinks) are of no help in treating hypoglycemia.
2. Then eat something that has a long-acting effect in raising your blood sugar (such as bread or pasta). Your doctor or nurse should have discussed this with you previously.
3. If the hypoglycemia may be delayed because Glargen has a long action.
3. If the hypoglycemia comes back again take another 10 to 20 g sugar.

4. Speak to a doctor immediately if you are not able to control the hypoglycemia or if it recurs.

Tell your relatives, friends and close colleagues the following:

If you are not able to swallow or if you are unconscious, you will require an injection of glucose or glucagon (a medicine which increases blood sugar). These injections are justified even if it is not certain that you have hypoglycemia.

This is a medicine

- A medicine is a product but not like any other product.
 - A medicine is a product that affects your health if it's not used properly: it can be health threatening.
 - Strictly adhere to the prescription of your Doctor and the use instructions prescribed, follow your pharmacist advice.
 - Your doctor and you pharmacist know the medicine, its use and side effect.
 - Don't stop the use of the treatment on your own during the prescribed time.
 - Don't retake. Don't increase the doses without doctor's advice.

Keep the medicines out of reach of children

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