

PACKAGE LEAFLET:
INFORMATION FOR THE USER

Insuman® Comb 15 100 IU/ml suspension for injection in a pre-filled pen

Insulin human

OptiSet®
sanofi aventis

OptiSet® Insulin human 100 IU/ml suspension for injection in a pre-filled pen

Read all of this leaflet carefully including the instructions for use of Insuman Comb 15, pre-filled pen, OptiSet, before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Insuman Comb 15

Insuman Comb 15 is a fluid (suspension) for injection under the skin. The insulin contained in Insuman Comb 15 is made by a biotechnology process and is identical with the body’s own insulin.

In this leaflet:

- What Insuman Comb 15 is and what it is used for
- Before you use Insuman Comb 15
- How to use Insuman Comb 15
- Possible side effects
- How to store Insuman Comb 15
- Further information

1. WHAT INSUMAN COMB 15 IS AND WHAT IT IS USED FOR

Insuman Comb 15 is a fluid (suspension) for injection under the skin. The insulin contained in Insuman Comb 15 is made by a biotechnology process and is identical with the body’s own insulin.

Insuman Comb 15 is an insulin preparation with a gradual onset and long duration of action. It comes in cartridges sealed in disposable pen injectors, OptiSet.

Insuman Comb 15 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 INSUMAN COMB 15

Do not use Insuman Comb 15

If you are allergic (hypersensitive) to insulin or any of the other ingredients of Insuman Comb 15.

Take special care with Insuman Comb 15 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

If you are elderly, speak to your doctor as you may need a lower dose.

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, injection 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,
- what you should do in emergency situations when you feel unwell or become ill.

Illnesses and injuries

In the following situations, the management of your diabetes may require a lot of care:

- 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.** 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.

Using 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 dosage 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 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.

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 the thyroid gland disorders),
- protease inhibitors (used to treat HIV)
- atypical antipsychotic medications (such as olanzapine and clozapine).

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.

Using Insuman Comb 15 with food and drink

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

Pregnancy and breast-feeding

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. However, there is no experience with the use of Insuman Comb 15 in pregnant women.

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 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 machinery). 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.

Important information about some of the ingredients of Insuman Comb 15 This medicinal product contains less than 1 mmol (23 mg) sodium per dose, i.e. it is essentially ‘sodium-free’.

3. HOW TO USE INSUMAN COMB 15

Dosage

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

- determine how much Insuman Comb 15 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 Insuman Comb 15.

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. See the box at the end of this leaflet for further information.

Frequency of administration

Insuman Comb 15 is injected under the skin 30 to 45 minutes before a meal.

Method of administration

Do NOT inject Insuman Comb 15 into a vein. OptiSet delivers insulin in increments of 2 units up to a maximum single dose of 40 units.

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

How to handle OptiSet

Insuman Comb 15 comes in cartridges sealed in disposable pen injectors, OptiSet.

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

A new injection 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.

Mix the insulin well and check it before first use. Later, you must mix the insulin well again immediately before each injection. Mixing is best done by gently tilting the pen back and forth at least 10 times. To assist in mixing, three tiny metal balls are present in the cartridge. After mixing, the suspension must have a uniform milky white appearance. It must not be used if it remains clear or if, for example, clumps, flakes, particles or anything similar are in the suspension or on the sides or bottom of the cartridge in the pen. A new pen with a uniform suspension on mixing must then be used.

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, OptiSet, refer to the Questions and Answers section of the attached OptiSet Instructions for Use, or have it checked by your doctor or pharmacist.

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

Special care before injection

Make sure that neither alcohol nor other disinfectants or other substances contaminate the insulin.

Do not mix insulin with any other medicines. Insuman Comb 15, pre-filled pen, OptiSet, is not designed to allow any other insulin to be mixed in the cartridge. 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

If you use more Insuman Comb 15 than you should

– If you have injected too much **Insuman Comb 15**, 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. For information on the treatment of hypoglycaemia, see box at the end of this leaflet.

If you forget to use Insuman Comb 15

– If you **have missed a dose of Insuman Comb 15** or if you **have not injected enough insulin**, your blood sugar level may become too high (hyperglycaemia).

Check your blood sugar frequently. For information on the treatment of hyperglycaemia, see box at the end of this leaflet.

– Do not take a double dose to make up for a forgotten dose.

If you stop using Insuman Comb 15

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 Insuman Comb 15 without speaking to a doctor, who will tell you what needs to be done.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Insuman Comb 15 can cause side effects, although not everybody gets them.

As with all insulin therapy, the most frequent side effect is **hypoglycaemia (low blood sugar)**. Serious hypoglycaemia may cause a heart attack or brain damage and may be life-threatening. For further information on the side effects of low blood sugar or high blood sugar, see the box at the end of this leaflet.

Severe allergic reactions to insulin may occur which may become life-threatening. Such reactions to insulin or to the excipients can cause 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 heart beat and sweating.

Side effects reported commonly

(Seen in less than 1 in 10 but more than 1 in 100 patients)

- Oedema**

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

- Injection site reactions**

Side effects reported uncommonly

(Seen in less than 1 in 100 but more than 1 in 1000 patients)

- Severe allergic reaction with low blood pressure (shock)**
- Injection site urticaria (itchy rash)**

Other side effects include

- Systemic allergic reactions**

Associated symptoms may include 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 heart beat and sweating.

- 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.

- Skin changes at the injection site (lipodystrophy)**

If you inject your insulin too often at the same skin site, fatty tissue under the skin at this site may either shrink or thicken.

Insulin that you inject in such a site may not work very well. Changing the injection site with each injection may help to prevent such skin changes.



For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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sanofi-aventis Belgium, Tél/Tel.: +32 (0)2 710 54 00
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5. HOW TO STORE INSUMAN COMB 15

Keep out of the reach and sight of children. Do not use Insuman Comb 15 after the expiry date which is stated on the carton and on the label of the cartridge. The expiry date refers to the last day of that month.

Not in-use pens
Store in a refrigerator (2°C – 8°C). Do not freeze. Do not put the pre-filled pen next to the freezer compartment or a freezer pack. Keep the pre-filled pen in the outer carton in order to protect from light.

In-use pens
Pre-filled pens in-use or carried as a spare may be stored for a maximum of 4 weeks not above 25°C away from direct heat (for example next to a heating unit) or direct light (direct sunlight or next to a lamp). The pen in-use must not be stored in a refrigerator. Do not use the pen after this time period. 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.

6. FURTHER INFORMATION

What Insuman Comb 15 contains

– The active substance is insulin human. One ml of Insuman Comb 15 contains 100 IU (International Units) of the active substance insulin human. 15% of the insulin is dissolved in water; the other 85% is present as tiny crystals of insulin protamine.

– The other ingredients are: protamine sulphate, metacresol, phenol, zinc chloride, sodium dihydrogen phosphate dihydrate, glycerol, sodium hydroxide, hydrochloric acid (for pH adjustment) and water for injections.

What Insuman Comb 15 looks like and contents of the pack

After mixing, Insuman Comb 15 is a uniformly milky fluid (suspension for injection), with no clumps, particles or flocculation visible. Insuman Comb 15 is supplied in pre-filled pens, OptiSet, containing 3 ml suspension, (300 IU). Packs of 3, 4, 5, 6, 9 and 10 pens of 3 ml are available. Not all pack sizes may be marketed.

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Detailed information on this medicine is available on the European Medicines Agency (EMA) web site:

<http://www.emea.europa.eu/>

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OptiSet is a disposable pen for the injection of insulin. Doses from 2 to 40 units can be set in steps of 2 units.

Talk with your healthcare professional about proper injection technique before using OptiSet.

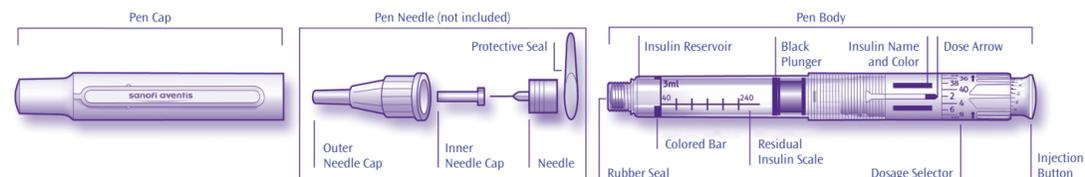
Read these instructions carefully before using your OptiSet. If you are not able to follow all the instructions completely on your own, use OptiSet only if you have help from a person who is able to follow the instructions.

If you have any questions about OptiSet or about diabetes, ask your healthcare professional or call the local sanofi-aventis number on the front of this leaflet.

Keep this leaflet for future reference each time you use OptiSet.

New information for use:

- Name of the insulin is printed on the pen.
- Dosage selector can only be turned in one direction.



Important information for use of OptiSet:

- Always attach a new needle before each use. Only use needles that are compatible for use with OptiSet.
- Always perform the safety test before each injection.
- If you are using a new OptiSet the initial safety test must be done with the 8 units preset by the manufacturer.
- The dosage selector can only be turned in one direction.
- Never turn the dosage selector (i.e. never change the dose) after injection button has been pulled out.
- This pen is only for your use. Do not share it with anyone else.
- If your injection is given by another person, special caution must be taken by this person to avoid accidental needle injury and transmission of infection.
- Never use OptiSet if it is damaged or if you are not sure that it is working properly.
- Always have a spare OptiSet in case your OptiSet is lost or damaged.

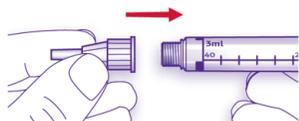
Step 1. Check and mix the insulin

- Take off the pen cap.
- Check the label on the pen and insulin reservoir to make sure you have the correct insulin.
- Mix the insulin by turning OptiSet slowly up and down at least 10 times (do not shake the OptiSet).
- Check the appearance of your insulin. It must have an evenly milky white appearance.

Step 2. Attach the needle

Always use a new sterile needle for each injection. This helps prevent contamination, and potential needle blocks.

- Remove the protective seal from a new needle.
- Line up the needle with the pen, and keep it straight as you attach it (screw or push on, depending on the needle type).



- If the needle is not kept straight while you attach it, it can damage the rubber seal and cause leakage, or the needle can be bent.



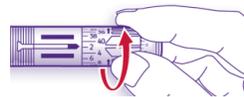
Step 3. Perform a safety test

Always perform the safety test before each injection. This ensures that you get an accurate dose by:

- making sure that pen and needle work properly
- removing air bubbles

If you are using a new OptiSet the initial safety test must be done with the 8 units preset by the manufacturer, otherwise the pen will not function properly.

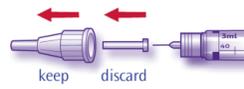
- Make sure the injection button is pressed in.
- Select the dose for the Safety Test.
 - New and unused OptiSet: a dose of 8 units is already preset by the manufacturer for the first safety test.
 - In-use OptiSet: select a dose of 2 units by turning the dosage selector forward till the dose arrow points to 2. The dosage selector will only turn in one direction.



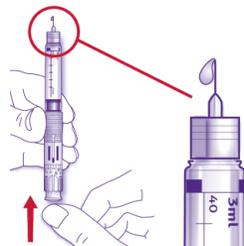
- Pull out the injection button completely in order to load the dose. Never turn the dosage selector after injection button has been pulled out.



- Take off the outer needle cap and keep it to remove the used needle after injection. Take off the inner needle cap and discard it.



- Hold the pen with the needle pointing upwards.
- Tap the insulin reservoir so that any air bubbles rise up towards the needle.
- Press the injection button all the way in. Check if insulin comes out of the needle tip.



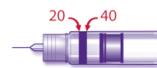
You may have to perform the safety test several times before insulin is seen.

- If no insulin comes out, check for air bubbles and repeat the safety test two more times.
- If still no insulin comes out, the needle may be blocked. Change the needle and try again.
- If no insulin comes out after changing the needle, your OptiSet may be damaged. Do not use this OptiSet.

Step 4. Select the dose

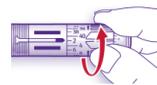
You can set the dose in steps of 2 units, from a minimum of 2 units to a maximum of 40 units. If you need a dose greater than 40 units, you should give it as two or more injections.

- Check if you have enough insulin for your dose.
 - 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.
 - 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.



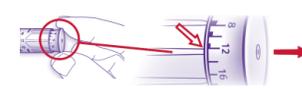
- Select your required dose by turning the dose selector forward.

- If you turned past your dose,
- and you have not yet pulled the injection button, you can keep turning forward till you reach your dose again,
 - and you have already pulled the injection button out, you must discard the dose that has been loaded **before** you turn the dosage selector again.



Step 5. Load the dose

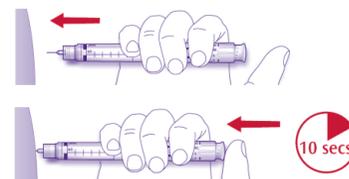
- Pull out the injection button completely in order to load the dose.
- Check if the selected dose is fully loaded. Note that the injection button only goes out as far as the amount of insulin that is left in the reservoir.
 - The injection button must be held out under tension during this check.
 - The last thick line visible on the injection button shows the amount of insulin loaded. When the injection button is held out only the top part of this thick line can be seen.
 - In this example, 12 units are loaded.
 - if you have selected 12 units you can inject your dose.
 - if you have selected more than 12 units then only 12 units of your total insulin dose can be injected with this pen.



- In this case what should you do:
- either you can inject what is remaining in the pen and complete your dose with a new OptiSet.
 - or use a new OptiSet for your full dose.

Step 6. Inject the dose

- Use the injection method as instructed by your health care professional.
- Insert the needle into the skin.
 - Deliver the dose by pressing the injection button in all the way. A clicking sound can be heard, which will stop when the injection button has been pressed in completely.
 - Keep the injection button pressed in and slowly count to 10 before you withdraw the needle from the skin. This ensures that the full dose will be delivered.



Step 7. Remove and discard the needle

Always remove the needle after each injection and store OptiSet without a needle attached.

This helps prevent:

- Contamination and/or infection
 - Entry of air into the insulin reservoir and leakage of insulin, which can cause inaccurate dosing.
- Put the outer needle cap back on the needle, and use it to unscrew the needle from the pen. To reduce the risk of accidental needle injury, never replace the inner needle cap.
 - If your injection is given by another person, special caution must be taken by this person when removing and disposing the needle. Follow recommended safety measures for removal and disposal of needles (e.g. a one handed capping technique) in order to reduce the risk of accidental needle injury and transmission of infectious diseases.

- Dispose of the needle safely, as instructed by your healthcare professional.
- Put the pen cap back on, then store the pen until your next injection.

Storage Instructions

Please check section 5 – How to store Insuman Comb 15 – of the reverse (insulin) side of this leaflet for OptiSet storage instructions.

If your OptiSet is in cool storage, take it out 1 to 2 hours before you inject to allow it to warm up to room temperature. Cold insulin is more painful to inject.

Discard your used OptiSet as required by your local regulations.

Maintenance

Protect your OptiSet from dust and dirt. You can clean the outside of your OptiSet by wiping it with a damp cloth.

Do not soak, wash or lubricate the pen as this may damage it.

Your OptiSet is designed to work accurately and safely. It should be handled with care.

Avoid situations where OptiSet might be damaged.

If you are concerned that your OptiSet may be damaged, discard it and use a new one.

Questions and Answers

Wrong dose selected.

- Follow the instructions in Step 4 to select the correct dose.

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

- Attach a new needle.
 - Press the injection button completely in and discard the insulin.
 - 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.

The dosage selector does not turn.

- You are turning in the wrong direction. The dosage selector can only be turned forward.
- You are turning forward while the injection button is pulled out. Press the injection button in completely to discard the dose and select again.

The amount indicated on the injection button is higher than the dose selected.

- Difference is 2 units. Discard insulin, then set your dose and check again. If the same error occurs again, OptiSet may be damaged, use a new OptiSet.
- Difference is more than 2 units. OptiSet is damaged, use a new OptiSet.

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

- There is not enough insulin in the reservoir
- you can inject the amount indicated on the injection button from this OptiSet and then inject the remaining dose using a new pen, or
 - you can inject the entire dose using a new pen.

The injection button cannot be pressed in.

- Make sure you pulled out the injection button completely.
- Attach a new needle.
- Press the injection button completely in to discard the insulin.
- Perform the safety test.

You don't hear clicking while injecting.

OptiSet is damaged, use a new OptiSet.

Insulin is leaking from the pen.

Needle may have been attached imprecisely (e.g. at a slant). Remove needle and replace with a new needle attaching 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 tapping will not interfere with the injection and dosage.