PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

OPTISULIN®

Insulin glargine, 3,64 mg per ml, solution for injection

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, please ask your doctor or your pharmacist.
- 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 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).

The other ingredients of OPTISULIN are: glycerol, hydrochloric acid, sodium hydroxide, water for injection and zinc chloride. The 10 ml vial also contains polysorbate 20 as an additional stabiliser.

WHAT OPTISULIN IS USED FOR:

OPTISULIN is a long-acting insulin, used to reduce high blood sugar in patients with diabetes mellitus.

BEFORE YOU USE OPTISULIN:

Do NOT use OPTISULIN:

- if you are hypersensitive (allergic) to insulin glargine or any of the other ingredients of OPTISULIN (see WHAT OPTISULIN CONTAINS)
- if your blood sugar is too low (hypoglycaemia)
- if your child is younger than 6 years.

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.

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 medication errors between OPTISULIN and other insulins, you should be instructed to always check the insulin label before each injection.

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.

Using OPTISULIN with food or drink:

Alcohol may mask the symptoms of hypoglycaemia.

Pregnancy and breastfeeding:

OPTISULIN should not be used if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

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.

TAKING/USING OTHER MEDICINES WITH OPTISULIN:

Always tell your healthcare professional 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.

Tell your doctor about all medicines that you are taking, including those you have bought 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.

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

HOW TO USE OPTISULIN:

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

Always take OPTISULIN exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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

- determine how much OPTISULIN per day you will need
- 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.

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 water-like, 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 injected more OPTISULIN than you should:

You may develop hypoglycaemia. 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 inject, missed a dose or injected too low a dose of OPTISULIN:

Your blood sugar level may become too high. 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.

Effects when treatment with OPTISULIN is stopped:

Do not stop treatment with OPTISULIN before consulting your doctor.

POSSIBLE SIDE EFFECTS:

OPTISULIN may have side effects.

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 taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

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.

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). OPTISULIN that you inject in such a site 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.

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.

Other side effects:

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.

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

Tell your doctor or pharmacist if you notice any of the side effects listed above or any other unwanted or unexpected effects. To prevent serious reactions, speak to a doctor immediately if a side effect is severe, occurred suddenly or gets worse rapidly.

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 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 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 more physical 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 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.

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

STORAGE AND DISPOSING OF 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.

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. Do not put OPTISULIN next to the freezer compartment of your refrigerator or next to a freezer pack.

Once in use, you can keep the vial/cartridge/disposable pen at a temperature of up to 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. The non-disposable pen containing the cartridge must not be stored in the refrigerator.

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).

PRESENTATION OF OPTISULIN:

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.

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

IDENTIFICATION OF OPTISULIN:

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.

REGISTRATION NUMBER:

41/21.1/0363

NAME AND ADDRESS OF THE REGISTRATION HOLDER:

sanofi-aventis south africa (pty) ltd

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