Patient Information Leaflet for OPTISULIN®

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

OPTISULIN®, 3,64 mg/mL (100 IU/mL), Solution for injection

Insulin glargine

Sugar free

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor, pharmacist, nurse or other health care provider.
- OPTISULIN 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 OPTISULIN is and what it is used for

OPTISULIN contains insulin glargine. This is a modified insulin, very similar to human insulin.

OPTISULIN is used to treat diabetes mellitus in adults, adolescents and children aged 2 years

and older. Diabetes mellitus is a disease where your body does not produce enough insulin to control the level of blood sugar. Insulin glargine has a long and steady blood-sugar-lowering action.

2. What you need to know before you use OPTISULIN

Do not use OPTISULIN:

- if you are hypersensitive (allergic) to insulin glargine or any of the other ingredients of OPTISULIN (listed in section 6)
- if your child is younger than 2 years.

Warnings and precautions:

Take special care with OPTISULIN:

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

If your blood sugar is too low (hypoglycaemia), follow the guidance for hypoglycaemia under section 4.

There is limited experience with the use of OPTISULIN in patients whose liver or kidneys do not function well.

Accidental mix-ups between OPTISULIN and other insulins, particularly short-acting insulins, have been reported. To avoid medicine errors between OPTISULIN and other insulins, you should always check the insulin label before each injection.

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). Contact your doctor if you are currently injecting into a lumpy area before you start injecting in a different area. Your doctor may tell you to check your blood sugar more closely, and to adjust the dose of your insulin or your other antidiabetic medicine.

Travel:

Before travelling 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 travelling
- timing of meals and administration while travelling
- the possible effects of changing to different time zones
- possible new health risks in the countries to be visited.

Illnesses and injuries:

If you are ill or have a major injury, then your blood sugar may increase (hyperglycaemia). If you are not eating enough your blood sugar may become too low (hypoglycaemia). In such situations, the management of your diabetes may require a change in your dose of OPTISULIN. Consult your doctor.

Children and adolescents:

Do not give OPTISULIN to children under the age of 2 years because the safety and efficacy have not been established.

Other medicines and OPTISULIN:

Always tell your health care provider if you are taking any other medicine (This includes complementary or traditional medicines).

Some medicines cause the blood sugar level to fall, some cause it to rise, others may have both effects, depending on the situation. In each case it may be necessary to adjust your OPTISULIN dosage to avoid too low or too high blood sugar levels.

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 mellitus

- angiotensin-converting enzyme (ACE) inhibitors (used to treat certain heart conditions or high blood pressure)
- disopyramide (used to treat certain heart conditions)
- fibrates (used to lower high levels of blood lipids)
- fluoxetine (used to treat depression)
- monoamine oxidase (MAO) inhibitors (used to treat depression)
- pentoxifylline, propoxyphene, salicylates (such as acetylsalicylic acid, used to relieve pain and lower fever)
- sulfonamide 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 manage symptoms of low blood sugar)
- 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)
- protease inhibitors (used to treat HIV)
- atypical antipsychotic medicines such as clozapine, olanzapine (used to treat schizophrenia)
- 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)

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 hypoglycaemia.

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

OPTISULIN with food or drink:

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

Pregnancy, breastfeeding and fertility:

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 using OPTISULIN.

Driving and using machines:

Your ability to concentrate or react may be reduced if you have too low (hypoglycaemia) or too high (hyperglycaemia) blood sugar or problems with your sight. Please keep this possible problem in mind in all situations where you might put yourself and others at risk (e.g. driving a car or operating machinery). You should contact your doctor about the advisability of driving if you have:

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

3. How to use OPTISULIN

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

Always use OPTISULIN exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

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

- determine how much OPTISULIN you will need per day
- 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 OPTISULIN
- show you in which skin area to inject OPTISULIN.

OPTISULIN is injected under the skin (subcutaneously).

Do NOT inject OPTISULIN in a vein, since this will change its action and may cause hypoglycaemia.

With each injection, change the puncture site within the particular area of skin that you are using. This will reduce the risk of skin shrinking or thickening or lumps at the site. Do not inject where the skin has pits, is thickened, or has lumps. Do not inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin.

Allow the solution to reach room temperature before using OPTISULIN.

Your doctor will tell you how long your treatment with OPTISULIN will last. Do not stop treatment early. If you have the impression that the effect of OPTISULIN is too strong or too weak, tell your doctor or pharmacist.

How to handle the vials/cartridges:

Look at the vial/cartridge before you use it. Only use it if the solution is clear, colourless and waterlike, and has no visible particles in it. OPTISULIN is a solution and does not require shaking or mixing before use.

Do not mix OPTISULIN with any other insulins or medicines. Do not dilute it. Mixing or diluting may change the action of OPTISULIN.

Before insertion of the cartridge into the non-disposable pen, the cartridge must be kept at room

temperature for 1 to 2 hours and the instructions for using the pen must be followed carefully.
Empty cartridges must not be refilled.
If the pen malfunctions, the solution may be drawn from the cartridge into a syringe (suitable for an insulin with 100 units/mL) and injected.

Mistakes in dosage:

Please discuss in advance with your doctor what you should do if you inject too much OPTISULIN, if you miss a dose or if you inject too low a dose.

If you use more OPTISULIN than you should:

You may develop hypoglycaemia (your blood sugar level may become too low). Check your blood sugar frequently. In general, to prevent hypoglycaemia you must eat more food and monitor your blood sugar. For information on the treatment of hypoglycaemia, refer to the section on side effects.
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use OPTISULIN:

If you have missed a dose of OPTISULIN or if you have not injected enough insulin, your blood sugar level may become too high (hyperglycaemia). Check your blood sugar frequently. Refer to the section on side effects for further information on hyperglycaemia.
Do not inject a double dose to make up for forgotten individual doses.

If you stop using OPTISULIN:

Do not stop treatment with OPTISULIN before consulting your doctor.

4. Possible side effects

OPTISULIN can have side effects.

Signed: EB

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

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

- Severe allergic reactions to insulins, including OPTISULIN, might occur. Such reactions to OPTISULIN or to the excipients can cause large-scale skin reactions, severe swelling of skin or mucous membranes (angioedema), shortness of breath, a fall in blood pressure and circulatory breakdown and may become life-threatening.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following**:**

- Too low blood sugar levels (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. Please refer to the end of this section for important further information about hypoglycaemia and its treatment.
- OPTISULIN treatment can cause the body to produce antibodies to insulin (substances that act against insulin). Rarely, this may require a change to your insulin dosage.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Skin and allergic reactions: If you inject OPTISULIN too often at the same skin site, fatty tissue under the skin at this site may shrink or thicken (called lipodystrophy). Lumps under the

skin may also be caused by build-up of a protein called amyloid (localised cutaneous amyloidosis). OPTISULIN that you inject into a lumpy area may not work very well. Changing the site with each injection may help to prevent such skin changes. You may also experience reactions at the injection site (e.g. reddening, unusually intense pain on injection, itching, hives, swelling or inflammation). They can also spread around the injection site. Most minor reactions to OPTISULIN usually resolve in a few days to a few weeks.

Less frequent side effects:

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

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

Hyperglycaemia and hypoglycaemia

If your blood sugar is too high (hyperglycaemia):

Your blood sugar level may be too high if, for example:

- you have not injected your insulin or not injected enough, or if it has become less effective, e.g. through incorrect storage
- you are doing less physical exercise, you are under stress (emotional distress, excitement), or if you have an injury, operation, feverish illness or certain other diseases
- you are taking or have taken certain other medicines.

Thirst, increased need to pass water, tiredness, dry skin, reddening of the face, loss of appetite, low blood pressure, fast heartbeat, and glucose and ketone bodies in the urine may be signs of too high blood sugar.

Test your blood sugar level and your urine for ketones as soon as any such symptoms occur. Consult a doctor immediately.

If your blood sugar is too low (hypoglycaemia):

Your blood sugar levels may fall too much if, for example:

- you inject too much OPTISULIN
- you miss meals or delay them
- you do not eat enough, or eat food containing less carbohydrates than normally (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 do more physical exercise than usual or a different type of physical activity
- you are recovering from an injury, operation or other stress
- you are recovering from a feverish illness or from another illness
- you are taking or have stopped taking certain other medicines.

Too low blood sugar levels are also more likely to occur if:

- you have just begun OPTISULIN treatment or changed to another insulin preparation
- your blood sugar levels are almost normal or are unstable
- you change the area of skin where you inject OPTISULIN (e.g. from the thigh to the upper arm)
- you suffer from severe kidney or liver disease, or some other disease such as hypothyroidism.

Symptoms that tell you that your blood sugar level is falling too much or too fast may be, for example: sweating, clammy skin, anxiety, fast heartbeat, high blood pressure, palpitations and irregular heartbeat, chest pain (angina pectoris). These symptoms often develop before the symptoms of a low sugar level in the brain.

Try always to keep familiar with your warning symptoms. If necessary, more frequent blood sugar

testing can help to identify mild hypoglycaemic episodes that might otherwise be overlooked.

What to do in case of hypoglycaemia?

1. Do not inject insulin, including OPTISULIN.
2. Immediately take about 10 to 20 g sugar, e.g. as glucose, sugar cubes or a sugar-sweetened beverage. **Caution:** please note that artificial sweeteners and foods with artificial sweeteners (e.g. diet drinks) are of no help in hypoglycaemia.
3. Then eat something that has a long-acting effect in raising your blood sugar (e.g. bread).
4. Consult a doctor immediately.

Always carry some sugar (at least 20 grams) with you. Carry some information (Medic-Alert) with you to show you are diabetic.

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 “Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of OPTISULIN.

You can report any side effects directly to Sanofi’s Pharmacovigilance Unit at za.drugsafety@sanofi.com (email) or 011 256 3700 (tel).

5. How to store OPTISULIN

- Store all medicines out of reach of children.
- The expiry date is printed on the carton and on the label of the vial/cartridge/disposable pen.
- Do not use OPTISULIN after the expiry date.

Unopened/not in use:

- Store at 2 °C to 8 °C (in a refrigerator).

- Keep the vial/cartridge/disposable pen in the original carton in order to protect from light.
- Do not allow it to freeze. Discard if frozen.
- Do not put OPTISULIN next to the freezer compartment of your refrigerator or next to a freezer pack.

Opened/in use cartridges, vials and disposable pens:

- Once in use, you can keep the vial/cartridge/disposable pen at or below 30 °C for up to 4 weeks in the outer carton for the vial and in the pen for the cartridge.
- Do not use it after this time.
- Opened cartridges and vials, whether or not refrigerated, must be discarded after 4 weeks from the first use.
- Unrefrigerated cartridges and vials, whether in use or not, must be discarded after 4 weeks.
- The non-disposable pen containing the cartridge, or the pen in use must not be stored in the refrigerator.
- The unused portion of the cartridge or vial must be discarded.
- It is helpful to note on the label the date of the first withdrawal from the vial.
- Always use a new vial/cartridge/disposable pen if you notice that your blood sugar control is unexpectedly getting worse. This is because the OPTISULIN may have lost some of its effectiveness.
- If you think you may have a problem with OPTISULIN, have it checked by your doctor or pharmacist.
- Only use OPTISULIN if the solution is clear, colourless and water-like and has no visible particles in it.
- 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 OPTISULIN contains:

The active substance is insulin glargine. 1 mL contains 3,64 mg insulin glargine, corresponding to 100 U human insulin.

OPTISULIN contains a preservative, metacresol (2,7 mg/mL), and a stabiliser, zinc chloride (0,0626 mg/mL).

The 10 mL vial also contains 0,02 mg/mL polysorbate 20 as an additional stabiliser.

The other ingredients of OPTISULIN are glycerol, hydrochloric acid, metacresol, polysorbate 20 (only in the 10 mL vial), sodium hydroxide, water for injection and zinc chloride.

What OPTISULIN looks like and contents of the pack:

3 mL *cartridge:* a clear, colourless solution for injection in a type 1 colourless glass cartridge.

10 mL *vial:* a clear, colourless solution for injection in a type 1 colourless glass vial, with a tear-off lid.

3 mL *cartridge:*

Packs containing 5 x 3 mL cartridges containing 3 mL of solution, to be used in conjunction with a reusable pen.

Packs containing 5 x disposable pens. Each pen contains a 3 mL cartridge containing 3 mL of solution.

10 mL *vial:*

Packs containing 1 x 10 mL vial, containing 10 mL of solution.

Holder of certificate of registration:

sanofi-aventis south africa (pty) ltd

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South Africa

Signed:

011 256 3700

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