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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 200 micrograms/ml solution for injection

octreotide

Read all of this leaflet carefully before you start taking 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 or pharmacist.
- 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 or pharmacist. 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 or 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 or experience any complications like fever, chills, abdominal pain, or yellowing of your skin or eyes; tell your doctor, as prolonged use of Octreotide may result in gallstone 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.

Octreotide may lower your heart rate and at very high doses may cause abnormal heart rhythm. Your doctor may monitor your heart rate during treatment.

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.

Your doctor may wish to check your pancreatic enzyme 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 taking, have recently taken or might take any other medicines.

You can generally continue taking 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.

If you are going to receive lutetium (177Lu) oxodotreotide, a radiopharmaceutical therapy, your doctor may stop and/or adapt octreotide treatment.

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.

Octreotide contains sodium
This medicinal product contains less than 1 mmol (23 mg) sodium per ml solution, i.e. essentially 'sodium-free'.

3. How to use Octreotide

Always use this medicine exactly as your doctor 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 health care 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 a Octreotide ampoule, check the solution for particles or a change of colour. Do not use it if you see anything unusual.

To prevent contamination the cap of the multidose vials should be punctured not more than 10 times.

If you use more Octreotide than you should
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
- high level of lactic acid in the blood
- abnormal heart rhythm.

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 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.

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The following information is intended for healthcare professionals only:

Intravenous infusion (for healthcare professionals)

Incompatibilities
This medicinal product must not be mixed with other medicinal products except those mentioned in section special precautions for disposal and other handling.

Special precautions for storage

Ampoules:
Store in a refrigerator (2 - 8 ° C). Do not freeze. Keep the ampoules in the outer carton in order to protect from light.
Ampoules may also be stored at 25 °C for up to two weeks.

Multidose vials:
Store in a refrigerator (2 - 8 ° C). Do not freeze. Keep the vial in the outer carton in order to protect from light.
Vials may also be stored at 25 °C for up to two weeks.

Special precautions for disposal and other handling

Ampoules:
Ampoules should be opened immediately prior to use and any unused solution should be discarded.

To reduce local discomfort, let the solution reach room temperature before injection. Avoid multiple injections at short intervals at the same site.

Administration by the subcutaneous route:
Octreotide should be administered by the subcutaneous route without dilution.

Administration by the intravenous route:
For i.v. use octreotide should be diluted with normal saline to a ratio of not less than 1 vol : 1 vol and not more than 1 vol : 9 vol. Since octreotide can affect glucose homeostasis, it is recommended that physiological saline solutions be used rather than dextrose.

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.

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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 swallowing or breathing, swelling and tingling, possibly with a drop in blood pressure with dizziness or loss of consciousness
- 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
- low level of platelet count in blood; this could result in increased bleeding or bruising.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard
By reporting side effects you can help provide more information on the safety of this medicine.

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. The expiry date refers to the last day of that month.

Store the ampoules and multidose vial in a refrigerator (2°C - 8°C). Do not freeze. Keep the ampoules and vials in the outer carton in order to protect from light.

Unopened Octreotide ampoules or vials may be stored for a maximum of 2 weeks below 25°C and in the original pack.

Once in use, a multidose vial may be stored for a maximum of 2 weeks stored in a refrigerator (2 - 8 °C) and in the original pack. You can use your multidose vial up to 10 times and you must return any remainder to your pharmacist if you have not used it within two weeks.

Chemical and physical in-use stability of the diluted solution has been demonstrated for 8 hours at 25°C. From a microbiological point of view, the product should be used immediately after dilution. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

If your doctor decides to stop your treatment, return any leftover medicine to the pharmacist. Only keep it if your doctor tells you to.

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 to protect the environment.

6. Content of the pack and other information

What Octreotide contains

The active substance is octreotide, as octreotide acetate.

One ampoule of 1 ml solution for injection contains octreotide acetate equivalent to 0.05 milligrams, 0.1 milligrams, 0.5 milligrams octreotide.

One multidose vial of 5 ml solution for injection contains octreotide acetate equivalent to 1 milligram octreotide. 1 ml of solution contains 0.2 milligrams octreotide

The other ingredients are: sodium acetate trihydrate, acetic acid, glacial, sodium chloride, water for injection, phenol (for the multidose vial only).

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

This medicinal product is presented as a clear colourless solution for injection.
Pack size of 5, 10 or 30 ampoules of 1 ml solution
Pack size of 1, 10 or 30 multidose vials of 5 ml solution.

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer
Sun Pharmaceutical Industries Europe B.V.
Polarisavenue 87
2132 JH Hoofddorp
The Netherlands

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Denmark:	Octreotid SUN 0,05, 0,1, 0,5 mg/1ml, 1 mg/5ml injektionsvæske, opløsning
Germany:	Octreotid SUN 0,05, 0,1, 0,5 mg/1ml, 1 mg/5ml Injektionslösung
Italy:	Octreotide SUN 0,05, 0,1, 0,5 mg/1ml, 1 mg/5 ml soluzione iniettabile
Spain:	Octreotida SUN 100 microgramos/ml solución inyectable EFG
Sweden:	Oktreotid SUN 50, 100, 200, 500 mikrogram/ml injektionsvätska, lösning
United Kingdom (Northern Ireland):	Octreotide 50, 100, 200, 500 micrograms/ml Solution for Injection

This leaflet was last revised in June 2022.

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Multidose vials:
Octreotide 200 µg /ml should only be administered by the subcutaneous route.

Octreotide should be administered by the subcutaneous route without dilution.

To prevent contamination, it is recommended to puncture the cap of the vial not more than 10 times. To reduce local discomfort, let the solution reach room temperature before injection. Avoid multiple injections at short intervals at the same site.

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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