

Insuman® Basal

100 IU/ml

suspension for injection

in a vial

Insulin human

sanofi aventis

Read all of this leaflet carefully 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.



In this leaflet:

1. What Insuman Basal is and what it is used for
2. Before you use Insuman Basal
3. How to use Insuman Basal
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1. WHAT INSUMAN BASAL IS AND WHAT IT IS USED FOR

Insuman Basal is a fluid (suspension) for injection under the skin. The insulin contained in Insuman Basal is made by a biotechnology process and is identical with the body's own insulin. Insuman Basal is an insulin preparation with a gradual onset and long duration of action. The insulin is present as tiny crystals of insulin protamine. Insuman Basal 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 BASAL

Do not use Insuman Basal

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

Do not inject Insuman Basal into a vein (blood vessel). Do not use it in insulin pumps or other infusion pumps – special insulin preparations are available for use in such devices.

Take special care with Insuman Basal

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

Special patient groups

If you have liver or kidneys problems or 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 the 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 Basal 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 Basal 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 Basal

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 BASAL

Dosage

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

- determine how much Insuman Basal 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 Basal. 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 Basal is injected under the skin 45 to 60 minutes before a meal.

Method of administration

Do NOT inject Insuman Basal into a vein. 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 the vials

Insuman Basal contains 100 IU insulin per ml. Only injection syringes designed for this insulin concentration (100 IU per ml) must be used. The injection syringes must not contain any other medicines or traces of medicines (such as traces of heparin). Before the first withdrawal of insulin you must remove the safety tear-off lid on the vial.

Mix the insulin well immediately before each injection. This is best done by rolling the vial tilted between the palms of the hands. Do not shake the vial vigorously as this could damage the insulin and cause froth to form. Froth can make it difficult for you to measure the correct dose. 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 vial. A new vial with a uniform suspension on mixing must then be used.

Always use a new vial if you notice that your blood sugar control is unexpectedly getting worse. This is because the insulin may have lost some of its effectiveness. If you think you may have a problem with your insulin, have it checked by your doctor or pharmacist.

Special care before injection

Before injection remove any air bubbles. Make sure that neither alcohol nor other disinfectants or other substances contaminate the insulin. Do not mix insulin with any other medicines.

Insuman Basal may be mixed with all Sanofi-Aventis human insulin preparations, EXCEPT those specially designed for use in insulin pumps. Also, it must NOT be mixed with animal source insulins or insulin analogues.

Your doctor will tell you if you have to mix Sanofi-Aventis human insulins. If you need to inject a mixture, draw the other insulin into the injection syringe before Insuman Basal. Inject as soon as you have mixed them. Do not mix insulins of different strengths (for example 100 IU per ml and 40 IU per ml).

Mistakes in dosage

If you use more Insuman Basal than you should

– If you **have injected too much Insuman Basal**, 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 Basal

– If you **have missed a dose of Insuman Basal** 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 Basal

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 Basal 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 Basal 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.

• Skin and allergic reactions

Other mild reactions at the injection site (such as injection site redness, unusually intense pain on injection site, itching, injection site swelling or injection site inflammation) may occur. They can also spread around the injection site. Most minor reactions to insulins usually resolve in a few days to a few weeks. Insulin treatment can cause the body to produce antibodies to insulin (substances that act against insulin). However, only very rarely, this will require a change to your insulin dosage.

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, occurs suddenly or gets worse rapidly.



5. HOW TO STORE INSUMAN BASAL

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

Unopened vials

Store in a refrigerator (2°C – 8°C). Do not freeze. Do not put Insuman Basal next to the freezer compartment or a freezer pack. Keep the vial in the outer carton in order to protect from light.

Opened vials

Once in-use, the vial may be stored for a maximum of 4 weeks not above 25°C in the outer carton away from direct heat (for example next to a heating unit) or direct light (direct sunlight or next to a lamp). Do not use the vial after this time period. It is recommended that the date of the first use be noted on the label.

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 Basal contains

- The active substance is insulin human. One ml of Insuman Basal contains 100 IU (International Units) of the active substance insulin human.
- 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 Basal looks like and contents of the pack

After mixing, Insuman Basal is a uniformly milky fluid (suspension for injection), with no clumps, particles or flocculation visible. Insuman Basal is supplied in vials containing 5 ml suspension (500 IU). Packs of 1 and 5 vials of 5 ml are available. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Detailed information on this medicine is available on the European Medicines Agency (EMA) web site:
<http://www.emea.europa.eu/>

HYPERGLYCAEMIA AND HYPOGLYCAEMIA

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

HYPERGLYCAEMIA (high blood sugar levels) If your blood sugar is too high (hyperglycaemia), you may not have injected enough insulin.

Why does hyperglycaemia occur?

Examples include:

- you have not injected your insulin or not injected enough, or if it has become less effective, for example through incorrect storage,
- you are doing less exercise than usual, you are under stress (emotional distress, excitement), or you have an injury, operation, infection or fever,
- you are taking or have taken certain other medicines (see section 2, “Using other medicines”).

Warning symptoms of hyperglycaemia

Thirst, increased need to urinate, tiredness, dry skin, reddening of the face, loss of appetite, low blood pressure, fast heart beat, and glucose and ketone bodies in urine. 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.

What should you do if you experience hyperglycaemia

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

HYPOGLYCAEMIA (low blood sugar levels)

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.

Why does hypoglycaemia occur?

Examples include:

- 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 are doing more 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 an illness or from fever,
- you are taking or have stopped taking certain other medicines (see section 2, “Using other medicines”).

Hypoglycaemia is also more likely to occur if:

- you have just begun insulin 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 insulin (for example from the thigh to the upper arm),
- you suffer from severe kidney or liver disease, or some other disease such as hypothyroidism.

Warning symptoms of hypoglycaemia

- In your body
 - Examples of symptoms that tell you that your blood sugar level is falling too much or too fast: sweating, clammy skin, anxiety, fast heart beat, high blood pressure, palpitations and irregular heart beat. These symptoms often develop before the symptoms of a low sugar level in the brain.
- In your brain
 - Examples of symptoms that indicate a low sugar level in the brain: 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 suffer from a certain type of nervous disease (diabetic autonomic neuropathy),
- you have recently suffered hypoglycaemia (for example the day before) or if it develops slowly,
- you have almost normal or, at least, greatly improved blood sugar levels,
- you have recently changed from an animal insulin to a human insulin such as Insuman,
- you are taking or have taken certain other medicines (see section 2, “Using other medicines”).

In such a case, you may develop severe hypoglycaemia (and even faint) before you are aware of the problem. Be familiar with your warning symptoms.

If necessary, more frequent blood sugar testing can help to identify mild hypoglycaemic episodes that may otherwise be overlooked. If you are not confident about recognising your warning symptoms, avoid situations (such as driving a car) in which you or others would be put at risk by hypoglycaemia.

What should you do if you experience hypoglycaemia

- Do not inject insulin. Immediately take about 10 to 20 g sugar, such as glucose, sugar cubes or a sugar-sweetened beverage. Caution: Artificial sweeteners and foods with artificial sweeteners (such as diet drinks) are of no help in treating hypoglycaemia.
- Then eat something that has a long-acting effect in raising your blood sugar (such as bread or pasta). Your doctor or nurse should have discussed this with you previously.
- If the hypoglycaemia comes back again take another 10 to 20g sugar.
- Speak to a doctor immediately if you are not able to control the hypoglycaemia or if it recurs.

Tell your relatives, friends and close colleagues the following:

If you are not able to swallow or if you are unconscious, you will require an injection of glucose or glucagon (a medicine which increases blood sugar). These injections are justified even if it is not certain that you have hypoglycaemia.

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