

# Lantus®

## 100 IU/ml OptiSet® solution for injection

Insulin glargine

✧ *Aventis*

### PACKAGE LEAFLET

#### Before you start using this medicine, please carefully read all of this leaflet including the Instructions for Use of OptiSet.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

#### In this leaflet:

1. What Lantus OptiSet is and what it is used for
2. Before you use Lantus OptiSet
3. How to use Lantus OptiSet
4. Possible side-effects
5. Storing Lantus OptiSet
6. Further information

#### Lantus 100 IU/ml OptiSet solution for injection

Insulin glargine

- The active substance is Insulin glargine. One millilitre of the solution contains 100 IU (International Units) of the active substance insulin glargine.
- Other ingredients of Lantus are: zinc chloride, m-cresol, glycerol, sodium hydroxide, hydrochloric acid and water for injections.

The marketing authorisation holder and manufacturer of Lantus OptiSet is: Aventis Pharma Deutschland GmbH, D-65926 Frankfurt am Main, Germany.

#### 1. WHAT LANTUS OPTISET IS AND WHAT IT IS USED FOR

Lantus is a clear, colourless solution for injection containing insulin glargine. Insulin glargine is a modified insulin, very similar to human insulin. It is made by a

recombinant DNA technology process using *Escherichia coli* microorganism. Insulin glargine has a long and steady blood-sugar-lowering action. Lantus OptiSet comes in cartridges sealed in disposable pen injectors. Each pen contains 3 ml solution (300 IU) and they are available in packs of 1, 3, 4, 5, 6, 8, 9 and 10 pens. Not all pack sizes may be marketed. Lantus is used to reduce high blood sugar in patients with diabetes mellitus. Diabetes mellitus is a disease where your body does not produce enough insulin to control the level of blood sugar.

#### 2. BEFORE YOU USE LANTUS OPTISET

##### Do not use Lantus OptiSet:

If you are hypersensitive (allergic) to insulin glargine or to any of the other ingredients of Lantus OptiSet (see above).

##### Take special care with Lantus OptiSet:

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

##### Special patient groups

There is limited experience with the use of Lantus in children less than 6 years old and in patients whose liver or kidneys do not function well.

##### 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 insulin 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 lot of care. In most cases you will need a doctor. **Make sure that you contact a doctor early.** If you have type 1 diabetes (insulin dependent diabetes mellitus), do not stop your insulin and continue to get enough carbohydrates. Always tell people who are caring for you or treating you that you require insulin.

##### Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine.

Inform your doctor if you are planning to become pregnant, or if you are already pregnant. Your insulin dosage 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.

##### Breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

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

#### 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:

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 insulin dosage to avoid too low or too high blood sugar levels. Be careful not only when you start another medicine, but also when you stop it.

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.

Medicines that may cause your blood sugar to fall include all other medicines for the treatment of diabetes, ACE inhibitors, disopyramide, fluoxetine, fibrates, MAO inhibitors, pentoxifylline, propoxyphene, salicylates and sulfonamide antibiotics. Medicines that may cause your blood sugar to rise include corticosteroids ("cortisone"), danazol, diazoxide, diuretics, glucagon, isoniazid, oestrogens and progestogens (e.g. in the contraceptive pill), phenothiazine derivatives, somatropin, sympathomimetic medicines (e.g. epinephrine, salbutamol, terbutaline), thyroid hormones, clozapine, olanzapine and protease inhibitors.

Your blood sugar level may either rise or fall if you take beta-blockers, clonidine or lithium salts or drink alcohol. Pentamidine may cause hypoglycaemia which may sometimes be followed by hyperglycaemia.

Beta-blockers like other sympatholytic medicines (e.g. clonidine, guanethidine, and reserpine) may weaken the warning symptoms of a hypoglycaemic reaction or suppress them entirely.

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

#### 3. HOW TO USE LANTUS OPTISET

Based on your life-style and the results of blood sugar (glucose) tests and your previous insulin usage, your doctor will

- determine how much Lantus 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 Lantus,
- show you in which skin area to inject Lantus.

Lantus is a long-acting insulin. Your doctor may tell you to use it in combination with a short-acting insulin or with tablets against high blood sugar.



Many factors may influence your blood sugar level. You should know these factors to be able to react correctly to changes in your blood sugar level and to prevent it from becoming too high or too low. See the box at the end of section 4 for further information.

You need one injection of Lantus every day, at the same time of the day. In children, only evening injection has been studied. Lantus OptiSet delivers insulin in increments of 2 units up to a maximum single dose of 40 units.

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

Your doctor will advise you in which area of the skin you should inject Lantus. With each injection, change the puncture site within the particular area of skin that you are using.

##### How to handle the pens

Lantus OptiSet comes in cartridges sealed in disposable pen injectors.

Read carefully the "Lantus OptiSet Instructions for Use" included in this package leaflet. You must use the pen as described in these Instructions for Use

A new needle must be attached before each use. Only use needles that have been approved for use with OptiSet.

A safety test must be performed before each injection.

Look at the cartridge before you use the pen. Do not use Lantus OptiSet if you notice particles in it. Only use Lantus OptiSet if the solution is clear, colourless and waterlike. Lantus is a solution and does not require shaking or mixing before use.

To prevent the possible transmission of disease, each pen must be used by one patient only.

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 Lantus OptiSet, please refer to the Troubleshooting section of the attached Lantus OptiSet Instructions for Use, or have it checked by your doctor or pharmacist.

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

Do not use the OptiSet if it is damaged or not working properly (due to mechanical defects), it has to be discarded and a new OptiSet has to be used.

##### Mistakes in dosage:

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

##### If you take more Lantus OptiSet than you should:

If you **have injected too much Lantus**, 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, see box at the end of section 4.

##### If you forget to take Lantus OptiSet:

If you have missed a dose of Lantus or if you have injected too low a dose, your blood sugar level may become too high. Check your blood sugar frequently. See the end of section 4 for further information on hyperglycaemia.

#### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Lantus OptiSet can have side effects.



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#### 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 see the box at the end of this section for important further information about hypoglycaemia and its treatment.

#### Too high blood sugar levels (hyperglycaemia)

Too high a blood sugar level tells you that you could have needed more insulin than you injected. Please see the box at the end of this section for further information.

#### Eye reactions

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

#### Skin side-effects and allergic reactions

If you inject your insulin too often at the same skin site, fatty tissue under the skin at this site may shrink or thicken (called lipodystrophy). Thickening of fatty tissue may occur in 1 to 2% of patients while shrinking may occur uncommonly. Insulin 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.

3 to 4% of patients may 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 insulins usually resolve in a few days to a few weeks.

Severe allergic reactions to insulins are rare. Such reactions to insulin or to the excipients can cause large-scale skin reactions, severe swelling of skin or mucous membranes (angio-oedema), shortness of breath, a fall in blood pressure and circulatory breakdown and may become life-threatening.

#### Other side-effects

Insulin 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, insulin 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,
- your insulin pen does not work properly,
- 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 (see section 2, "Taking/using other medicines").

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

Test your blood sugar level and your urine for ketones as soon as any such symptoms occur. Severe hyperglycaemia or ketoacidosis must always be treated by a doctor, normally in a hospital.

#### If your blood sugar is too low (hypoglycaemia)

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

- you inject too much insulin,
- 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 take 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 (see section 2, "Taking/using other medicines").

#### Too low blood sugar levels are 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 Lantus hypoglycaemia, 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 (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 heart beat, 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.

The following symptoms indicate a low sugar level in the brain: 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 ("warning symptoms") 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, due to diabetes, suffer from a certain type of nervous disease (autonomic neuropathy),
- you have recently suffered hypoglycaemia (e.g. 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 Lantus,
- you are taking or have taken certain other medicines (see section 2, "Taking/using other medicines").

In such a case, you may develop severe hypoglycaemia (and even faint) before you are aware of the problem. 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. While you are not confident about recognising your warning symptoms, avoid situations (e.g. driving a car) in which you or others would be put at risk by hypoglycaemia.

#### What to do in case of hypoglycaemia?

1. Do not inject insulin. Immediately take about 10 to 20g sugar, e.g. as glucose, sugar cubes or a sugar-sweetened beverage. (Measure once as spoonfuls or lumps of sugar or glucose tablets to see how much this means.) Caution: please remember that artificial sweeteners and foods with artificial sweeteners (e.g. diet drinks) are of no help in hypoglycaemia.
2. Then eat something that has a long-acting effect in raising your blood sugar (e.g. bread). Your doctor or nurse will have discussed this with you. The recovery of hypoglycaemia may be delayed because Lantus has a long action.
3. If the hypoglycaemia comes back again take another 10 to 20g sugar.
4. Speak to a doctor immediately if you are not able to control the hypoglycaemia or if it recurs.

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

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

#### 5. STORING LANTUS OPTISET

Keep out of the reach and sight of children.

Do not use Lantus OptiSet after the expiry date printed on the carton and on the cartridge.

Store at 2°C–8°C (e.g. in a refrigerator). Keep the container in the outer carton in order to protect from light. Do not allow it to freeze. Do not put Lantus OptiSet next to the freezer compartment of your refrigerator or next to a freezer pack.

Keep a new pen at room temperature for 1 or 2 hours before use.

Pens in use must not be stored in a refrigerator.

If the pen has been taken out of the cool storage place either for use or to be carried as a spare you can keep it at a temperature of up to 25°C for up to 4 weeks. Do not use it after this time.

Remove the needle after the injection and store the pen without the needle. Also, be sure to remove the needle before disposing of the pen. Needles must not be re-used.

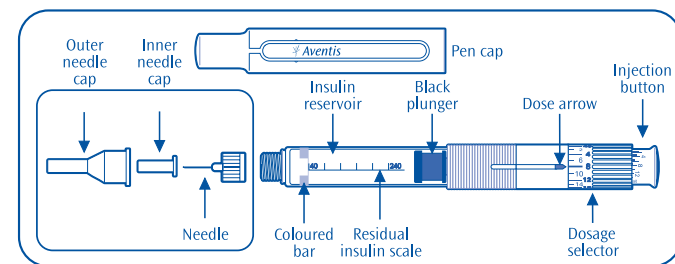
#### 6. FURTHER INFORMATION

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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This leaflet was last approved on January 2005

**LANTUS OPTISET INSTRUCTIONS FOR USE**  
Please read these Instructions for Use carefully and completely before using OptiSet for the first time. Keep this leaflet for future reference for each time you use OptiSet.



Schematic diagram of the pen

**Important information for use of OptiSet**

- A new needle must be attached before each use (see section 2).
- A safety test must be performed before each injection (see section 3).
- Never turn the dosage selector (change the dose) after injection button has been pulled out.
- This pen is for your use only; do not share it with anyone else.
- If a problem occurs with OptiSet, please refer to the section "Troubleshooting".
- Never use OptiSet if it is damaged or if you are not sure that it is working properly.

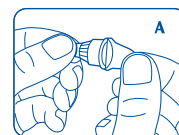
**Step 1. Check your insulin**

Remove the pen cap. Check the label on the insulin reservoir to make sure you have the correct insulin. Check the appearance of your insulin. The insulin solution must be clear, colourless, with no solid particles visible, and must have a water-like consistency.

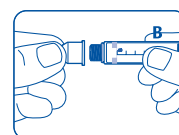
**Step 2. Attaching the needle**

Attach a new needle before use. Only use needles that have been approved for use with OptiSet.

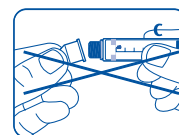
**A** Remove the protective cap from the needle container.



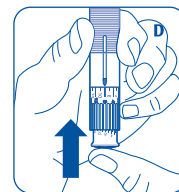
**B** Carefully attach the needle together with the outer needle cap, **straight** onto the pen (screw or push on, depending on the needle type).



**C** Do not attach the needle at a slant. This may cause it to break or lead to leakage and incorrect dosing. Do not force the needle.



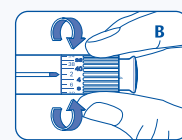
**D** Make sure the injection button is pressed in.



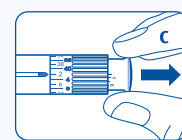
**Step 3. Safety test**

Prior to each injection a safety test has to be performed. Always attach a new needle before performing the safety test. **If you are using a new and unused OptiSet**, you should use a dose of 8 units, already preset by the manufacturer, for the first safety test. Follow step A. **Otherwise**, you should set a dose of 2 units for the safety test. Follow step B.

**A** For new and unused OptiSet only: Check that the dose arrow is pointing to the number 8. If that it is not the case, use a new OptiSet. Now go directly to step C.



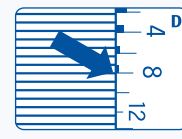
**B** For an OptiSet already in use: Turn the dosage selector until the dose arrow points to 2 (the dosage selector may be turned in either direction).



**C** Pull the injection button out as far as it will go.

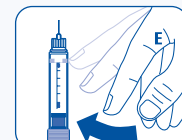
**Never turn the dosage selector once the injection button has been pulled out.**

**D** Check if the numbers on the injection button match with the dose you chose on the dosage selector:

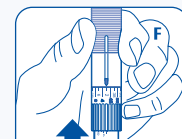


- Black lines show the number of units. These lines change from thin to thick.
- Pull out the button completely and hold it out.
- The last thick bar visible (only the top part can be seen) shows the amount of insulin loaded. You may need to turn the pen to see the last thick bar.
- If it is difficult to see, you can hold the pen at an angle.
- In this picture, 8 units are loaded.

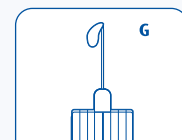
**E** Remove the outer and inner needle caps. Hold the pen with the needle pointing upwards and tap the insulin reservoir gently with the finger so that any air bubbles rise up towards the needle.



**F** Press in the injection button completely, to expel the dose. A clicking sound can be heard, which will stop when the injection button has been pressed completely.



**G** If insulin has been expelled through the needle, then your pen and the needle are working properly.

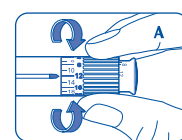


If no insulin appears at the needle tip, repeat the safety test (steps 3B-G) until it does. If no insulin is expelled from the needle even after the safety test has been repeated, check for air bubbles: If air bubbles are present repeat the safety test until air bubbles are removed. If no air bubbles are present the needle may be blocked. Please change the needle.

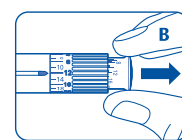
**Step 4. Setting and loading the insulin dose**

You can set the dose in steps of 2 units, from a minimum of 2 units to a maximum of 40 units. If you need a dose greater than 40 units, you should give it as two or more injections.

**A** Turn the dosage selector in either direction until the dose arrow points to the required dose.



**B** Pull out the injection button as far as it will go in order to load the dose.



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Text Freigabe:

Gesamtfreigabe:

Druckfertig  Ja  Nein

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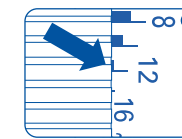
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**Never turn the dosage selector once the injection button has been pulled out.**

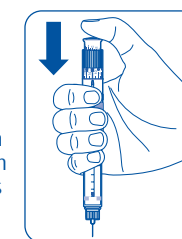
**C** Check if the numbers on the injection button match with the dose you chose on the dosage selector:



- Black lines show the number of units. These lines change from thin to thick.
- Pull out the button completely and hold it out.
- The last thick bar visible (only the top part can be seen) shows the amount of insulin loaded. You may need to turn the pen to see the last thick bar.
- If it is difficult to see, you can hold the pen at an angle.
- In this example, 12 units are loaded.

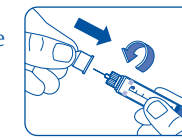
**Step 5. Injecting the insulin dose**

Use the injection technique as advised by your health care professional. Insert the needle into the skin. Press in the injection button completely. A clicking sound can be heard, which will stop when the injection button has been pressed completely. Then slowly count to 10 while holding down the injection button before withdrawing the needle. This ensures that the full dose of insulin has been injected.



**Step 6. Removing the needle**

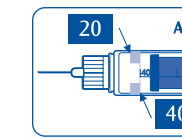
To avoid injuries replace only the outer needle cap onto the needle. Unscrew the needle by turning the needle cap. Dispose of the used needle safely. Remove the needle after each injection and discard it. This will prevent contamination as well as leakage, air bubbles and potential needle blocks. Needles must not be reused. Now replace the pen cap on the pen.



**Checking the reservoir for remaining insulin**

The residual insulin scale on the transparent insulin reservoir shows approximately how much insulin remains in the OptiSet. This scale must not be used to set the insulin dose.

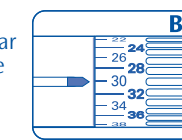
**A** If the black plunger is at the beginning of the coloured bar, then there are approximately 40 units of insulin available. If the black plunger is at the end of the coloured bar, then there are approximately 20 units of insulin available.



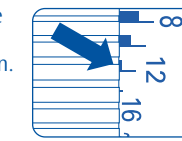
- When the level of insulin in the reservoir is low, the injection button allows you to check the dose:
- Black lines show the number of units. These lines change from thin to thick.
- Pull out the button completely and hold it out.
- The last thick bar visible (only the top part can be seen) shows the amount of insulin loaded. You may need to turn the pen to see the last thick bar.
- If it is difficult to see, you can hold the pen at an angle.
- If you are unsure whether you have enough insulin remaining for your next dose, discard this OptiSet and start a new one.

Example:

If you have set the dose arrow to 30 units (**B**) and the injection button can only be pulled out to as far as 12 units (**C**), then only 12 units of insulin can be injected with this pen.



In this example, either the other 18 units will have to be injected using a new pen, or the entire 30 units dose will have to be injected using a new pen.



**TROUBLESHOOTING**

**Wrong dose selected**

- If you have pulled out the injection button: Never correct the dosage selector while the injection button is pulled out. This will damage OptiSet. Press the injection button in completely to discard the dose and select again.
- If you have not yet pulled out the injection button: you can still change the dose by turning the dosage selector to the right or left.

**The injection button cannot be pressed.**

1. Make sure you pulled the injection button out completely.
2. Check if needle is attached properly or if needle is blocked.
3. Attach a new needle
4. Push the injection button completely in to discard the insulin.
5. Perform the safety test.

**Dose has been selected and the injection button has been pulled out and pressed in again without a needle attached**

1. Attach a new needle
  2. Press in the injection button completely in and discard the insulin.
  3. Perform the safety test.
- If the safety test is successful OptiSet is ready for use. If test is not successful, the pen might be damaged. Use a new OptiSet. If in any doubt whether the pen is working correctly use a new OptiSet

**You don't hear clicking while injecting**

OptiSet is damaged, use a new OptiSet

**Insulin is leaking from the pen**

Needle has been attached imprecisely (e.g. at a slant). Remove needle and replace with a new needle putting it on straight. Perform the safety test.

**Air bubbles are present in the reservoir**

Small amounts of air may be present in the needle and insulin reservoir during normal use. You must remove this air by performing the safety test. The tiny air bubbles in the insulin reservoir that do not move with gentle tapping will not interfere with the injection and dosage.

**The amount indicated on the injection button is lower than the dose selected**

There is not enough insulin in the reservoir, see section "Checking the reservoir for remaining insulin".

**OptiSet is damaged or is not working properly**

Do not force it. Do not try to repair nor use tools on it. Use a new OptiSet.

**The amount indicated on the injection button is more than 2 units higher than the dose selected**

OptiSet is damaged, use a new OptiSet