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Package leaflet: Information for the patient

Caprelsa 100 mg

film-coated tablets

Caprelsa 300 mg

film-coated tablets

vandetanib

Is this leaflet hard to see or read?
Phone 0800 035 2525 for help

In addition to this leaflet you will be given the Patient Alert Card, which contains important safety information that you need to know before you are given Caprelsa and during treatment with Caprelsa.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet and the patient alert card. You may need to read it again.
- It is important that you keep the Alert Card with you during treatment.
- 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 Caprelsa is and what it is used for
2. What you need to know before you take Caprelsa
3. How to take Caprelsa
4. Possible side effects
5. How to store Caprelsa
6. Contents of the pack and other information

1. What Caprelsa is and what it is used for

Caprelsa is a treatment for adults and children aged 5 years and above with:

Type of medullary thyroid cancer that is called Rearranged during Transfection (RET) mutant and which cannot be removed by surgery or has spread to other parts of the body.

Caprelsa works by slowing down the growth of new blood vessels in tumours (cancers). This cuts off the supply of food and oxygen to the tumour. Caprelsa may also act directly on cancer cells to kill them or slow down their growth.

2. What you need to know before you take Caprelsa

Do not take Caprelsa:

- if you are allergic to vandetanib or any of the other ingredients of this medicine (listed in Section 6).
- if you have a heart problem that you were born with called ‘congenital long QTc syndrome’. This is seen on an electrocardiogram (ECG).
- if you are breast-feeding.
- if you are taking any of the following medicines: arsenic, cisapride (used to treat heartburn), erythromycin intravenous and moxifloxacin (used to treat infection), toremifene (used to treat breast cancer), mizolastine (used to treat allergies), Class IA and III antiarrhythmics (used to control heart rhythm).

Do not take Caprelsa if any of the above applies to you. If you are not sure, talk to your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking Caprelsa:

- If you are sensitive to the sun. Some people who are taking Caprelsa become more sensitive to the sun. This can cause sunburn. While you are taking Caprelsa, protect yourself when you go outside by always using sunscreen and wearing clothes to avoid exposure to the sun.
- If you have high blood pressure.
- If you have or have had an aneurysm (enlargement and weakening of a blood vessel wall) or a tear in a blood vessel wall.
- If you need to have a surgical procedure. Your doctor may consider stopping Caprelsa if you will be undergoing a major surgical procedure as Caprelsa may affect wound healing. Caprelsa may be restarted once adequate wound healing is established.
- If you have any kidney problems.

Severe Cutaneous Adverse Reactions (SCARs), including Stevens-Johnson syndrome (SJS) / toxic epidermal necrolysis (TEN), have been reported in association with vandetanib treatment. Stop using Caprelsa and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Determination of RET status of your cancer will be needed, before initiating Caprelsa treatment.

Monitoring of your blood and your heart:

Your doctor or nurse should perform tests to check the levels of your blood potassium, calcium, magnesium, and thyroid-stimulating hormone (TSH) as well as the electrical activity of your heart with a test called an electrocardiogram (ECG). You should have these tests:

- Before starting Caprelsa
- Regularly during Caprelsa treatment
- 1, 3 and 6 weeks after starting Caprelsa
- 12 weeks after starting Caprelsa
- Every 3 months thereafter
- If your doctor or pharmacist changes your dose of Caprelsa
- As you start taking medicines that affect your heart
- As instructed by your doctor or pharmacist

Children

Caprelsa should not be given to children below 5 years of age.

Other medicines and Caprelsa

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines that you buy without a prescription and herbal medicines.

This is because Caprelsa can affect the way some medicines work and some medicines can have an effect on Caprelsa.

Tell your doctor or pharmacist if you are taking any of the following medicines:

- itraconazole, ketoconazole, ritonavir, clarithromycin, rifampicin and moxifloxacin (medicines used to treat infections)
- carbamazepine and phenobarbital (used to control seizures)
- ondansetron (used to treat nausea and vomiting)

- cisapride (used to treat heart burn), pimozide (used to treat uncontrolled repeated movements of the body and verbal outbursts) and halofantrine and lumefantrine (used to treat malaria)
- methadone (used to treat addiction), haloperidol, chlorpromazine, sulpiride, amisulpride, and zuclopenthixol, (used to treat mental illness)
- pentamidine (used to treat infection)
- vitamin K antagonists and dabigatran often referred to as ‘blood thinners’
- cyclosporine and tacrolimus (used to treat transplant rejection), digoxin (used to treat irregular heart rate), and metformin (used to control your blood sugar)
- proton pump inhibitors (used to treat heartburn)

You will also find this information in the Patient Alert Card you have been given by your doctor. It is important that you keep this Alert Card and show it to your partner or caregivers.

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 for advice before taking this medicine. This is because Caprelsa may harm an unborn child. Your doctor will discuss with you the benefits and risks of taking Caprelsa during this time.

- If you may become pregnant you must use effective contraception when you are taking Caprelsa and for at least four months after the last dose of Caprelsa.

You must not breast-feed during treatment with Caprelsa for the safety of your baby.

Driving and using machines

Use caution before driving or using machines. Keep in mind Caprelsa may make you feel tired, weak, or cause blurred vision.

3. How to take Caprelsa

Use in adults

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

- The recommended dose is 300 mg each day.
- Take Caprelsa about the same time each day.
- Caprelsa may be taken with or without food.

Use in children and adolescents

The doctor will tell you how many tablets of Caprelsa to give to your child. The amount of Caprelsa given will depend on your child's body weight and height. The total daily dose in children must not exceed 300 mg. The treatment may either be given to your child as a once-daily dose, an every other day dosing or a repeating 7-day schedule as indicated in the dosing guide that has been given to you by your doctor. It is important that you keep this dosing guide and show it to your caregiver.

If you have trouble swallowing the tablet

If you have trouble swallowing the tablet, you can mix it with water as follows:

- Take half a glass of still (non-carbonated) water. Only use water, do not use any other liquids.
- Put the tablet into the water.
- Stir the tablet until it has dispersed into the water. This may take about 10 minutes.
- Then drink it straight away.

To make sure there is no medicine left, refill the glass halfway with water and drink it.

If you get side effects

If you get side effects always tell your doctor. Your doctor may tell you to take Caprelsa at a lower or increased dose (such as two 100 mg tablets or one 100 mg tablet). Your doctor may also prescribe other medicines to help control your side effects. The side effects of Caprelsa are listed in Section 4.

If you take more Caprelsa than you should

If you take more Caprelsa than you have been prescribed, talk to a doctor or go to a hospital straight away.

If you forget to take Caprelsa

What to do if you forget to take a tablet depends on how long it is until your next dose.

- **If it is 12 hours or more until your next dose:** Take the missed tablet as soon as you remember. Then take the next dose at the normal time.
- **If it is less than 12 hours until your next dose:** Skip the missed dose. Then take the next dose at the normal time.

Do not take a double dose (two doses at the same time) to make up for a forgotten tablet.

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. If you get side effects, your doctor may tell you to take Caprelsa at a lower dose. Your doctor may also prescribe other medicines to help control your side effects.

Tell your doctor straight away if you notice any of the following side effects – you may need urgent medical treatment:

- Fainting, dizziness or heart rhythm changes. These may be signs of a change in the electrical activity of your heart. They are seen in 8% of people taking Caprelsa for medullary thyroid cancer. Your doctor may recommend you take Caprelsa at a lower dose or stop taking Caprelsa. Caprelsa has uncommonly been associated with life-threatening changes in heart rhythm.
- Stop using Caprelsa and seek medical attention immediately if you notice any of the following symptoms: reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson-syndrome, toxic epidermal necrolysis).
- Severe diarrhoea.
- Serious breathlessness, or sudden worsening breathlessness, possibly with a cough or a high temperature (fever). This may mean that you have an inflammation of the lungs called ‘interstitial lung disease’. This is uncommon (affects less than 1 in 100 people) but can be life-threatening.
- Seizures, headache, confusion or finding it difficult to concentrate. These may be signs of a condition called RPLS (Reversible Posterior Leukoencephalopathy Syndrome). These usually go away when Caprelsa is stopped. RPLS is uncommon (affects less than 1 in 100 people).

Tell your doctor straight away if you notice any of the side effects above.

Other side effects include:

Very common (affects more than 1 in 10 people):

- Diarrhoea. Your doctor may prescribe a medicine to treat this. If it gets severe, tell your doctor straight away.
- Abdominal pain.
- Skin rash or acne.
- Depression.
- Tiredness.
- Feeling sick (nausea).
- Upset stomach (dyspepsia).
- Nail disorders.
- Being sick (vomiting).
- Loss of appetite (anorexia).
- Weakness (asthenia).
- High blood pressure. Your doctor may prescribe a medicine to treat this.
- Headache.
- Fatigue.
- Trouble sleeping (insomnia).
- Inflammation of the nasal passages.
- Inflammation of the main air passages to the lungs.
- Upper respiratory tract infections.
- Urinary tract infections.
- Numbness or tingling of the skin.
- Abnormal sensation of the skin.
- Dizziness.
- Pain.
- Swelling caused by excess fluid (oedema).
- Stones or calcium deposits in the urinary tract (nephrolithiasis).
- Blurred vision, including mild changes in the eye which can lead to blurred vision (corneal opacity).
- Sensitivity of the skin to sunlight. While you are taking Caprelsa, protect yourself when you go outside by always using sun cream and wearing clothes to avoid exposure to the sun.

Common (affects less than 1 in 10 people)

- Dehydration.
- Severe high blood pressure.
- Weight loss.
- Stroke or other conditions where the brain may not get enough blood.
- A type of rash that affects the hands and feet (hand foot syndrome).
- Sore mouth (stomatitis).
- Dry mouth.
- Pneumonia.
- Toxins in the blood as a complication of infection.
- Flu.
- Inflammation of the urinary bladder.
- Inflammation of the sinuses.
- Inflammation of the voice box (larynx).
- Inflammation of a follicle, especially a hair follicle.
- Boil.
- Fungal infection.
- Kidney infection.
- Loss of body fluid (dehydration).
- Anxiety.
- Tremor.
- Drowsiness.
- Fainting.
- Feeling unsteady.
- Increased pressure in the eye (glaucoma).
- Coughing up of blood.
- Inflammation of the lung tissue.
- Difficulty swallowing.
- Constipation.
- Inflammation of the lining of the stomach (gastritis).
- Gastrointestinal bleeding.
- Gallstones (cholelithiasis).
- Painful urination.
- Kidney failure.
- Frequent urination.
- Urgent desire to urinate.
- Fever.
- Nose bleed (epistaxis).
- Dry eye.
- An irritation of the eyes (conjunctivitis).
- Visual impairment.
- Halo vision.
- Seeing flashes of light (photopsia).
- Disorder of the cornea of the eye (keratopathy).
- A type of diarrhoea (colitis).
- Loss of hair from the head or body (alopecia).
- Changes in taste of foods (dysgeusia).

Uncommon (affects less than 1 in 100 people)

- Heart failure.
- Inflammation of the appendix (appendicitis).
- Bacterial infection.
- Inflammation of the diverticula (small bulging pouches that can form in your digestive system).
- Bacterial skin infection.
- Abdominal wall abscess.
- Malnutrition.
- Involuntary muscle contraction (convulsions).
- Rapidly alternating muscular contraction and relaxation (clonus).
- Swelling of the brain.
- Clouding of the lens of the eye.
- Heart rate and rhythm disorders.
- Loss of heart function.
- Failure of the lungs to function properly.
- Pneumonia that happens when you breathe in foreign matter into your lungs.
- Bowel obstruction.
- Hole in your bowel.
- Inability to control your bowel movements.
- Abnormal color of urine.
- Lack of urine.
- Inability to heal properly.
- Inflammation of the pancreas (pancreatitis).
- Blistering of skin (bullous dermatitis).

Not known (frequency cannot be estimated from available data)

- An enlargement and weakening of a blood vessel wall or a tear in a blood vessel wall (aneurysms and artery dissections).
- Reddish non-elevated, target like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes, which can be preceded by fever and flu like symptoms. These serious skin rashes can be potentially life threatening (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- A skin reaction that causes red spots or patches on the skin, that may look like a target or “bulls-eye” with a dark red centre surrounded by paler red rings (erythema multiforme).

The following side effects may be shown in tests that may be carried out by your doctor:

- Protein or blood in your urine (shown in a urine test).
- Heart rhythm changes (shown in an ECG). Your doctor may tell you to stop taking Caprelsa or take Caprelsa at a lower dose.
- Abnormalities in your liver or pancreas (shown in blood tests). These do not usually cause symptoms but your doctor may want to monitor them.
- Decreased levels of calcium in your blood. Your doctor may need to prescribe or change your thyroid hormone treatment.
- Decreased levels of potassium in your blood.
- Increased levels of calcium in your blood.
- Increased levels of glucose in your blood.
- Decreased levels of sodium in your blood.
- Decrease in thyroid function.
- Increased levels of red cells in your blood.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist **straight away**.

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 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 Caprelsa

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 blister and the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not throw away 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 Caprelsa contains

- The active substance is vandetanib. Each tablet contains 100 or 300 mg of vandetanib.
- The other ingredients are calcium hydrogen phosphate dihydrate, microcrystalline cellulose, crospovidone (type A), povidone (K29-32), magnesium stearate, hypromellose, macrogol and titanium dioxide (E171).

What Caprelsa looks like and contents of the pack

Caprelsa 100 mg is a white round film-coated tablet with “Z100” imprinted on one side.

Caprelsa 300 mg is a white oval-shaped film-coated tablet with “Z300” imprinted on one side.

Caprelsa comes in blister packs of 30 tablets.

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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