

Lenglar Insulin Glargine Injection USP 100 IU/mL (Recombinant DNA Origin) Solution for injection (3 mL Cartridge)

Lenglar Insulin Glargine Injection USP 100 IU/mL (Recombinant DNA Origin) Solution for injection in Multi-dose Dispopen-2 (Pre-filled Pen of 3 mL Cartridge)

Insulin Glargine Injection 100 IU/mL

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What Lenglar products is used for

Lenglar products is used to treat diabetes.

Your doctor may tell you to use **Lenglar as a longer-acting** insulin. Do not change your insulin unless your doctor tells you to. Be very careful if you do change insulin. Each type of insulin has a different **colour on the pack** and the cartridge so that you can easily tell the difference.

How Lenglar products works

Lenglar products contains Insulin Glargine, which is used to treat diabetes. You get diabetes if your pancreas does not make enough insulin to control the level of glucose in your blood (blood sugar). Lenglar products is used to control glucose in the long term. Lenglar is a long acting human insulin analogue

Before you use Lenglar products

- *When you must not use it*

Do not take this medicine if you are allergic to Insulin Glargine or any other ingredients of this medicine (listed in Product Description)

- *Before you start to use it*

Do not use Lenglar products if you think hypoglycaemia (low blood sugar) is starting. Further in this leaflet it tells you how to deal with mild hypoglycaemia.

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine. The amount of insulin you need usually falls during the first three months of pregnancy and increases for the remaining six months. If you are breast-feeding, you may need to alter your insulin intake or diet.

Take special care with Lenglar products

- If your blood sugar levels are well controlled by your current insulin therapy, you may not feel the warning symptoms when your blood sugar is falling too low. You must think carefully about when to have your meals, how often to exercise and how much to do. You must also keep a close watch on your blood sugar levels by testing your blood glucose often.

- It was reported the early warning symptoms were less obvious or different for people who experience hypoglycaemia (low blood sugar) after switching from animal insulin to Insulin Glargine. If you often have hypoglycaemia or have difficulty recognising the symptoms, please discuss this with your doctor.

- If you answer YES to any of the following questions, tell your diabetes specialist nurse, doctor or pharmacist.
 - Have you recently become ill?
 - Do you have trouble with your kidneys or liver?
 - Are you exercising more than usual?

- The amount of insulin you need may also change if you drink alcohol.

- You should also tell your diabetes

specialist nurse, doctor or pharmacist if you are planning to go abroad. The time difference between countries may mean that you have to have your injections and meals at different times to when you are at home.

Taking other medicines

Some medicines 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 too low or too high. Be careful when you start or stop taking another medicine.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Before taking a medicine ask your doctor if it can affect your blood sugar level and what action, if any, you need to take.

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

- all 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.

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

- corticosteroids (such as "cortisone" used to treat inflammation),
- danazol (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 hypoglycaemia),
- isoniazid (used to treat tuberculosis),
- oestrogens and progestogens (such as in the contraceptive pill used for birth control),
- phenothiazine derivatives (used to treat psychiatric disorders),
- somatropin (growth hormone),
- sympathomimetic medicines (such as epinephrine [adrenaline], or salbutamol, terbutaline used to treat asthma),
- thyroid hormones (used to treat thyroid gland disorders),
- atypical antipsychotic medicines (such as clozapine, olanzapine),
- 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 hypoglycaemia which may sometimes be followed by hyperglycaemia.

Beta-blockers like other sympatholytic

medicines (such as clonidine, guanethidine, and reserpine) may weaken or suppress entirely the first warning symptoms which help you to recognise a hypoglycaemia.

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

How to use Lenglar products

- How much to use

Always check the pack and the cartridge label for the name and type of the insulin when you get it from your pharmacy.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Dosage

- Individualize and adjust the dosage of Lenglar based on the individual's metabolic needs, blood glucose monitoring results and glycemic control goal. Your doctor has told you which insulin to use, how much, when and how often to inject. These instructions are only for you. Follow them exactly and visit your diabetes clinic regularly.

- Dosage adjustments may be needed with changes in physical activity, changes in meal patterns (i.e., macronutrient content or timing of food intake), during acute illness, or changes in renal or hepatic function. Dosage adjustments should only be made under medical supervision with appropriate glucose monitoring

- If you change your insulin type (for example from animal to Insulin

Glargine), you may have to take more or less than before. This might just be for the first injection or it may be a gradual change over several weeks or months.

- Inject Lenglar product subcutaneously
- Lenglar, under no circumstances should be given into a vein via an insulin pump.

Preparing Lenglar products

- Visually inspect Lenglar cartridges for particulate matter and discoloration prior to administration. Only use if the solution is clear and colourless with no visible particles.

- Do not shake vigorously as this may cause frothing which may interfere with the correct measurement of the dose. The cartridge should be examined frequently and should not be used if clumps of material are present or if solid white particles stick to the bottom or sides of the cartridge, giving it a frosted appearance. Check each time before you inject yourself.

Getting the pen ready to use

First wash your hands.
Read the instructions on how to use your Insulin Pen Injector. Please follow the instructions carefully. Here are some reminders.

- Use a clean needle.
- Prime your Lenglar before each use. This checks that insulin comes out and clears the air bubbles. There may still be some small air bubbles left in the pen – these are harmless. But if the air bubbles are too large it may affect the insulin dose.

Injecting Lenglar product

- First wash your hands.
- Before you make an injection, clean your skin as you have been instructed.
- Clean the rubber stopper on the cartridge,

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but do not remove the stopper.

• Administration (injection method) as per pen & cartridge rather than vial with syringe & needle. Your doctor will tell you how to do this. **Do not share your needles or your pen.**

• Inject under the skin, as you were taught. Do not inject directly into a vein.

• After your injection, pull the needle out and apply gentle pressure over the injection site for several seconds to make sure you have taken the whole dose. Do not rub the area you have just injected. Make sure you inject at least half an inch (1 cm) from where you last injected and that you 'rotate' the places you inject, as you have been taught.

• Do not dilute or mix Lenglar with any other insulin or solution

After injecting

As soon as you have done the injection, cap the needle and carefully unscrew the needle from the pen. This will keep the insulin sterile, prevent leaks, stops air from entering the pen and prevents the needle from getting clogged. Do not share your needles or pen with anyone. Afterward, put the cap back on your pen.

Further injections.

Every time you use a pen you must use a new needle. Before every injection, clear any air bubbles. You can see how much insulin is left by holding the Lenglar with the needle pointing up. The scale on the cartridge shows about how many units you have left.

Do not mix any other insulin in your disposable pen. Once the Lenglar is empty, do not use it again. Please get rid of it carefully - your pharmacist or diabetes nurse will tell you how to do

this.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Use Lenglar for the duration that the doctor recommends.

- If you forget to use it

If you take less Lenglar than you need, your blood sugar levels may increase. Check your blood sugar.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else may have use too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. If you take more Lenglar than you need, your blood sugar may become low. Check your blood sugar.

While you are using it

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Lenglar.

Tell your doctor immediately if you become pregnant while using this medication.

Take Lenglar product only with a doctor's prescription.

If you experience hypoglycaemia (low blood sugar), eat glucose tablets, sugar or drink a sugary drink. Then eat fruit, biscuits, or a sandwich, as your doctor

has advised you and have some rest. This will often get you over mild hypoglycaemia or a minor insulin overdose. If you get worse and your breathing is shallow and your skin gets pale, tell your doctor at once.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give Lenglar to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Your ability to concentrate and react may be reduced if you have hypoglycaemia (low blood sugar). Please remember this in all situations where you might put yourself and others at risk (e.g. driving a car or operating machinery). You should contact your diabetes specialist nurse or doctor about the advisability of driving if you have:

- Frequent episodes of hypoglycaemia.
- reduced or absent warning signs of hypoglycaemia.

Side effects

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

Insulin Glargine may cause hypoglycaemia (low blood sugar). The first symptoms of hypoglycemia come early and include the following:

- tiredness
- nervousness or shakiness
- headache
- rapid heartbeat
- feeling sick
- cold sweat

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Systemic allergy. The symptoms are as follows:

- fall in blood pressure
- difficulty in breathing
- fast heart beat
- rash over the whole body
- wheezing
- sweating

If you think you are having this sort of insulin allergy with Lenglar product, tell your doctor at once.

Local allergy. Immediate-type allergic reactions to insulin are rare. Such reactions to insulin (including insulin glargine) or the excipients may, for example, be associated with Redness, Itching, Swelling, Rash or small bumps or Warmth or mild pain at the affected area.

Lipodystrophy (thickening or pitting of the skin). If you notice your skin thickening or pitting at the injection site, change your injection site and tell your doctor.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Lenglar

- Storage

Keep out of the reach and sight of children.

Before the first use store your Lenglar in a refrigerator (2°C – 8°C). **Do not freeze.**

You can keep your 'in use' cartridge or pre-fill pen at room temperature (below 30°C) for up to 28 days. Do not put it near heat or in the sun.

Do not use Lenglar after the expiry date which is stated on the label and the carton. The expiry date refers to the last day of that month.

Do not use Lenglar, if it is coloured or it has solid particles in it. You must use it only if it looks like water. Check this each time you inject yourself.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Lenglar appears as a 3 mL cartridge containing a colourless liquid that is equivalent to 300 international units of Insulin Glargine.

One filled cartridge are assembled in the Dispopen-2 disposable pen. Dispopen-2 is a 3 mL solution filled cartridge, fitted in a Dispopen pasted with label, dark blue colour dose dial with grey colour thump pad and transparent cartridge cover.

Lenglar® 3 mL cartridge can be used with Wockhardt's mypen®2 (Reusable Insulin Delivery Device)

- Ingredients

- Active ingredient(s)

Lenglar active substance is Insulin Glargine.

- Inactive ingredients

Zinc Chloride, m-Cresol, Glycerol (85%), Sodium Hydroxide (for pH adjustment), Hydrochloric acid (for pH adjustment) and Water for Injection (WFI).

- MAL number(s):

Manufacturer

WOCKHARDT LIMITED
E1/1, Wockhardt Infrastructure Development Ltd, Special Economic zone, E-1, Shendra MIDC Five Star Industrial Area, Shendra, Chhatrapati Sambhajnagar-431154, Maharashtra State, India

Product Registration Holder

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MALAYSIA

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