Package leaflet: Information for the user

Octreotide 50 micrograms/ml solution for injection
Octreotide 100 micrograms/ml solution for injection
Octreotide 500 micrograms/ml solution for injection

Octreotide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or 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

1. What Octreotide is and what it is used for

Octreotide is a synthetic compound derived from somatostatin, a substance normally found in the human body which inhibits the effects of certain hormones such as growth hormone. The advantages of Octreotide over somatostatin are that it is stronger and its effects last longer.

Octreotide is used:
- in **acromegaly**, a condition where the body produces too much growth hormone. Normally, growth hormone controls growth of tissues, organs, and bones. Too much growth hormone leads to an increase in the size of bones and tissues, especially in the hands and feet. Octreotide markedly reduces the symptoms of acromegaly, which include headache, excessive perspiration, numbness of the hands and feet, tiredness, and joint pain.
- to relieve symptoms associated with some tumours of the gastrointestinal tract (e.g. carcinoid tumours, VIPomas, glucagonomas, gastrinomas, insulinomas). In these conditions, there is overproduction of some specific hormones and other related substances by the stomach, bowels, or pancreas. This overproduction upsets the natural hormonal balance of the body and results in a variety of symptoms, such as flushing, diarrhoea, low blood pressure, rash, and weight loss.
- Treatment with Octreotide helps to control these symptoms.
- to prevent complications following surgery of the pancreas gland. Treatment with Octreotide helps to lower the risk of complications (e.g. abscess in the abdomen, inflammation of the pancreas gland) after the surgery.
- to stop bleeding and to protect from re-bleeding from ruptured gastro-oesophageal varices in patients suffering from cirrhosis (chronic liver disease). Treatment with Octreotide helps to control bleeding and reduce transfusion requirements.
- to treat pituitary tumours that produce too much thyroid-stimulating hormone (TSH). Too much thyroid-stimulating hormone (TSH) leads to hyperthyroidism.
  Octreotide is used to treat people with pituitary tumours that produce too much thyroid-stimulating hormone (TSH):
  - when other types of treatment (surgery or radiotherapy) are not suitable or have not worked;
  - after radiotherapy, to cover the interim period until the radiotherapy becomes fully effective.

2. What you need to know before you use Octreotide

Do not use Octreotide:

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

Warnings and precautions
Talk to your doctor before using Octreotide:
- If you know that you have gallstones now, or have had them in the past; tell your doctor, as prolonged use of Octreotide may result in gallstones formation. Your doctor may wish to check your gallbladder periodically.
- If you have problems with your blood sugar levels, either too high (diabetes) or too low (hypoglycaemia). When Octreotide is used to treat bleeding from gastro-oesophageal varices; monitoring of blood sugar level is mandatory.
- If you have a history of vitamin B12 deprivation your doctor may wish to check your vitamin B12 level periodically.

Test and checks
If you receive treatment with Octreotide over a long period of time, your doctor may wish to check your thyroid function periodically.

Your doctor will check your liver function.

Children
There is little experience with the use of Octreotide in children.

Other medicines and Octreotide
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

You can generally continue using other medicines while on Octreotide. However, certain medicines, such as cimetidine, ciclosporin, bromocriptine, quinidine and terfenadine have been reported to be affected by Octreotide.

If you are taking a medicine to control your blood pressure (e.g. a beta blocker or a calcium channel blocker) or an agent to control your fluid and electrolyte balance, your doctor may need to adjust the dosage.

If you are diabetic, your doctor may need to adjust your insulin dosage.

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.

Octreotide should only be used during pregnancy if clearly needed.

Women of child-bearing age should use an effective contraceptive method during treatment.

Do not breast-feed while using Octreotide. It is not known whether Octreotide passes into breast milk.

Driving and using machines
Octreotide has no or negligible effects on the ability to drive and use machines. However, some of the side effects you may experience while using Octreotide, such as headache and tiredness, may reduce your ability to drive and use machines safely.

3. How to use Octreotide

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Depending on the condition being treated, Octreotide is given by:
- subcutaneous (under the skin) injection or
- intravenous (into a vein) infusion.

If you have liver cirrhosis (chronic liver disease), your doctor may need to adjust your maintenance dose.

Your doctor or nurse will explain to you how to inject Octreotide under the skin, but infusion into a vein must always be performed by a healthcare professional.

- **Subcutaneous injection**

The upper arms, thighs, and abdomen are good areas for subcutaneous injection.

Choose a new site for each subcutaneous injection so that you do not irritate a particular area. Patients who will be injecting themselves must receive precise instructions from the doctor or nurse.

If you store the medicine in the refrigerator, it is recommended that you allow it to reach room temperature before using it. This will reduce the risk of pain at the site of injection. You can warm it up in your hand but do not heat it.

A few people experience pain at the site of the subcutaneous injection. This pain usually only lasts a short time. If this happens to you, you can relieve this by gently rubbing the site of injection for a few seconds afterwards.

Before using an Octreotide vial, check the solution for particles or a change of colour. Do not use it if you see anything unusual.

If you use more Octreotide than you should
No life-threatening reactions have been reported after overdose of Octreotide.
The symptoms of overdose are: irregular heart beat, low blood pressure, cardiac arrest, reduced supply of oxygen to the brain, severe upper stomach pain, yellow skin and eyes, nausea, loss of appetite, diarrhoea, weakness, tiredness, lack of energy, weight loss, abdominal swelling, discomfort and high level of lactic acid in the blood.

If you think that an overdose has happened and you experience such symptoms, tell your doctor straight away.

If you forget to use Octreotide
Administer one dose as soon as you remember, and then continue as usual. It will not do any harm if you miss a dose, but you could get some temporary re-appearance of symptoms until you get back on schedule.

Do not inject a double dose of Octreotide to make up for forgotten individual doses.

If you stop using Octreotide
If you interrupt your treatment with Octreotide your symptoms may come back. Therefore, do not stop using Octreotide unless your doctor tells you to.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects could be serious. Tell your doctor straight away if you get any of the following:

Very common (may affect more than 1 in 10 people):
- Gallstones, leading to sudden back pain.
- Too much sugar in the blood.

The following information is intended for healthcare professionals only:

- **Intravenous infusion (for health-care professionals)**

Octreotide (octreotide acetate) is physically and chemically stable for 24 hours in sterile physiological saline solutions. Because Octreotide can affect glucose homeostasis, it is recommended that physiological saline solutions be used rather than dextrose. The diluted solutions are physically and chemically stable for at least 24 hours below 25°C. From a microbiological point of view, the diluted solution should preferably be used immediately. If the solution is not used immediately, storage prior to use is the responsibility of the user and should be at 2 to 8 °C. Before administration the solution has to be brought to room temperature again.

The total time between dilution with infusion media, storage in a refrigerator, and end of administration must not be longer than 24 hours.

When Octreotide is to be administered as intravenous infusion, the contents of one 0.5 mg vial should normally be dissolved in 60 mL physiological saline, and the resulting solution should be infused by means of an infusion pump. This should be repeated as often as necessary until the prescribed duration of treatment is reached.

Before using an Octreotide vial, check the solution for particles or a change of colour. Do not use it if you see anything unusual.

- **Subcutaneous administration**

For subcutaneous use Octreotide Kabi should not be diluted.

Common (may affect up to 1 in 10 people):
- Underactive thyroid gland (hypothyroidism) causing changes in heart rate, appetite or weight; tiredness, feeling cold, or swelling at the front of the neck.
- Changes in thyroid function tests.
- Inflammation of the gallbladder (cholecystitis); symptoms may include pain in the upper right abdomen, fever, nausea, yellowing of the skin and eyes (jaundice).
- Too little sugar in the blood
- Impaired glucose tolerance.
- Slow heart beat.

Uncommon (may affect up to 1 in 100 people):
- Thirst, low urine output, dark urine, dry flushed skin.
- Fast heart beat.

Other serious side effects
- Hypersensitivity (allergic) reactions including skin rash.
- A type of an allergic reaction (anaphylaxis) which causes difficulty in breathing or dizziness.
- An inflammation of the pancreas gland (pancreatitis); symptoms may include sudden pain in the upper abdomen, nausea, vomiting, diarrhoea.;
- Liver inflammation (hepatitis); symptoms may include yellowing of the skin and eyes (jaundice), nausea, vomiting, loss of appetite, generally feeling unwell, itching, light-coloured urine.
- Irregular heart beat.

Tell your doctor straight away if you notice any of the side effects above.

Other side effects:
Tell your doctor, pharmacist or nurse if you notice any of the side effects listed below. They are usually mild and tend to disappear as treatment progresses.

Very common (may affect more than 1 in 10 people):
- Diarrhoea.
- Abdominal pain.
- Nausea.
- Constipation.
- Flatulence (wind).
- Headache.
- Local pain at the injection site.

Common (may affect up to 1 in 10 people):
- Stomach discomfort after meal (dyspepsia).
- Vomiting.
- Feeling of fullness in the stomach.
- Fatty stools.
- Loose stools.
- Discolouration of faeces.
- Dizziness.
- Loss of appetite.
- Change in liver function tests.
- Hair loss.
- Shortness of breath.
- Weakness.

If you get any side effects, please tell your doctor, nurse or pharmacist.

A few people experience pain at the site of the subcutaneous injection. This pain usually only lasts a short time. If this happens to you, you can relieve this by gently rubbing the site of injection for a few seconds afterwards.

If you are administering Octreotide by subcutaneous injection, it may help to reduce the risk of gastrointestinal side effects if you avoid eating meals around the time of injection. It is therefore recommended that you inject Octreotide between meals or when you go to bed.

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. You can also report side effects directly via the national reporting system listed below:

For UK - You can report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

For Ireland – You can report side effects directly via;
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

For Malta - Healthcare professionals are asked to report any suspected adverse reactions to The Medicines
Authority at the following contact details;
ADR Reporting,
The Medicines Authority
Post-Licensing Directorate
203 Level 3, Rue D'Argens
GŻR-1368 Gżira
Website: www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt

5. How to store Octreotide

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 label after "**EXP**". The expiry date refers to the last day of that month.

Store the vial in a refrigerator (2 °C to 8 °C).

For day-to-day use unopened vials may be stored **at room temperature for up to two weeks.**

Keep the vial in the outer carton in order to protect from light.
For single use only.

Diluted solution: Chemical and physical in-use stability of the diluted solution has been demonstrated for 24 hours at room temperature. From a microbiological point of view, the product should be used immediately after it is diluted. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

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 Octreotide contains

- The active substance is octreotide as octreotide acetate.
- Octreotide is available in three different strenghts:
  50 micrograms/ml: One vial of 1 ml solution for injection contains octreotide acetate equivalent to 50 micrograms octreotide.
  100 micrograms/ml: One vial of 1 ml solution for injection contains octreotide acetate equivalent to 100 micrograms octreotide.
  500 micrograms/ml: One vial of 1 ml solution for injection contains octreotide acetate equivalent to 500 micrograms octreotide.
- The other ingredients are: (S)-lactic acid, sodium hydrogen carbonate (for pH adjustment), mannitol, water for injections.

What Octreotide solution for injection looks like and contents of the pack

Octreotide solution for injection is a clear, colourless to slightly brownish solution.

Pack sizes:
1 vial.
5 vials.
30 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Fresenius Kabi Limited
Cestrian Court, Eastgate Way,
Manor Park, Runcorn,
Cheshire,
WA7 1NT
UK

Manufacturer
Fresenius Kabi Deutschland GmbH
Else-Kröner-Straße 1
61352 Bad Homburg v.d.H.
Germany
Tel.: 06172-686 0

This medicinal product is authorised in the Member States of the EEA under the following names:

Octreotide 0.05 mg/ml	
Belgium	Octreotide Fresenius Kabi 0,05 mg/ml
Czech Republic	Octreotide Kabi 0,05 mg/ml
Denmark	Octreotide Fresenius Kabi
France	Octreotide Kabi 50 microgrammes/1 ml, solution injectable
Germany	Octreotid Kabi 0,05 mg/ml Injektionslösung
Greece	Octreotide Kabi
Ireland	Octreotide 50 micrograms/ml solution for injection
Italy	Octreotide Kabi 0,05 mg/ml soluzione iniettabile
Luxembourg	Octreotid Kabi 0,05 mg/ml Injektionslösung
Malta	Octreotide 50 micrograms/ml solution for injection
Netherlands	Octreotide Fresenius Kabi 0,05 mg/ml
Norway	Octreotide Fresenius Kabi
Poland	Octreotide Kabi
Portugal	OCTREOTIDO KABI
Slovenia	Oktreotid Kabi 0,05 mg/ml raztopina za injiciranje
Spain	Octreotida 50 microgramos/ml solución inyectable EFG
Sweden	Octreotide Fresenius Kabi
United Kingdom	Octreotide 50 micrograms/ml solution for injection

Octreotide 0.1 mg/ml	
Belgium	Octreotide Fresenius Kabi 0,1 mg/ml
Bulgaria	Octreotide Kabi 0,1 mg/ml инжекционен разтвор
Czech Republic	Octreotide Kabi 0,1 mg/ml
Denmark	Octreotide Fresenius Kabi
France	Octreotide Kabi 100 microgrammes/1 ml, solution injectable
Germany	Octreotid Kabi 0,1 mg/ml Injektionslösung
Greece	Octreotide Kabi
Ireland	Octreotide 100 micrograms/ml solution for injection
Italy	Octreotide Kabi 0,1 mg/ml soluzione iniettabile
Luxembourg	Octreotid Kabi 0,1 mg/ml Injektionslösung
Malta	Octreotide 100 micrograms/ml solution for injection
Netherlands	Octreotide Fresenius Kabi 0,1 mg/ml
Norway	Octreotide Fresenius Kabi
Poland	Octreotide Kabi
Portugal	OCTREOTIDO KABI
Romania	Octreotid Kabi 0,1 mg/ml soluție injectabilă
Slovak Republic	Octreotide Kabi 0,1 mg/ml
Slovenia	Oktreotid Kabi 0,1 mg/ml raztopina za injiciranje
Spain	Octreotida 100 microgramos/ml solución inyectable EFG
Sweden	Octreotide Fresenius Kabi
United Kingdom	Octreotide 100 micrograms/ml solution for injection

Octreotide 0.5 mg/ml	
Belgium	Octreotide Fresenius Kabi 0,5 mg/ml
Czech Republic	Octreotide Kabi 0,5 mg/ml
Denmark	Octreotide Fresenius Kabi
France	Octreotide Kabi 500 microgrammes/1 ml, solution injectable
Germany	Octreotid Kabi 0,5 mg/ml Injektionslösung
Greece	Octreotide Kabi
Ireland	Octreotide 500 micrograms/ml solution for injection
Italy	Octreotide Kabi 0,5 mg/ml soluzione iniettabile
Luxembourg	Octreotid Kabi 0,5 mg/ml Injektionslösung
Malta	Octreotide 500 micrograms/ml solution for injection
Netherlands	Octreotide Fresenius Kabi 0,5 mg/ml
Norway	Octreotide Fresenius Kabi
Poland	Octreotide Kabi
Portugal	OCTREOTIDO KABI
Slovak Republic	Octreotide Kabi 0,5 mg/ml
Slovenia	Oktreotid Kabi 0,5 mg/ml raztopina za injiciranje
Spain	Octreotida 500 microgramos/ml solución inyectable EFG
Sweden	Octreotide Fresenius Kabi
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FRESENIUS KABI

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How much Octreotide to use

The dose of Octreotide depends on the condition being treated.
- Acromegaly

Treatment is usually started at 0.05 to 0.1 mg every 8 or 12 hours by subcutaneous injection. It is then changed according to its effect and relief of symptoms (such as tiredness, sweating and headache). In most patients the optimal daily dose will be 0.1 mg 3 times/day. A maximum dose of 1.5 mg/day should not be exceeded.

- **Tumours of the gastrointestinal tract**

Treatment is usually started at 0.05 mg once or twice a day by subcutaneous injection. Depending on response and tolerability, the dosage can be gradually increased to 0.1 mg to 0.2 mg 3 times/day. In carcinoid tumours, therapy should be discontinued if there is no improvement after 1 week of treatment at the maximum tolerated dose.

- **Complications following pancreatic surgery**

The usual dosage is 0.1 mg 3 times/day by subcutaneous injection for 1 week, starting at least 1 hour before surgery.

- **Bleeding gastro-oesophageal varices**

The recommended dosage is 25 micrograms/hour for 5 days by continuous intravenous infusion. Monitoring of blood sugar level is necessary during treatment.

- **TSH-secreting pituitary adenomas**

The dosage most generally effective is 100 micrograms three times a day by subcutaneous injection. The dose can be adjusted according to the responses of TSH and thyroid hormones. At least 5 days of treatment will be needed to judge the efficacy.

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