

## Package leaflet: Information for the patient

### Ocyesa 20 mg prolonged-release solution for injection in pre-filled pen

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 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 Ocyesa is and what it is used for
2. What you need to know before you use Ocyesa
3. How to use Ocyesa
4. Possible side effects
5. How to store Ocyesa
6. Contents of the pack and other information

#### 1. What Ocyesa is and what it is used for

Ocyesa contains the active substance octreotide. Octreotide belongs to the pharmaco-therapeutic group pituitary and hypothalamic hormones and analogues, somatostatin and analogues. Octreotide is a synthetic form of somatostatin, a natural substance found in the human body that controls the release of human growth hormone. Octreotide works in the same way as somatostatin, but its action lasts longer so it does not need to be taken so often.

Ocyesa is used for maintenance treatment in adults with acromegaly, a condition wherein the body produces too much growth hormone. It is used in patients in whom medicines like somatostatin have already been shown to be of benefit.

Normally, growth hormone regulates the growth of tissues, organs and bones. In people with acromegaly, increased production of growth hormone (usually from a non-cancerous tumour in the pituitary gland) leads to enlargement of bones and certain tissues, and symptoms such as headache, excessive sweating, numbness in the hands and feet, tiredness and joint pain. Treatment with Ocyesa can help relieve the symptoms.

#### 2. What you need to know before you use Ocyesa

##### Do not use Ocyesa

- 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 or pharmacist before using Ocyesa or during treatment if you have:

- **heart problems** since the medicine can affect the rate and regularity of your heartbeat.
- **gallbladder problems**, since prolonged use of Ocyesa can cause gallstones to form.
- **diabetes**, since Ocyesa may affect your blood sugar. Persistently increased blood sugar levels may occur during long-term use. Low blood sugar levels have also been reported. Therefore, your doctor

may recommend monitoring your blood sugar levels and treatment of diabetes.

If you have Type 1 diabetes and you are being treated with insulin, your doses may need to be reduced during treatment with Oczyesa.

- ever had **lack of vitamin B12**. Since this medicine can decrease vitamin B12 levels in the blood, your doctor may wish to check your vitamin B12 level periodically during treatment with Oczyesa.

### Monitoring during treatment

Tumours of the pituitary gland that produce excess growth hormone and lead to acromegaly sometimes expand, causing serious complications such as visual problems. It is essential that you are monitored for tumour growth while taking Oczyesa. If evidence of tumour expansion appears, your doctor may prescribe a different treatment.

Your doctor will regularly check your liver function during treatment and will also check your thyroid function if you are treated with Oczyesa over a long period of time.

### **Children and adolescents**

Oczyesa is not recommended in children and adolescents below the age of 18. The safety and benefits of this medicine are not known in this age group.

### **Other medicines and Oczyesa**

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

Tell your doctor if you are taking any of the following medicines, since their activity or side effects may change when used together with Oczyesa. If you take these medicines, your doctor may need to adjust the doses of these medicines:

- medicines called beta blockers (e.g. atenolol, metoprolol) and calcium channel blockers (e.g. amlodipine, verapamil), used to treat high blood pressure or heart diseases;
- medicines to control your fluid and electrolyte balance;
- insulin or other medicines to treat diabetes;
- quinidine: a medicine to treat irregular heart rhythm;
- terfenadine: a medicine to treat allergic conditions;
- ciclosporin: a medicine to suppress transplant rejection, treat severe skin diseases, severe eye and joint inflammation.

### **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 or pharmacist for advice before taking this medicine.

If you are pregnant, the use of Oczyesa should be avoided.

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

Women who can get pregnant should use effective contraception during treatment.

### **Driving and using machines**

Oczyesa has no or negligible influence on the ability to drive and use machines. Avoid driving or using machines if your ability to react is reduced due to side effects such as dizziness, asthenia or headache.

### **Oczyesa contains alcohol**

This medicine contains 63 mg of alcohol (ethanol) in each dose unit which is equivalent to 63 mg/1 mL (6.5% w/w). The amount in 1 dose of this medicine is equivalent to less than 2 mL beer or 1 mL wine. The small amount of alcohol in this medicine will not have any noticeable effects.

### 3. How to use Oczyesa

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

**The recommended dose** is 20 mg every 4 weeks. Oczyesa may be given up to 1 week before or 1 week after the scheduled 4-week dose in exceptional circumstances (e.g., missed dose, non-adherence to treatment, etc.).

If you are switching from another treatment with octreotide or lanreotide, the first dose of Oczyesa should be given at the end of the daily or monthly dosing interval of the previous treatment.

Your doctor will assess how the treatment works for you in terms of IGF-I and symptom control on a regular basis. Should control not be maintained or the medicine not be tolerated, you may be switched to another somatostatin analogue.

Oczyesa is given as a single injection under the skin (subcutaneously (SC)) of the belly, thigh or buttock. The injection should not be given in any other area. When receiving monthly injections, it is important to change the site where the injection is given each time. You may receive multiple injections in the same area, but each injection must be given in a different spot.

You should receive training on the right way to inject Oczyesa. Read the 'Instructions for use' for the pre-filled pen carefully before using Oczyesa.

Detailed instructions on how to use Oczyesa are provided at the end of this leaflet.

#### If you use more Oczyesa than you should

If you have used more Oczyesa than you should, you need to contact your doctor immediately.

The symptoms of an overdose are: abnormal or irregular heartbeat, low blood pressure, cardiac arrest (heart stops beating), reduced supply of oxygen to the brain, severe upper stomach pain, yellow skin and eyes, nausea (feeling sick), loss of appetite, diarrhoea, weakness, tiredness, lack of energy, weight loss, enlarged liver, discomfort, and high level of lactic acid in the blood.

#### If you forget to use Oczyesa

Do not take a double dose to make up for a forgotten dose. Administer the next dose as soon as you remember.

#### If you stop using Oczyesa

Do not stop taking this medicine without discussing with your doctor first. If you stop taking Oczyesa, your acromegaly symptoms may come back.

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 immediately if you get any of the following:**

**Very common** (may affect more than 1 in 10 people)

- Gallstones (cholelithiasis), leading to sudden back pain
- High blood glucose levels (hyperglycaemia)

**Common** (may affect up to 1 in 10 people)

- Underactive thyroid gland (hypothyroidism) with tiredness, weight gain, and skin and hair changes
- Changes in thyroid function (thyroid disorder), as measured by blood tests
- Inflammation of the gallbladder (cholecystitis); symptoms may include pain in the upper right abdomen (belly), fever, nausea
- Low blood glucose levels (hypoglycaemia)
- Condition where the body has difficulty maintaining normal glucose levels (impaired glucose tolerance)
- Slow heartbeat (bradycardia)

**Uncommon** (may affect up to 1 in 100 people)

- Non-aggressive tumour of liver blood vessels
- Dehydration; symptoms may include thirst, low urine output, dark urine, dry flushed skin
- Fast heartbeat (tachycardia)

**Not known** (frequency cannot be estimated from the available data)

- Hypersensitivity (allergic) reactions, including skin rash
- A sudden, severe 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
- Reduced flow of bile from the liver because of a blockage (cholestasis)
- Liver inflammation (hepatitis, cholestatic hepatitis); symptoms may include nausea, vomiting, loss of appetite, generally feeling unwell, itching, light-coloured urine
- Yellowing of the skin and eyes (jaundice)
- Low blood levels of platelets, components that help the blood to clot (thrombocytopenia), which can lead to bleeding and bruising.

**Other side effects**

Tell your doctor or pharmacist 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)

- Abdominal pain
- Constipation
- Nausea
- Diarrhoea
- Flatulence (wind)
- Headache
- Local reactions at the injection site

**Common** (may affect up to 1 in 10 people)

- Dizziness
- Weakness
- Difficulty breathing (dyspnoea)
- Indigestion (dyspepsia)
- Discomfort or bloating or swelling of your belly (abdominal distension)
- Vomiting
- Excess fat in stool (steatorrhoea)
- Discoloured stool
- Loss of appetite (anorexia)
- Increased blood level of bilirubin (hyperbilirubinaemia), a waste product from breakdown of red blood cells
- Increased levels of liver enzymes (transaminases increased)
- Hair loss (alopecia)
- Itching (pruritus)
- Rash
- Joint pain (arthralgia)

**Not known** (frequency cannot be estimated from the available data)

- Itchy rash (urticaria)
- Increased liver enzyme levels (alkaline phosphatase, gamma-glutamyl transferase) in the blood

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

or search 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 Ocyesa**

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, pouch and pre-filled pen label after 'EXP'. The expiry date refers to the last day of that month.

Do not refrigerate.

Store in the original package in order to protect from oxygen and light.

Do not use this medicine if you notice visible particles or if it is cloudy.

Ocyesa is for single use only. Any used pre-filled pen should be discarded.

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 Ocyesa contains

- The active substance is octreotide hydrochloride equivalent to 20 mg octreotide. The volume of each pre-filled pen is 1 ml containing 20 mg octreotide.
- The other ingredients are glycerol dioleate, soybean phosphatidylcholine, ethanol anhydrous (see also section 2, 'Ocyesa contains alcohol'), propylene glycol (E 1520), edetic acid, ethanolamine.

### What Ocyesa looks like and contents of the pack

Ocyesa is a prolonged-release solution for injection. Each pre-filled pen contains a yellowish to yellow clear liquid.

Each pack contains 1 pre-filled pen with stopper, a non-visible needle with a protective cap and a needle shield, fitted in an autoinjector.

The pre-filled pen is contained in a sealed aluminium pouch. The package contains a small white cylinder, included for storage purposes only.

### Marketing Authorisation Holder

Camurus AB  
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SE-224 84 Lund  
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### Manufacturer

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Soldattorpsvägen 5  
SE-216 13 Limhamn  
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## INSTRUCTIONS FOR USE

### Ocyesa 20 mg prolonged-release solution for injection in pre-filled pen

octreotide

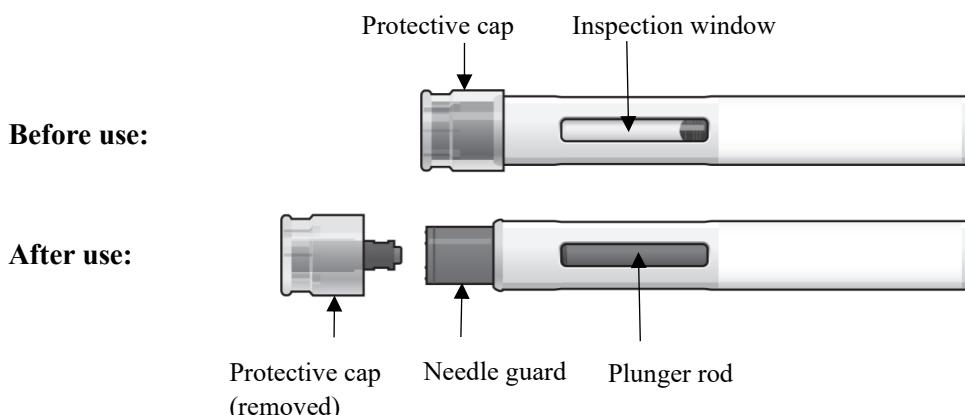
Single use  
Pre-filled pen  
Subcutaneous use

The instructions for use contain information on how to use Ocyesa.

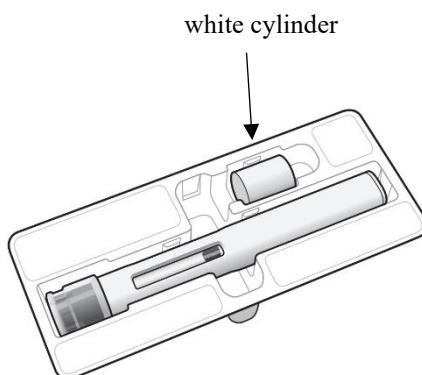
Read the instructions for use **all the way through** before using the Ocyesa pre-filled pen. Keep the instructions for use as you may need to read them again.

**Do not inject yourself or someone else until you have been shown how to use the Ocyesa pre-filled pen.** Your healthcare provider will show you or your caregiver how to prepare and inject a dose of this medicine before you try to do it for the first time. Call your healthcare provider if you have any questions.

## The parts of the Ozyesa pre-filled pen before and after use



**Note:** Packaging contains a small white cylinder, included for storage purposes only. **Do not remove!**



### Important information you need to know before injecting this medicine

- **For single use only** (do not reuse Ozyesa pre-filled pen).
- **For subcutaneous injection only** (inject directly into fatty layer under the skin).
- **Do not inject** intravascular (into the blood), intradermal (into the skin layer) or intramuscular (into the muscle).
- **Do not** use this medicine after the **expiry date** shown on the carton, pouch or on the pen label.
- **Do not** use if the pre-filled pen appears damaged.
- **Do not** use if the packaging (carton and pouch) or the seal is damaged.
- **Do not** remove the protective cap until you are ready to inject.

### Storing the Ozyesa pre-filled pen

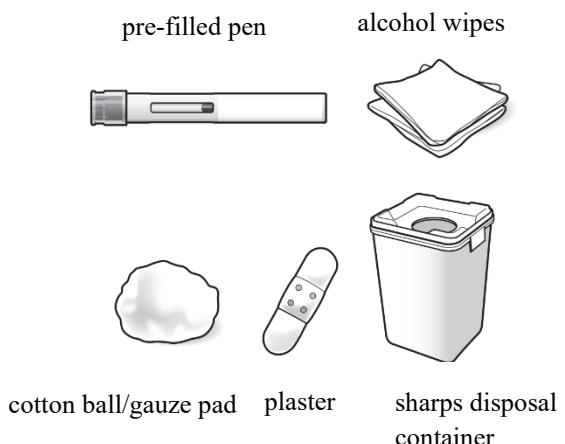
- Store the pre-filled pen in the original package in order to protect from oxygen and light.
- **Do not** refrigerate the pre-filled pen.
- **Keep Ozyesa out of the sight and reach of children.**

## **Preparing to inject Ozyesa**

### **Step 1. Gather equipment**

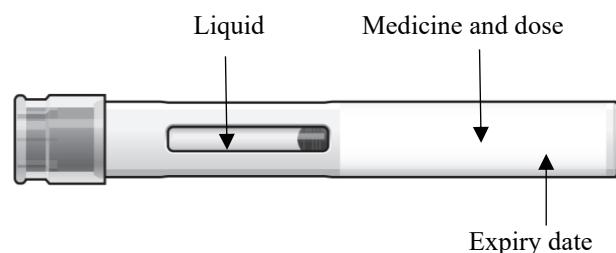
Place all the equipment needed for the injection on a clean flat surface:

- Ozyesa pre-filled pen
- alcohol wipe (not included)
- cotton ball or gauze pad (not included)
- plaster (not included)
- a sharps disposal container (not included) (see Step 10)



### **Step 2. Inspect the Ozyesa pre-filled pen**

- Remove the pouch from the cardboard box. Open the pouch and remove the pre-filled pen.
- Check the label to be sure that you have the correct medicine.
- Check the **expiry date** shown on the cardboard box, the pouch or on the pre-filled pen label. Do not use the Ozyesa pre-filled pen if the expiry date has passed.
- Check that the **liquid is yellowish to yellow and clear**. You may see an air bubble. This is normal.
- **Do not use this medicine if you notice visible particles or if it is cloudy.**



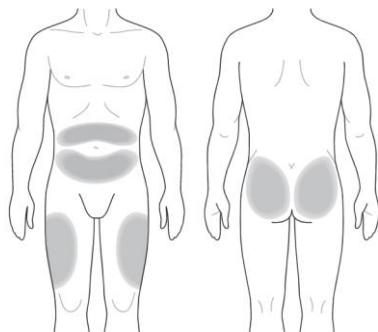
### **Step 3. Wash your hands**

- Wash your hands well with soap and water. Dry your hands completely.



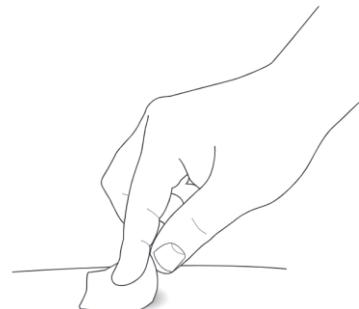
#### Step 4. Choose the injection site

- Choose an injection area (belly, thigh, or buttock). Choose an injection site in the injection area where there is enough fatty (subcutaneous) tissue. Each injection area can have multiple injection sites.
- You may need help from someone who has been instructed in how to give your injection if you cannot reach certain injection areas.
- **Do not** inject into skin that is tender, damaged, bruised or scarred.
- **Do not** inject in a recently used injection site in the chosen injection area.
- **Do not** inject within 5 cm of the navel.



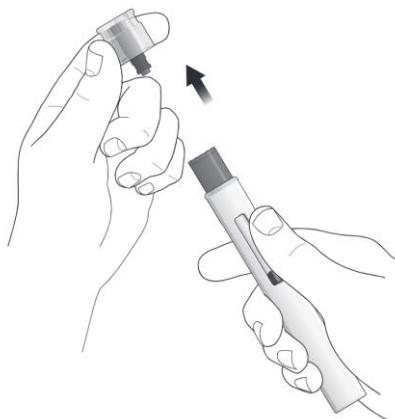
#### Step 5. Clean the injection site

- Clean the injection site with an alcohol wipe.
- Let the injection site air dry before injecting.
- **Do not** touch the cleaned area again before the injection.



#### Step 6. Remove and throw away the protective cap

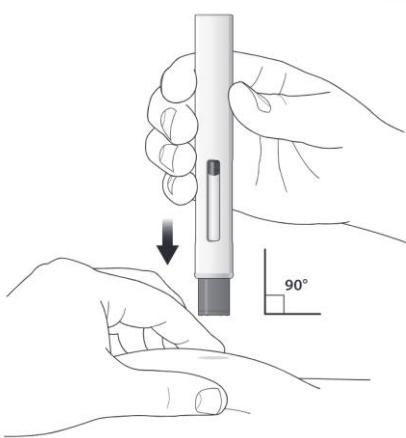
- Hold the Oczyesa pre-filled pen pointed up with one hand. With the other hand pull the protective cap straight off. It may take some force to remove. Do not wiggle or twist the cap.
- **Do not recap.** Throw away the protective cap right away.
- You may see a drop of liquid at the end of the needle. This is normal.
- **Do not** touch or press the needle guard. This could activate the pre-filled pen.



#### Injecting Oczyesa

#### Step 7. Prepare to start the injection

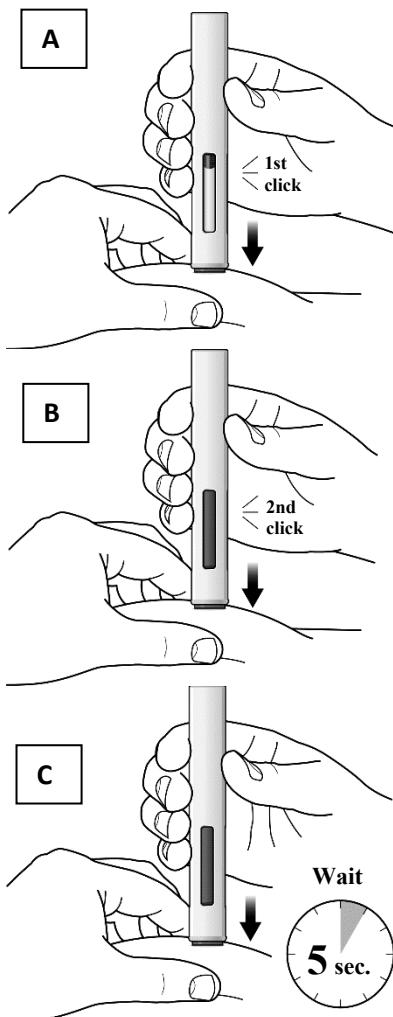
- Pinch and hold the skin at the injection site between your thumb and fingers. **Hold the pinch until the injection is complete.**
- With your other hand hold the pre-filled pen so that you can see the inspection window.
- Place the pre-filled pen straight (at a 90 ° angle) and flat against the pinched skin.



### Step 8. Give the injection

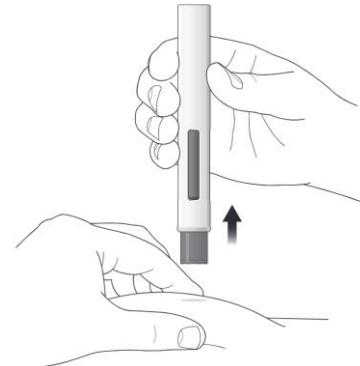
Inject Oczyesa by following the steps in figures A, B and C.

- Push the pre-filled pen all the way down and hold the pre-filled pen against the skin. This will make the needle guard slide up into the pre-filled pen.
- You will hear a **first click** to let you know the injection has started.
- The plunger rod will move down through the inspection window.
- Continue to **hold** the pre-filled pen down.
- When you hear the **second click**, continue to keep the pre-filled pen down for an additional **5 seconds**.
- Check that the plunger rod is completely seen in the inspection window.



### Step 9. Remove the Oczyesa pre-filled pen

- Remove the pre-filled pen from the skin. The injection is now completed, and the pinched skin can be released.
- The needle remains hidden by the needle guard to protect against needle-stick injury.
- You may have a small amount of blood or liquid at the injection site. This is normal. Use a cotton ball or gauze pad on the area and apply a plaster if needed.
- Do not** rub the injection site.



### Dispose of Oczyesa pre-filled pen

#### Step 10. Dispose of the Oczyesa pre-filled pen

Throw away (dispose of) the used Oczyesa pre-filled pen in a puncture resistant sharps disposal container right after use.

**Do not** throw away (dispose of) Oczyesa pre-filled pens in your household waste.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

