

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE  
PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

# **BASAGLAR**

## **solution for injection in a pre-filled pen**

### **Active ingredient and its quantity:**

Each pre-filled pen contains a 3 mL cartridge.

Each 1 mL contains: 100 units (3.64 mg) of insulin glargine.

**Inactive ingredients and allergens:** see "Important information about some of the ingredients of this medicine" in section 2 and section 6 "Additional information".

**Read this leaflet carefully in its entirety before using the medicine.** Keep this leaflet. You may need to read it again. This leaflet contains concise information about the medicine. If you have any further questions, contact your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

### **For adults:**

Note that the Ministry of Health has approved a one-time switch between an original medicine and a biosimilar medicine and vice versa. Your doctor will give you an explanation about the medicine and the meaning of this switch. Every switch of a biological medicine must be performed by the attending doctor. The brand name of the medicine that appears on the prescription must be identical to the brand name that appears on the package of the medicine dispensed to you by the pharmacy. In any case of doubt, refer to the pharmacist or attending doctor.

### **For children:**

Note that each time you receive the medicine at the pharmacy, it is important that you make sure that you receive the same medicine that was prescribed for you by your attending specialist. If the medicine you received looks different from that which you usually receive, or if the instructions for use have changed, please refer to the pharmacist immediately to make sure that you have received the correct medicine. Any switch or change in dosage of a medicine containing insulin glargine must be made by the attending specialist only. Please check that the brand name of the preparation prescribed for you by the specialist is identical to the name of the medicine you received from the pharmacist.

## **1. WHAT IS THE MEDICINE INTENDED FOR?**

**Basaglar** is a preparation for the treatment of adults, adolescents and children 6 years and over with type 1 diabetes or for the treatment of adults with type 2 diabetes who need a basal (long-acting) insulin to control hyperglycemia.

Diabetes mellitus is a disease in which your body does not produce enough insulin to control the level of blood sugar. Insulin glargine is an insulin that has undergone modification and is very similar to human insulin.

Insulin glargine has a long and steady blood-sugar-lowering action.

**Therapeutic group:** medicines to treat diabetes, injectable long-acting insulins and analogues.

## **2. BEFORE USING THE MEDICINE**

### **Do not use the medicine if:**

you are sensitive (allergic) to insulin glargine or to any of the other ingredients contained in this medicine (see section 6).

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

Talk to your doctor, pharmacist or nurse before you start using Basaglar.

Follow closely the instructions for posology, monitoring (blood and urine tests), diet and physical activity (physical work and exercise) as discussed with your doctor.

### **Tests and follow-up**

During the course of treatment with this medicine, perform blood and urine tests.

If your blood sugar is too low (hypoglycemia), follow the guidance for hypoglycemia (see box at the end of this leaflet).

### **Skin changes at the injection site.**

The injection site should be rotated to prevent skin changes such as lumps under the skin. The insulin may not work very well if you inject into a lumpy area (see section 3 “How should you use the medicine?”). Contact your doctor if you are currently injecting into a lumpy area before you start injecting into a different area. Your doctor may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medications dose.

### **Travel**

Before traveling, consult your doctor. You may need to talk about:

- the availability of your insulin in the country you are visiting,
- supplies of insulin, syringes etc.,
- correct storage of your insulin while traveling,
- timing of meals and insulin administration while traveling,
- the possible effects of changing to different time zones,
- possible new health risks in the countries to be visited,
- what you should do in emergency situations when you feel unwell or become ill.

### **Illnesses and injuries**

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

- If you are ill or have a major injury – your blood sugar level may increase (hyperglycemia).
- If you are not eating enough - your blood sugar level may become too low (hypoglycemia).

In most cases you will need a doctor. **Contact a doctor as soon as possible.**

If you have type 1 diabetes (insulin dependent diabetes mellitus), do not stop your insulin and continue to consume enough carbohydrates. Always tell people who are caring for you or treating you that you require insulin.

Insulin treatment can cause the body to produce antibodies to insulin (substances that act against insulin). However, only very rarely, this will require a change to your insulin dose.

Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who were treated with pioglitazone (an oral anti-diabetic medicine used to treat type 2 diabetes mellitus) and insulin experienced the development of heart failure. Inform your doctor as soon as possible if you experience signs of heart failure such as unusual shortness of breath or rapid increase in weight or localized swelling (edema).

### **Drug interactions**

Some medicines can cause changes in the blood sugar level (decrease, increase or both depending on the situation). In each case, it may be necessary to adjust your insulin dose to avoid blood sugar levels that are either too low or too high. Be careful when you start or stop taking another medicine.

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

Before taking a medicine ask your doctor if it can affect your blood sugar level and what action, if any, you need to take.

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

**Medicines that may cause your blood sugar level to fall (hypoglycemia) include:**

- other medicines to treat diabetes,
- angiotensin converting enzyme (ACE) inhibitors (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 blood lipids),
- monoamine oxidase (MAO) inhibitors (used to treat depression),
- pentoxifylline, propoxyphene, salicylates (such as aspirin, used to relieve pain and lower fever),
- sulfonamide antibiotics.

**Medicines that may cause your blood sugar level to rise (hyperglycemia) include:**

- corticosteroids (such as “cortisone” used to treat inflammation),
- danazol (a medicine acting on ovulation),
- diazoxide (used to treat high blood pressure),
- diuretics (used to treat high blood pressure or excessive fluid retention),
- glucagon (pancreas hormone, used to treat severe hypoglycemia),
- isoniazid (used to treat tuberculosis),
- estrogens and progestogens (such as in the contraceptive pill),
- phenothiazine derivatives (used to treat psychiatric disorders),
- somatropin (growth hormone),
- sympathomimetic medicines (such as epinephrine [adrenaline], salbutamol, terbutaline, used to treat asthma),
- thyroid hormones (used to treat thyroid gland disorders),
- atypical antipsychotic medicines (such as olanzapine and clozapine),
- protease inhibitors (used to treat HIV).

**Your blood sugar level may either rise or fall if you take:**

- beta-blockers (used to treat high blood pressure),
- clonidine (used to treat high blood pressure),
- lithium salts (used to treat psychiatric disorders).

Pentamidine (used to treat some infections caused by parasites) may cause hypoglycemia which may sometimes be followed by hyperglycemia.

Beta-blockers, like other sympatholytic medicines (such as clonidine, guanethidine, and reserpine - to treat high blood pressure) may weaken or suppress entirely the first warning symptoms which help you to recognize a hypoglycemia.

If you are not sure whether you are taking one of those medicines, ask your doctor or pharmacist.

**Pregnancy, breastfeeding and fertility**

Do not use this medicine without consulting a doctor if you are pregnant, think you may be pregnant, are planning to become pregnant or are breastfeeding.

Your insulin dose may need to be changed during pregnancy and after giving birth. Strict control of your diabetes, and prevention of hypoglycemia, is important for the health of your baby.

If you are breastfeeding consult your doctor as you may require adjustments in your insulin doses and your diet.

**Using the medicine and alcohol consumption**

Your blood sugar levels may either rise or fall if you drink alcohol.

**Driving and using machines**

Your ability to concentrate or react may be impaired if:

- you have hypoglycemia (low blood sugar levels),
- you have hyperglycemia (high blood sugar levels),
- you have problems with your sight.

Keep this in mind in all situations where you might put yourself and others at risk (such as driving a car or using machines). You should contact your doctor for advice on driving if:

- you have frequent episodes of hypoglycemia,
- the first warning symptoms which help you to recognize hypoglycemia are reduced or absent.

**Important information about some of the ingredients of this medicine**

This medicine contains less than 1 mmol (23 mg) sodium per dose, i.e. it is essentially ‘sodium-free’.

### **3. HOW SHOULD YOU USE THE MEDICINE?**

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about the dosage and manner of treatment with this medicine. The dosage and manner of treatment will be determined only by your doctor.

Although **Basaglar** contains the same active substance as Toujeo (insulin glargine 300 units/mL), these medicines are not interchangeable. The switch from one insulin therapy to another requires medical prescription, medical supervision and blood glucose monitoring. Please consult your doctor for further information.

#### **Dose**

Based on your lifestyle and the results of your blood sugar (glucose) tests and your previous insulin usage, your doctor will:

- determine how much **Basaglar** per day you will need and at what time,
- tell you when to check your blood sugar level, and whether you need to carry out urine tests,
- tell you when you may need to inject a higher or lower dose of **Basaglar**.

**Basaglar** is a long-acting insulin. Your doctor may tell you to use it in combination with a short-acting insulin or with tablets used to treat high blood sugar levels.

Many factors may influence your blood sugar level. You should know these factors so that you are able to react correctly to changes in your blood sugar level and to prevent it from becoming too high or too low. See the instructions in the box at the end of this leaflet for further information.

#### **Use in children and adolescents**

This medicine is not intended for children below 6 years of age. The efficacy and safety of the preparation in children above the age of 6 have only been evaluated following its injection in the evening.

#### **Frequency of administration**

You need one injection of **Basaglar** every day, at the same time of the day.

#### **Do not exceed the recommended dose.**

#### **Method of administration**

**Basaglar** is injected under the skin. **Do NOT inject Basaglar** into a vein, since this will change its action and may cause hypoglycemia.

Your doctor will show you in which area of the skin you should inject **Basaglar**. With each injection, change the puncture site within the particular area of skin that you are using in order to help prevent skin changes at the injection area (see section 2, 'Before using the medicine' and section 4, 'Side effects').

#### **How to handle Basaglar KwikPen**

**Basaglar** KwikPen is a pre-filled pen containing insulin glargine.

**Read carefully the Basaglar KwikPen Instructions for Use included with this package leaflet. You must use the pen as described in these Instructions for Use.**

A new needle must be attached before each injection. Only use needles that are compatible for use with **Basaglar** KwikPen (see **Basaglar** KwikPen Instructions for Use).

A safety test must be performed before each injection.

Look at the cartridge before you use the pen. Do not use **Basaglar** KwikPen if you notice particles in it. Only use **Basaglar** KwikPen if the solution is clear, colorless and water-like. Do not shake or mix it before use.

To prevent the possible transmission of disease, never share your pen with anyone else. Each pen must be

used only by you.

Make sure that neither alcohol nor other disinfectants or other substances contaminate the insulin.

Always use a new pen if you notice that your blood sugar control is unexpectedly getting worse. If you think you may have a problem with **Basaglar** KwikPen, consult your doctor, pharmacist or nurse.

Empty pens must not be re-filled and must be properly discarded.

Do not use **Basaglar** KwikPen if it is damaged or not working properly, it has to be discarded, and a new KwikPen has to be used.

### **Insulin Mix-ups**

You must always check the name of the product as it appears on the insulin label before each injection to avoid mix-ups between **Basaglar** and other insulins.

### **If you use more Basaglar than you should**

- If you **have injected too much Basaglar**, your blood sugar level may become too low (hypoglycemia). Check your blood sugar frequently. In general, to prevent hypoglycemia you must eat more food and monitor your blood sugar. For information on the treatment of hypoglycemia, see the instructions in the box at the end of this leaflet.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, go immediately to the doctor or a hospital Emergency Room and bring the medicine package with you.

### **If you forget to use Basaglar**

- If you have missed a dose of **Basaglar** or if you have **not injected enough insulin**, your blood sugar level may become too high (hyperglycemia). Check your blood sugar frequently. For information on the treatment of hyperglycemia, see the instructions in the box at the end of this leaflet.
- Do not inject a double dose to make up for a forgotten dose.

### **If you stop using Basaglar**

Discontinuation of use could lead to severe hyperglycemia (very high blood sugar) and ketoacidosis (build-up of acid in the blood because the body is breaking down fat instead of sugar). Do not stop using **Basaglar** without speaking to a doctor, who will tell you what needs to be done.

Persist with the treatment as recommended by the doctor. Even if there is an improvement in your health, do not discontinue treatment with this medicine without consulting the doctor.

**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 a doctor, pharmacist or nurse.**

## **4. SIDE EFFECTS**

As with any medicine, the use of **Basaglar** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

**If you notice signs of your blood sugar being too low (hypoglycemia)**, take action to increase your blood sugar levels **immediately** (see the instructions in the box at the end of this leaflet). Hypoglycemia (low blood sugar) can be very serious and is very common with insulin treatment (may affect more than 1 in 10 users). If your blood sugar level falls too low, you may become unconscious. Serious hypoglycemia may cause brain damage and may be life-threatening. For more information, see the instructions in the box at the end of this leaflet.

**Severe allergic reactions** (rare, may affect up to 1 in 1,000 users) – the signs may include large-scale skin reactions (rash and itching all over the body), severe swelling of skin or mucous membranes (angioedema), shortness of breath, a fall in blood pressure with rapid heartbeat and sweating. Severe allergic reactions to insulins may become life-threatening. Tell the doctor immediately if you notice signs of severe allergic

reaction.

- **Skin changes at the injection site**

If you inject insulin too often at the same place, the skin may either shrink (lipoatrophy) (*may affect up to 1 in 100 users*) or thicken (lipohypertrophy) (*may affect up to 1 in 10 users*). Lumps under the skin may also be caused by build-up of a protein called amyloid (cutaneous amyloidosis; the frequency of this phenomenon is not known). The insulin that you inject may not work very well if you inject into a lumpy area. Change the injection site with each injection to help prevent these skin changes.

**Common reported side effects** (may affect up to 1 in 10 users)

- **Skin and allergic reactions at the injection site**

The signs may include redness, unusually intense pain when injecting, itching, rash, swelling or inflammation. They can spread around the injection site. Most minor reactions to insulins usually disappear in a few days to a few weeks.

**Rare reported side effects** (may affect up to 1 in 1,000 users)

- **Eye reactions**

A marked change (improvement or worsening) in your blood sugar control can disturb your vision temporarily. If you have proliferative retinopathy (an eye disease related to diabetes), severe hypoglycemic attacks may cause temporary loss of vision.

- **General reactions**

In rare cases, insulin treatment may also cause temporary build-up of water in the body, with swelling in the calves and ankles.

**Very rare reported side effects** (may affect up to 1 in 10,000 users)

In very rare cases, taste disorders and muscular pain can occur.

**Use in children and adolescents**

In general, the side effects in children and adolescents 18 years of age or less are similar to those seen in adults.

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

There is no experience in children under 2 years of age.

**If a side effect occurs, if any of the side effects worsen, or if you are suffering from a side effect not mentioned in this 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 due to Drug Treatment" that can be found on the Home Page of the Ministry of Health's website

([www.health.gov.il](http://www.health.gov.il)), which refers to the online form for reporting side effects, or via the following link:

<https://sideeffects.health.gov.il>

## **5. HOW TO STORE THE MEDICINE?**

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 to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use this medicine after the expiry date (exp. date) which is stated on the carton and on the label of the pen. The expiry date refers to the last day of that month.

**Storage conditions:**

Unused pens

Store in a refrigerator (2°C - 8°C). Do not freeze.

Do not put **Basaglar** next to the freezer compartment or a freezer pack.

Keep the pre-filled pen in the outer carton in order to protect from light.

### Pens in use

Pre-filled pens in use or carried as a spare may be stored for a maximum of 28 days up to 30°C and away from direct heat or direct light. The pen in use must not be stored in the refrigerator. Do not use it after this time period. The pen cap must be put back on the pen after each injection in order to protect from light.

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 protect the environment.

## **6. ADDITIONAL INFORMATION**

### **In addition to the active ingredient, the medicine also contains the following inactive ingredients:**

Glycerin, metacresol, zinc oxide, sodium hydroxide solution 10%, hydrochloric acid solution 10% and water for injections.

### **What the medicine looks like and the contents of the pack:**

**Basaglar 100 units/mL solution for injection in a pre-filled pen, KwikPen**, is a clear and colorless solution. Each pen contains 3 mL of solution for injection (equivalent to 300 units). Packs of 1, 2, 5 and 10 pre-filled pens of 3 mL are available.

Not all pack sizes may be marketed.

### **License holder and address:**

Eli Lilly Israel Ltd., 4 HaSheizaf Street, P.O.Box 4246, Ra'anana 4366411.

### **Manufacturer and address:**

Lilly France S.A.S., Fegersheim, France.

**Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 155-01-34409-00

Revised in November 2021 according to MOHs guidelines.

### **HYPERGLYCAEMIA AND HYPOGLYCAEMIA**

**Always carry at least 20 grams of sugar with you, in addition to information identifying you as a diabetic.**

#### **HYPERGLYCEMIA (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,
- your insulin pen does not work properly,
- 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 (see section 2, "Drug interactions")

#### **Warning symptoms of hyperglycemia**

Thirst, increased need to urinate, tiredness, dry skin, redness of the face, loss of appetite, low blood pressure, fast heartbeat, and glucose and ketone bodies in the 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.

### **HYPOGLYCEMIA (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 recognize 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 carbohydrates than normal (sugar and substances similar to sugar are called carbohydrates; however, artificial sweeteners are NOT carbohydrates),
- you lose carbohydrates due to vomiting or diarrhea,
- 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 (see section 2, "Drug interactions").

### **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 **Basaglar**, hypoglycemia, 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 changed 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 heartbeat, 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 behavior, lapses in concentration, impaired reactions, depression, confusion, speech disturbances (sometimes total loss of speech), visual disorders, trembling, paralysis, tingling sensations, 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,
- you have had diabetes for a long time,

- you suffer from a certain type of nervous disease (diabetic autonomic neuropathy),
- you have recently suffered from 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 **Basaglar**,
- you are taking or have taken certain other medicines (see section 2, "Drug interactions")

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 hypoglycemic episodes that may otherwise be overlooked. If you are not confident about recognizing 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 grams of 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.  
The recovery of hypoglycemia may be delayed because **Basaglar** has a long action.
3. If the hypoglycemia comes back again, take another 10 to 20 grams of 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.

It is advisable to test your blood sugar immediately after taking glucose, to check that you really have hypoglycemia.