PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

BASAGLAR®, 100 units/ml, solution for injection

Insulin Glargine

Read all of this leaflet carefully before you start using BASAGLAR.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- BASAGLAR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What BASAGLAR is and what it is used for
2. What you need to know before you use BASAGLAR
3. How to use BASAGLAR
4. Possible side effects
5. How to store BASAGLAR
6. Contents of the pack and other information

1. What BASAGLAR is and what it is used for

BASAGLAR is a solution for injection containing insulin glargine. Insulin glargine is a modified insulin, very similar to human insulin.

BASAGLAR is used to treat diabetes mellitus in adults, adolescents and children aged 6 years and above.

2. What you need to know before you use BASAGLAR

Do not use BASAGLAR

- If you are hypersensitive (allergic) to insulin glargine or any of the other ingredients of BASAGLAR (listed in section 6).
- BASAGLAR is not recommended during pregnancy or for mothers who are breastfeeding their babies.

Warnings and precautions

Take special care with BASAGLAR if your blood sugar is too low (hypoglycaemia):

If your blood sugar level falls too much you may become unconscious. Serious hypoglycaemia 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.

Hypoglycaemia (low blood sugar) 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, hypoglycaemia (low blood sugar), 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.
- In your body, symptoms of low blood sugar include 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 include 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 hypoglycaemia (low blood sugar) 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 hypoglycaemia (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 below "**Other medicines and BASAGLAR** ").

- In such a case, you may develop severe hypoglycaemia (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 hypoglycaemia.

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 well if you inject into a lumpy area (See How to use BASAGLAR). 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.

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 then your blood sugar level may increase (hyperglycaemia).
- If you are not eating enough your blood sugar level may become too low (hypoglycaemia). In most cases you will need a doctor. **Make sure that you contact a doctor early.**

Insulin mix-ups

The insulin label must always be checked before each injection to avoid medication errors between different insulins.

Thiazolidinediones (TZDs) e.g. pioglitazone in combination with insulin are associated with an increased risk of oedema and heart failure; especially in patients with underlying cardiac disease. Therefore if you experience signs of shortness of breath or rapid increase of weight you must inform your doctor as soon as possible.

Other medicines and BASAGLAR

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional 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 either too low or too high. Be careful when you start or stop taking another medicine.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. 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 inhibitors (MAOIs) (used to treat depression),
- pentoxifylline, propoxyphene salicylates (such as aspirin and NSAIDs, used to relieve pain and lower fever),
- somatostatin analogues (such as octreotide, used to treat an uncommon condition in which you make too much growth hormone),
- sulphonamide antibiotics.

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), 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 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.

BASAGLAR with food and drink:

Carefully follow your doctor's instructions regarding food intake and the use of BASAGLAR.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking this medicine.

- BASAGLAR is not recommended for use during pregnancy or by mothers who are breastfeeding their babies.
- Inform your doctor if you are planning to become pregnant, or if you are already pregnant. Your insulin dose may need to be changed during pregnancy and after giving birth. Particularly careful control of your diabetes, and prevention of hypoglycaemia, is important for the health of your baby.

Driving and using machinery

It is not always possible to predict to what extent BASAGLAR may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which BASAGLAR affects them.

Your ability to concentrate or react may be reduced if:

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

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

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

BASAGLAR contains sodium

This medicine contains less than 1 mmol (23 mg) sodium per dose, which means it is essentially 'sodium-free'.

3. How to use BASAGLAR

Do not share medicines prescribed for you with any other person.

Always use BASAGLAR exactly as described in this leaflet or as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- BASAGLAR should be administered once daily at any time but at the same time each day.
- Your BASAGLAR regimen (dose and timing) should be individually adjusted for you by your doctor.

Before starting therapy with BASAGLAR Kwikpen (pre-filled pen), patients should read the "User Manual" that accompanies the delivery device, to ensure the correct use thereof.

The BASAGLAR cartridges are to be used only in conjunction with a reusable pen device recommended for the use with Lilly insulin cartridges. The "User Manual" for using the pen must be followed carefully for loading the cartridge, attaching the needle, and administering the insulin injection.

- 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.

Your doctor will tell you how long your treatment with BASAGLAR will last. Do not stop treatment early because this could lead to severe hyperglycaemia (very high blood sugar) and ketoacidosis (build-up of acid in the blood because the body is breaking down fat instead of sugar). If you have the impression that the effect of BASAGLAR is too strong or too weak, tell your doctor or pharmacist.

Use in children and adolescents

- BASAGLAR can be used in adolescents and children aged 6 years and above. There is no experience with the use of BASAGLAR in children below the age of 6 years.

Method of administration

- BASAGLAR is injected under the skin.
- Do not inject BASAGLAR in a vein, since this will change its action and may cause hypoglycaemia.
- 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.

If you use more BASAGLAR than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you have injected too much BASAGLAR, your blood sugar level may become too low (hypoglycaemia). Check your blood sugar frequently. In general, to prevent hypoglycaemia you must eat more food and monitor your blood sugar.
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 hypoglycaemia.
Then eat something that has a long-acting effect in raising your blood sugar (such as bread or pasta). Your doctor or healthcare professional should have discussed this with you previously. The recovery of hypoglycaemia may be delayed because BASAGLAR has a long action. If the hypoglycaemia comes back again, take another 10 to 20 g sugar.

Speak to a doctor immediately if you are not able to control the hypoglycaemia 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 hypoglycaemia.

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

If you stop using BASAGLAR

- This could lead to severe hyperglycaemia (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 BASAGLAR without speaking to a doctor, who will tell you what needs to be done.

4. Possible side effects

BASAGLAR can have side effects.

Not all side effects reported for BASAGLAR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BASAGLAR, please consult your health care provider for advice.

If any of the following happens, stop using BASAGLAR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Hypoglycaemia (low blood sugar) can be very serious. If your blood sugar level falls too much you may become unconscious. Serious hypoglycaemia may cause brain damage and may be life-threatening. If you have symptoms of low blood sugar, take actions to increase your blood sugar level immediately.
- If you experience the following symptoms, contact your doctor immediately: 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. These could be symptoms of severe allergic reactions to BASAGLAR and may become life-threatening.

These are all very serious side effects. If you have them, you may have had a serious reaction to BASAGLAR. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- Skin changes at the injection site: Fatty tissue under the skin at the injection site may either shrink (lipoatrophy) or thicken (lipohypertrophy). Lumps under the skin may also be caused by build-up of a protein called amyloid (cutaneous amyloidosis, how often they occur is not known). The insulin 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.
- Skin and allergic reactions: Reddening, unusually intense pain on injection, itching, hives, swelling or inflammation. They can also spread around the injection site.
- Severe allergic reactions to insulins: 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. These could be symptoms of severe allergic reactions to insulins and may become life-threatening.
- 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 hypoglycaemic attacks may cause temporary loss of vision.

Less frequent occurrence:

- General disorders: Insulin treatment may also cause temporary build-up of water in the body, with swelling in the calves and ankles.
- Dysgeusia (taste disorders) and myalgia (muscular pain) can occur.
- Insulin treatment can cause the body to produce antibodies to insulin (substances that act against insulin). This may require a change to your insulin dose.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of BASAGLAR.

Alternately, report suspected adverse events to the company at: ade_za@lilly.com.

5. How to store BASAGLAR

- Store in a refrigerator between 2 °C – 8 °C.
- Keep in original container until required for use.
- Do not freeze. Do not store BASAGLAR next to the freezer compartment or a freezer pack.
- Once in-use store at or below 30 °C for a period up to 28 days. The unused portion must be discarded. Protect from light.
- Do not use after the expiry date which is stated on the carton and on the label.
- Do not use BASAGLAR if you notice particles in it. Only use BASAGLAR if the solution is clear, colourless.
- Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BASAGLAR contains

Each ml of the solution for injection contains 100 units of the active ingredient, insulin glargine, equivalent to 3,64 mg.

Other excipients include: zinc oxide, metacresol, glycerol, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment), water for injection.

What BASAGLAR looks like and contents of the pack

BASAGLAR is a clear and colourless solution, in a 3 ml type 1 colourless glass cartridge. The solution should be free from visible particulate matter.

Presentation of BASAGLAR

Cartridge: 3 ml solution in a cartridge (type 1 colourless glass) with a plunger (grey chlorobutyl rubber) and a disc seal (laminate of red polyisoprene and cream bromobutyl or grey chlorobutyl rubber) with aluminium seal. Cartridges are packed into blisters. Blisters are packed in an outer cardboard carton. Cartridges are to be used only in conjunction with a reusable pen device recommended for the use with Lilly insulin cartridges. Packs of 1, 2, 5 and multipacks containing 10 cartridges (2 packs of 5 cartridges) are available. Not all pack sizes may be marketed.

Pre-filled pen: 3 ml solution in a cartridge (type 1 colourless glass) with a plunger (grey chlorobutyl rubber) and a disc seal (laminate of red polyisoprene and cream bromobutyl or grey chlorobutyl rubber) with aluminium seal. The cartridge is sealed in a disposable pen injector. Pre-filled pens are packed in an outer cardboard carton. Packs of 1, 2, 5 and multipacks containing 10 pens (2 packs of 5 pens) are available. Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Registration Details for Botswana		
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Please report any suspected ADRs to BoMRA through e-reporting https://primaryreporting.who-umc.org/BW and e-mail reportadr@bomra.co.bw.		
Registration Details for Namibia		
Basaglar Solution for injection 100IU/ml	Reg. No.: 17/21.1/0014	Schedule: NS2