teva

Package leaflet:
Information for the patient

Olatuton 10 mg, 20 mg and 30 mg Powder and Solvent for Prolonged-release Suspension 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 Olatuton is and what it is used for

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

Olatuton is used:
- to treat acromegaly

Acromegaly is 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. Olatuton markedly reduces the symptoms of acromegaly, which include headache, excessive perspiration, numbness of the hands and feet, tiredness, and joint pain. In most cases, the overproduction of growth hormone is caused by an enlargement in the pituitary gland (a pituitary adenoma); Olatuton treatment may reduce the size of the adenoma.

Olatuton is used to treat people with acromegaly:
- when other types of treatment for acromegaly (surgery or radiotherapy) are not suitable or haven't worked
- after radiotherapy, to cover the interim period until the radiotherapy becomes fully effective.

- to relieve symptoms associated with overproduction of some specific hormones and other related substances by the stomach, bowels or pancreas

Overproduction of specific hormones and other related natural substances can be caused by some rare conditions of the stomach, bowels or pancreas. This 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 Olatuton helps to control these symptoms.

- to treat neuroendocrine tumours located in the gut (e.g. appendix, small intestine or colon)

Neuroendocrine tumours are rare tumours which can be found in different parts of the body. Olatuton is also used to control the growth of these tumours, when they are located in the gut (e.g. appendix, small intestine or colon).

- to treat pituitary tumours that produce too much thyroid-stimulating hormone (TSH).

Too much thyroid-stimulating hormone (TSH) leads to hyperthyroidism. Olatuton 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 Olatuton

Follow all instructions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

Read the following explanations before you use Olatuton.

Do not use Olatuton:
- 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 Olatuton:
- 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 Olatuton may result in gallstone formation. Your doctor may wish to check your gallbladder periodically.
- if you know that you have diabetes, as Olatuton can affect blood sugar levels. If you are diabetic, your sugar levels should be checked regularly.
- 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 Olatuton 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 Olatuton in children.

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

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 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 (^{177}Lu) oxodotreotide, a radiopharmaceutical therapy, your doctor may stop and/or adapt Olatuton treatment for a short period of time.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Olatuton 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 Olatuton. It is not known whether Olatuton passes into breast milk.

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

Olatuton contains sodium
Olatuton contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially "sodium-free".

3 How to use Olatuton

Olatuton must always be administered as an injection into the muscle of the buttocks. With repeated administration, the left and right buttock should be used alternately.

If you use more Olatuton than you should
No life-threatening reactions have been reported after overdose of Olatuton.

The symptoms of overdose are: hot flushes, frequent urination, tiredness, depression, anxiety and lack of concentration.

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

If you forget to use Olatuton
If your injection is forgotten, it is recommended that you are given it as soon as it is remembered, and then continue as usual. It will not do any harm if a dose is a few days late, but you could get some temporary re-appearance of symptoms until you get back on schedule.

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

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

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, causing 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
- 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.

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 Olatuton

Keep this medicine out of the sight and reach of children.

Store in the original package in order to protect from light.
Store in a refrigerator (2°C - 8°C). Do not freeze.
Olatuton may be stored below 25°C on the day of injection.
Do not store Olatuton after reconstitution (it must be used immediately).

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice particles or a change of colour.

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 Olatuton contains
- The active substance is octreotide.
  One vial contains 10 mg, 20 mg or 30 mg octreotide (as octreotide acetate).
- The other ingredients are:
  In powder (vial): poly(DL-lactide-co-glycolide) and mannitol (E421).
  In solvent (pre-filled syringe): carmellose sodium, mannitol (E421), poloxamer and water for injections.

What Olatuton looks like and contents of the pack

Olatuton 10 mg: Each pack contains 1 glass vial of 10 mg octreotide with rubber stopper sealed with an aluminium cap with a dark blue flip-off seal, 1 pre-filled glass syringe with 2 ml solvent, 1 safety injection needle and 1 vial adapter or 3 vials of 10 mg octreotide, 3 pre-filled syringes with 2 ml solvent, 3 safety injection needles and 3 vial adapters.

Olatuton 20 mg: Each pack contains 1 glass vial of 20 mg octreotide with rubber stopper sealed with an aluminium cap with an orange flip-off seal, 1 pre-filled glass syringe with 2 ml solvent, 1 safety injection needle and 1 vial adapter or 3 vials of 20 mg octreotide, 3 pre-filled syringes with 2 ml solvent, 3 safety injection needles and 3 vial adapters.

Olatuton 30 mg: Each pack contains 1 glass vial of 30 mg octreotide with rubber stopper sealed with an aluminium cap with a dark red flip-off seal, 1 pre-filled glass syringe with 2 ml solvent, 1 safety injection needle and 1 vial adapter or 3 vials of 30 mg octreotide, 3 pre-filled syringes with 2 ml solvent, 3 safety injection needles and 3 vial adapters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer:
PLIVA Hrvatska d.o.o. (PLIVA Croatia Ltd.), Prilaz baruna Filipovića 25, Zagreb, 10000, Croatia

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PL 00289/2219, PL 00289/2220 and PL 00289/2221

The following information is intended for healthcare professionals only:

How much Olatuton to use

Acromegaly
It is recommended to start treatment with the administration of 20 mg Olatuton at 4-week intervals for 3 months. Patients on treatment with s.c. octreotide can start treatment with Olatuton the day after the last dose of s.c. octreotide. Subsequent dosage adjustment should be based on serum growth hormone (GH) and insulin-like growth factor-1/somatomedin C (IGF-1) concentrations and clinical symptoms.

For patients in whom, within this 3-month period, clinical symptoms and biochemical parameters (GH; IGF-1) are not fully controlled (GH concentrations still above 2.5 microgram/L), the dose may be increased to 30 mg every 4 weeks. If after 3 months, GH, IGF-1, and/or symptoms are not adequately controlled at a dose of 30 mg, the dose may be increased to 40 mg every 4 weeks.

For patients whose GH concentrations are consistently below 1 microgram/L, whose IGF-1 serum concentrations normalised, and in whom most reversible signs/symptoms of acromegaly have disappeared after 3 months of treatment with 20 mg, 10 mg Olatuton may be administered every 4 weeks. However, particularly in this group of patients, it is recommended to closely monitor adequate control of serum GH and IGF-1 concentrations, and clinical signs/symptoms at this low dose of Olatuton.

For patients on a stable dose of Olatuton, assessment of GH and IGF-1 should be made every 6 months.

Gastro-entero-pancreatic endocrine tumours

- *Treatment of patients with symptoms associated with functional gastro-entero-pancreatic neuroendocrine tumours.*
  It is recommended to start treatment with the administration of 20 mg Olatuton at 4-week intervals. Patients on treatment with s.c. octreotide should continue at the previously effective dosage for 2 weeks after the first injection of Olatuton.

  For patients in whom symptoms and biological markers are well controlled after 3 months of treatment, the dose may be reduced to 10 mg Olatuton every 4 weeks.

  For patients in whom symptoms are only partially controlled after 3 months of treatment, the dose may be increased to 30 mg Olatuton every 4 weeks.

  For days when symptoms associated with gastro-entero-pancreatic tumours may increase during treatment with Olatuton, additional administration of s.c. octreotide is recommended at the dose used prior to the Olatuton treatment. This may occur mainly in the first 2 months of treatment until therapeutic concentrations of octreotide are reached.

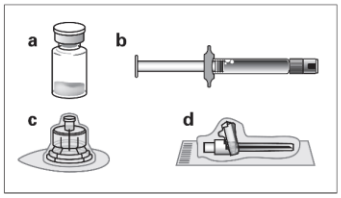
- *Treatment of patients with advanced Neuroendocrine Tumours of the midgut or of unknown origin where non-midgut sites of origin have been excluded.*
  The recommended dose of Olatuton is 30 mg administered every 4 weeks. Treatment with Olatuton for tumour control should be continued in the absence of tumour progression.

Treatment of TSH-secreting adenomas
Treatment with Olatuton should be started at a dose of 20 mg at 4-weekly intervals for 3 months before considering dose adjustment. The dose is then adjusted on the basis of the TSH and thyroid hormone response.

Instructions for preparation and intramuscular injection for Olatuton

FOR DEEP INTRAMUSCULAR INJECTION ONLY

Included in the injection kit:



a. one vial containing Olatuton powder
b. one pre-filled syringe containing the vehicle solution for reconstitution
c. one vial adapter for drug product reconstitution
d. one safety injection needle.

Follow the instructions below carefully to ensure proper reconstitution of Olatuton before deep intramuscular injection.

There are 3 critical actions in the reconstitution of Olatuton. **Not following them could result in failure to deliver the drug appropriately.**

- **The injection kit must reach room temperature**. Remove the injection kit from the fridge and let the kit stand at room temperature for a minimum of 30 minutes before reconstitution, but do not exceed 24 hours.
- After adding the diluent solution, **ensure that the powder is fully saturated** by letting the vial stand for 5 minutes.
- After saturation, **shake the vial moderately** in a horizontal direction for a minimum of 30 seconds **until a uniform suspension is formed**. The Olatuton suspension must only be prepared **immediately** before administration.

Olatuton should only be administered by a trained healthcare professional.

Step 1

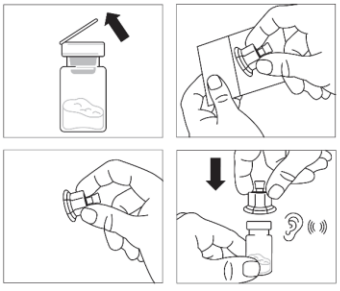
- Remove the Olatuton injection kit from refrigerated storage.

ATTENTION: It is essential to start the reconstitution process only after the injection kit reaches room temperature. Let the kit stand at room temperature for a minimum of 30 minutes before reconstitution, but do not exceed 24 hours.

Note: The injection kit can be re-refrigerated if needed.

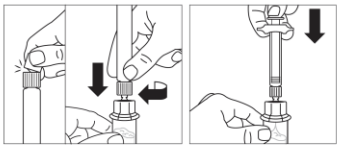
Step 2

- Remove the plastic cap from the vial and clean the rubber stopper of the vial with an alcohol wipe.
- Peel the blister film and remove the vial adapter from its packaging, by holding between the white luer cap and the skirt. **DO NOT** touch the tip of the access device at any place.
- Place the vial on a flat surface. Position the vial adapter on top of the vial and push it fully down so that it snaps in place, confirmed by an audible "click".
- Clean the tip of the vial adapter with an alcohol wipe.



Step 3

- Snap off the smooth white cap from the syringe Pre-filled with diluent solution and screw the syringe onto the vial adapter.
- Slowly push the plunger all the way down to transfer all the diluent solution in the vial.



Step 4

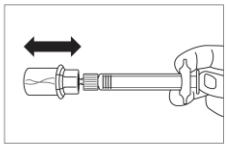
ATTENTION: It is essential to let the vial stand for 5 minutes to ensure that the diluent has fully saturated the powder.
Note: It is normal if the plunger rod moves up as there might be a slight overpressure in the vial.

- **At this stage prepare the patient for injection.**

Step 5

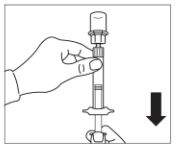
- After the saturation period, make sure that the plunger is pushed all the way down in the syringe.

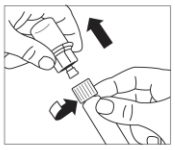
ATTENTION: Keep the plunger pressed and shake the vial **moderately** in a horizontal direction **for a minimum of 30 seconds** so that the powder is completely suspended (uniform milky suspension). **Repeat moderate shaking for another 30 seconds if the powder is not completely suspended.**



Step 6

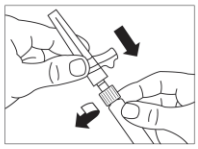
- Turn syringe and vial upside down, slowly pull the plunger back and draw the entire contents from the vial into the syringe.
- Unscrew the syringe from the vial adapter.

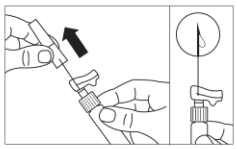




Step 7

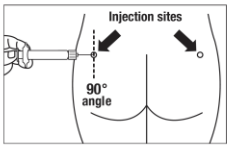
- Prepare the injection site with an alcohol wipe.
- Screw the safety injection needle onto the syringe.
- If immediate administration is delayed, gently **re-shake** the syringe to ensure a milky uniform suspension.
- Pull the protective cover straight off the needle.
- Gently tap the syringe to remove any visible bubbles and expel them from the syringe.
- Proceed **immediately** to Step 8 for administration to the patient.
  Any delay may result in sedimentation.





Step 8

- Olatuton must be given only by deep intramuscular injection, **NEVER** intravenously.
- Insert the needle fully into the left or right gluteus at a 90° angle to the skin.
- Slowly pull back the plunger to check that no blood vessel has been penetrated (reposition if a blood vessel has been penetrated).
- Depress the plunger with **steady pressure** until the syringe is empty.
  Withdraw the needle from the injection site and activate the safety guard (as shown in **Step 9**).



Step 9

- Activate the safety guard over the needle in one of the 2 methods shown:
  - either press the hinged section of the safety guard down onto a hard surface (figure A)
  - or push the hinge forward with your finger (figure B).
- An audible "click" confirms the proper activation.
- Note: Record injection site on patient's record and **alternate monthly**.
- Dispose of syringe immediately (in a sharps container).