


Tipo di materiale ISTRUZIONE PIEGATA		Descrizione OCTREOTIDE Solution		LINEA	Destinazione SUBMISSION	Paese UK	Codice	 Fotocompositore		
Formato mm 199 x 590/37	Disegno	N. colori 1	Colore 1 BLACK	Colore 2	Colore 3	Colore 4	TIPO CARTA	TACCHE LAETUS	Corpo 10	

22-02-23

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Package leaflet: Information for the user

OCTREOTIDE CHEMI 50 micrograms /ml,
 Solution for injection in prefilled syringe
OCTREOTIDE CHEMI 100 micrograms /ml,
 Solution for injection in prefilled syringe
OCTREOTIDE CHEMI 500 micrograms /ml,
 Solution for injection in prefilled syringe
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 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 Chemi is and what it is used for.
2. What you need to know before you use Octreotide Chemi.
3. How to use Octreotide Chemi.
4. Possible side effects.
5. How to store Octreotide Chemi.
6. Contents of the pack and other information.

1. What Octreotide Chemi is and what it is used for

Octreotide Chemi 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 Chemi over somatostatin are that it is stronger and its effects last longer.

Octreotide Chemi 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 Chemi 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 Chemi helps to control these symptoms.
- to prevent **complications following surgery of the pancreas gland**. Treatment with Octreotide Chemi helps lower 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 Chemi 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 Chemi 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 Chemi
Do not use Octreotide Chemi

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

Warnings and precautions

Talk to your doctor before taking Octreotide Chemi:

- if you know that you have gallstones now, or have had them in the past; tell your doctor, as prolonged use of Octreotide Chemi 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 Chemi 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 Chemi 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 Chemi in children.

Other medicines and Octreotide Chemi

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 Chemi. However, certain medicines, such as cimetidine, ciclosporin, bromocriptine, quinidine and terfenadine have been reported to be affected by Octreotide Chemi.

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 a planning to have a baby, ask your doctor for advice before taking this medicine.

Octreotide Chemi 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 Chemi. It is not known whether Octreotide Chemi passes into breast milk.

Driving and using machines

Octreotide Chemi 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 Chemi, such as headache and tiredness, may reduce your ability to drive and use machines safely.

Octreotide Chemi contains sodium

Octreotide Chemi contains less than 1 mmol sodium (23 mg) per dose, which means it is essentially “sodium-free”.

3. How to use Octreotide Chemi

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 Chemi 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 Chemi 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 Chemi ampoule, check the solution for particles or a change of colour. Do not use it if you see anything unusual.

If you use more Octreotide Chemi 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 and high level of lactic acid in the blood and 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 Chemi

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 Chemi to make up for forgotten individual doses.

If you stop using Octreotide Chemi

If you interrupt your treatment with Octreotide Chemi your symptoms may come back. Therefore, do not stop using Octreotide Chemi 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.

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.

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- 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 can cause 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 Chemi 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 Chemi 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, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Octreotide Chemi

- Store in a refrigerator (2°C to 8°C).
- For day by day use the product may be stored below 30°C for up to 30 days.
- Do not freeze. Store in the original package in order to protect the product from light.
- After dilution in sodium chloride 0.9% solution when stored in glass bottles: chemical and physical in-use stability has been demonstrated for 24 hours at 25°C. From a microbiological point of view, the product should be used immediately.

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

Do not use this medicine if you notice particles or anything unusual in the appearance of the solution.

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. Contents of the pack and other information

What Octreotide Chemi contains

- The active substance is octreotide as octreotide acetate
 - The other ingredients are: (S)- Lactic acid, Sodium Chloride, Sodium Hydroxide and Water for Injections.
- Each prefilled syringe with 1 ml of solution for injection contains 50 micrograms of octreotide as octreotide acetate.
 Each prefilled syringe with 1 ml of solution for injection contains 100 micrograms of octreotide as octreotide acetate.
 Each prefilled syringe with 1 ml of solution for injection contains 500 micrograms of octreotide as octreotide acetate

What Octreotide Chemi looks like and content of the pack.

The medicinal product is available as prefilled syringes containing 1 ml of a clear, colourless solution for injection. Packs of 5, 6 or 30 prefilled syringes in thermoformed white, opaque PVC blister, sealed with an aluminium foil. Not all pack sizes may be marketed.

Marketing Authorisation Holder

To be completed nationally

Manufacturer

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This leaflet was last revised in September 2021

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

Italia: Octreotide Chemi 50 - 100 - 500 microgrammi/ml soluzione iniettabile in siringa preriempita
 Germany: Octreotid-hameln 50 - 100 - 500 Mikrogramm/ml Injektionslösung
 UK: OCTREOTIDE 50 - 100 - 500 micrograms /ml, Solution for injection in prefilled syringe

 The following information is intended for medical or healthcare professionals only.
 This is an extract from the SmPC to help you with the administration Octreotide Chemi.

For parenteral use only: Subcutaneous (SC) or Intravenous (IV)

Storage

Store in a refrigerator (2°C - 8°C).
 Do not freeze. Store the prefilled syringes in the blister in the original packaging in order to protect the product from the light.

Storage conditions after dilution in sodium chloride 0.9 % solution when stored in glass bottle

Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C.
 From a microbiological point of view, the product should be used immediately.

Use

To reduce local discomfort, let the solution reach the room temperature before injection. Avoid multiple injections at short intervals at the same site.
 Prio to administration, the solution should be inspected visually for changes of colour or presence of particles.
 Do not use unless the solution is clear and free from visible solid particles.

• **Intravenous infusion (for healthcare professionals)**

When Octreotide Chemi is to be administered as intravenous infusion, the content of one 500 micrograms of prefilled syringe 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 the treatment is reached.

Disposal

Any solution or item used (or that has been in contact) with Octreotide Chemi solution for injection must be discarded according to local recommendations for injections.

How much Octreotide Chemi to use

The dose of Octreotide Chemi 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.