Teva Pharmaceuticals (Pty) Ltd
Product name: Octreotide Teva 10, 20, 30
Dosage form and strength: Long-acting release suspension for injection
Registration Number: 54/34/0425; 54/34/0426; 54/34/0427

PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS:

S4

OCTREOTIDE TEVA 10

Prolonged release suspension for injection)

10 mg octreotide (as octreotide acetate)

Contains sugar (mannitol):

Powder: 41 mg mannitol per vial.

Suspension vehicle: 12 mg mannitol per 2 ml.

After reconstitution: 53 mg mannitol per vial.

OCTREOTIDE TEVA 20

Prolonged release suspension for injection)

20 mg octreotide (as octreotide acetate)

Contains sugar (mannitol):

Powder: 81,9 mg mannitol per vial.

Suspension vehicle: 12 mg mannitol per 2 ml.

After reconstitution: 93,9 mg mannitol per vial.

OCTREOTIDE TEVA 30

Prolonged release suspension for injection)

30 mg octreotide (as octreotide acetate)

Contains sugar (mannitol):

Powder: 122,9 mg mannitol per vial.

Suspension vehicle: 12 mg mannitol per 2 ml.

After reconstitution: 134,9 mg mannitol per vial.

Read all of this leaflet carefully before you start taking OCTREOTIDE TEVA:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

WHAT IS IN THE LEAFLET:

1. WHAT OCTREOTIDE TEVA IS AND WHAT IT IS USED FOR:

OCTREOTIDE TEVA 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.

- OCTREOTIDE TEVA is used to treat people with acromegaly (which is a hormonal disorder whereby your pituitary glands produce too much growth hormone):
  - who are adequately controlled on s.c. treatment with a somatostatin analogue,
  - 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.

- OCTREOTIDE TEVA is used to treat patients with carcinoid tumours (a type of cancer):
- 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 OCTREOTIDE TEVA 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. OCTREOTIDE TEVA is also used to control the growth of these tumours, when they are located in the gut (e.g. appendix, small intestine or colon).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE OCTREOTIDE TEVA:

OCTREOTIDE TEVA should not be administered to you:

- if you are hypersensitive (allergic) to octreotide or to any of the other ingredients of OCTREOTIDE TEVA.

Warnings and precautions:

Tell your doctor or healthcare professional before being given the injection.

Special care should be taken with OCTREOTIDE TEVA:

- if you receive treatment with OCTREOTIDE TEVA over a long period of time, your doctor may wish to check your thyroid function periodically.

- if you are taking medicines such as beta blockers, calcium channel blockers, or medicines to control fluid and electrolyte balance, your doctor should be informed.
- if you know that you have gallstones now or have had them in the past; tell your doctor, as prolonged use of OCTREOTIDE TEVA may result in gallstone formation. Your doctor may wish to check your gallbladder periodically.
- if you know that you have diabetes, as OCTREOTIDE TEVA 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.
- if you start experiencing loose, pale stools, abdominal bloating and weight loss. This could be a sign of problems with your pancreas.

Children and adolescents:

There is not much information about the use of OCTREOTIDE TEVA in children.

Other medicines with OCTREOTIDE TEVA:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor:

If you are taking a medicine to control your blood pressure (e.g. a beta blocker or a calcium channel blocker) or a medicine 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 taking certain medicines, such as cimetidine, ciclosporin, bromocriptine, quinidine, terfenadine and certain radiopharmaceuticals have been reported to be affected by OCTREOTIDE TEVA.

Pregnancy, breastfeeding and fertility:

Pregnancy:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving OCTREOTIDE TEVA.
OCTREOTIDE TEVA should not be administered to you if you are pregnant.
If you are a woman of child-bearing age, you should use an effective contraceptive method during treatment.

Breastfeeding:

Do not breastfeed your baby while you are being treated with OCTREOTIDE TEVA. It is not known whether OCTREOTIDE TEVA passes into breast milk.

Driving and using machine:

You may experience side effects while using OCTREOTIDE TEVA, such as dizziness, headache and tiredness, and it may reduce your ability to drive and use machines safely.

It is not always possible to predict to what extent OCTREOTIDE TEVA may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which OCTREOTIDE TEVA affects you.

OCTREOTIDE TEVA contains mannitol:

Patients with the rare hereditary condition of mannitol intolerance should not use OCTREOTIDE TEVA.

3. HOW TO USE OCTREOTIDE TEVA:

You will not be expected to give yourself OCTREOTIDE TEVA. It will be given to you by a person who is qualified to do so.

OCTREOTIDE TEVA must always be administered as an injection into the muscle of the buttocks.

If you were administered more OCTREOTIDE TEVA than you should:

Since a healthcare professional will administer OCTREOTIDE TEVA, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use OCTREOTIDE TEVA:

Since a healthcare professional will administer OCTREOTIDE TEVA, it is unlikely that the dose will be missed.

If you stop using OCTREOTIDE TEVA:

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

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

4. POSSIBLE SIDE EFFECTS:

OCTREOTIDE TEVA can have side effects.

Not all side effects reported for OCTREOTIDE TEVA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while being treated with OCTREOTIDE TEVA, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using OCTREOTIDE TEVA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting (dizziness).

These are all very serious side effects. If you have them, you may have had a serious reaction to OCTREOTIDE TEVA. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- 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)
- gallstones, causing sudden back pain.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- diarrhoea
- stomach pain
- feeling sick (nausea)
- constipation
- flatulence (wind)
- loose stools
- feeling of fullness in the stomach
- discolouration of faeces
- fatty stools
- headache
- bile sediment consists of cholesterol crystals, calcium bilirubinate pigment, and other calcium salts and is usually detected on transabdominal ultrasonography
- too much sugar in the blood
- too little sugar in the blood
- impaired glucose tolerance
- loss of appetite
- local pain at the injection site
- abnormal physical weakness
- change in liver function tests
- hair loss
- difficulty breathing

- slow heartbeat

Less frequent side effects:

- dehydration
- fast heartbeat

Side effects reported after OCTREOTIDE TEVA was marketed with unknown frequency:

- low level of platelet count in blood; this could result in increased bleeding or bruising
- hives
- an inflammation of the pancreas gland (pancreatitis)
- acute 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 heartbeat
- increased liver enzymes

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get 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 to SAHPRA via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of OCTREOTIDE TEVA.

5. HOW TO STORE OCTREOTIDE TEVA:

- Store all medicines out of reach of children.
- Store in a refrigerator (2 °C – 8 °C). Do not freeze.
- Keep the container in the outer carton in order to protect from light.
- Do not use OCTREOTIDE TEVA if you notice particles or a change of colour.
- Do not use this medicine after the expiry date which is stated on the carton and the vial after "EXP". The expiry date refers to the last day of that month.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What OCTREOTIDE TEVA contains:

The active substance in OCTREOTIDE TEVA 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).

In suspension vehicle (prefilled syringe): carmellose sodium, poloxamer 188, water for injections.

What OCTREOTIDE TEVA looks like and contents of the pack:

OCTREOTIDE TEVA consist of 8 mL Type I internally siliconised, clear glass vial, with a grey rubber stopper and sealed with aluminium flip-off cap of different colour (dark blue, orange and red-granate flip-off caps are used for 10 mg, 20 mg and 30 mg strengths respectively).

1. Suspension vehicle consists of 3 mL, internally siliconised, Type I, clear glass pre-fillable syringe

with tip cap stoppered with a 9,25mm, grey colour, bromobutyl plunger stopper. A plunger rod is attached at the back end of the plunger stopper.

Cardboard box containing:

One glass vial containing: microspheres for injection,

One glass prefilled syringe (containing the suspension vehicle),

Administration components (i.e., a vial adapter and a safety needle).

HOLDER OF THE CERTIFICATE OF REGISTRATION:

Teva Pharmaceuticals (Pty) Ltd

Maxwell Office Park

Magwa Crescent West

Waterfall City

Midrand

Gauteng

South Africa

2090

Tel no.: + 27 (0) 11 055 0200

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15 March 2023

REGISTRATION NUMBER:

OCTREOTIDE TEVA 10: 54/34/0425

OCTREOTIDE TEVA 20: 54/34/0426

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