

Package leaflet: Information for the user

Insuman[®] Rapid

100 IU/ml solution for injection in a cartridge

insulin human

<p>Read all of this leaflet carefully before you start using this medicine because it contains important information for you. The instructions for using the insulin pen are provided with your insulin pen. Refer to them before using your medicine.</p> <ul style="list-style-type: none">– Keep this leaflet. You may need to read it again. – If you have any further questions, ask your doctor, pharmacist or a nurse. – This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours. – If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
--

What is in this leaflet

- What Insuman Rapid is and what it is used for
- What you need to know before you use Insuman Rapid
- How to use Insuman Rapid
- Possible side effects
- How to store Insuman Rapid
- Contents of the pack and other information

1. What Insuman Rapid is and what it is used for

Insuman Rapid contains the active substance insulin human which is made by a biotechnology process and is identical with the body’s own insulin. Insuman Rapid is an insulin solution with a rapid onset and short duration of action.

Therapeutic indications

Insuman Rapid is used to reduce high blood sugar in patients with diabetes mellitus who need treatment with insulin. Diabetes mellitus is a disease where your body does not produce enough insulin to control the level of blood sugar. Insuman Rapid may also be used for treating hyperglycaemic coma (coma caused by too much blood sugar) and ketoacidosis (build-up of acid in the blood because the body is breaking down fat instead of sugar) as well as for controlling blood sugar before, during and after surgery.

2. What you need to know before you use Insuman Rapid

Contraindications

Do not use Insuman Rapid

If you are allergic to insulin or any of the other ingredients of this medicine (listed in section 6).

Precautions for use: special warnings

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Insuman Rapid.

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

If you are allergic to this medicine or to animal insulins, talk to 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. Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who were treated with pioglitazone and insulin experienced the development of heart failure. Inform your doctor as soon as possible if you experience signs of heart failure such as unusual shortness of breath or rapid increase in weight or localised swelling (oedema).

Other medicines and Insuman Rapid

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 dose 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, have recently taken or might take any other medicines. 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 orhigh 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], salbutamol, terbutaline used to treat asthma),
- thyroid hormones (used to treat the thyroid gland disorders),
- protease inhibitors (used to treat HIV),
- atypical antipsychotic medicines (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.

Insuman Rapid with alcohol

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Inform your doctor if you are planning to become pregnant, or if you are already pregnant. Your insulin dose 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 Rapid 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 using machines). 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 Rapid

This medicine contains less than 1 mmol (23 mg) sodium per dose, i.e. it is essentially “sodium-free”.

3. How to use Insuman Rapid
Dose
Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Based on your life-style and the results of your blood sugar (glucose) tests, your doctor will: <ul style="list-style-type: none">– determine how much Insuman Rapid 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 Rapid. 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 Rapid is injected under the skin 15 to 20 minutes before a meal.
Method of administration
Insuman Rapid is a solution for injection under the skin or, in exceptional circumstances, into a vein (blood vessel). 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. Insulin administration into a vein for example to treat severe hyperglycaemia and ketoacidosis, requires experience and special safety precautions. For these reasons, it must be done in a clinic or a similar setting. Do not use Insuman Rapid in insulin pumps - special insulin preparations are available for use in such devices. Also do not use it in peristaltic pumps with silicone tubing.

How to handle the cartridges
The Insuman Rapid cartridges are to be used only in conjunction with the pens OptiPen, CliKSTAR, Tactipen, Autopen 24 or AllStar to ensure you get the correct dose. Not all of these pens may be marketed in your country. The pen should be used as recommended in the information provided by the device manufacturer. The manufacturer’s instructions for using the pen must be followed carefully for loading the cartridge, attaching the injection needle, and administering the insulin injection. Keep the cartridge at room temperature for 1 or 2 hours before inserting it into the pen. Look at the cartridge before you use it. Only use it if the solution is clear, colourless, with no solid particles visible, and has a water-like consistency.

Special care before injection
Before injection remove any air bubbles (see instructions for using the pen). Make sure that neither alcohol nor other disinfectants or other substances contaminate the insulin.

- Do not re-fill and re-use empty cartridges.
- Do not add any other insulin to the cartridge.
- Do not mix Insuman Rapid with any other medicines.

Problems with the pen?
Refer to the manufacturer’s instructions for using the pen.
If the insulin pen is damaged or not working properly (due to mechanical defects) it has to be discarded, and a new insulin pen has to be used.
If the pen does not function well, you can draw the insulin from the cartridge into an injection syringe. Therefore, keep injection syringes and needles as well. However, use only those injection syringes which are designed for an insulin concentration of 100 IU (International Units) per ml.

If you use more Insuman Rapid than you should
– If you **have injected too much Insuman Rapid**, 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 Rapid
– If you **have missed a dose of Insuman Rapid** 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 Rapid
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 Rapid 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 medicine, ask your doctor, pharmacist or nurse.

Insulin Mix-ups

You must always check the insulin label before each injection to avoid mix-ups between Insuman Rapid and other insulins.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them. <p><u>Most serious side effects</u></p> Side effects reported uncommonly (may affect up to 1 in 100 people) <ul style="list-style-type: none">• Severe allergic reaction with low blood pressure (shock) Side effects reported with a frequency not known (cannot be estimated from the available data) <ul style="list-style-type: none">• 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 (angiooedema), shortness of breath, a fall in blood pressure with rapid heart beat and sweating. <u>Other side effects</u> Side effects reported commonly (may affect up to 1 in 10 people) <ul style="list-style-type: none">• 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

- Injection site urticaria (itchy rash)

Side effects reported with a frequency not known

- Sodium retention

- 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 antibodies

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 dose.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Insuman Rapid

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the carton and on the label of the cartridge after “EXP”. The expiry date refers to the last day of that month.

Unopened cartridges

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

HYPERGLYCAEMIA AND HYPOGLYCAEMIA

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

- 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, “Other medicines and Insuman Rapid”).

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 heartbeat. 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);

In-use cartridges

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Insuman Rapid contains

– The active substance is insulin human. One ml of Insuman Rapid contains 100 IU (International Units) of the active substance insulin human.
– The other ingredients are: metacresol, sodium dihydrogen phosphate dihydrate, glycerol, sodium hydroxide (see section 2 under “Important information about some of the ingredients of Insuman Rapid”), hydrochloric acid (for pH adjustment) and water for injections.

What Insuman Rapid looks like and contents of the pack

Insuman Rapid is a clear, colourless solution for injection, with no solid particles visible, and of a water-like consistency.

Insuman Rapid is supplied in cartridges containing 3 ml solution (300 IU). Packs of 3, 4, 5, 6, 9 and 10 cartridges of 3 ml are available. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Sanofi-Aventis Deutschland GmbH
D-65926 Frankfurt am Main
Germany

This leaflet was last revised in September 2013

– 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, “Other medicines and Insuman Rapid”).

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 20 g 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.