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EPAR summary for the public

Caprelsa

vandetanib

This is a summary of the European public assessment report (EPAR) for Caprelsa. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Caprelsa.

For practical information about using Caprelsa, patients should read the package leaflet or contact their doctor or pharmacist.

What is Caprelsa and what is it used for?

Caprelsa is a cancer medicine that is used in adults and children above 5 years of age to treat medullary thyroid cancer, a cancer that starts off in the cells in the thyroid gland that produce the hormone calcitonin. The medicine is used when the disease is spreading quickly and causes symptoms, and when the cancer cannot be removed by surgery and has progressed or spread to other parts of the body.

Caprelsa contains the active substance vandetanib.

How is Caprelsa used?

The medicine can only be obtained with a prescription and treatment with Caprelsa should be started and supervised by a doctor who has experience of treating medullary thyroid cancer, of using cancer medicines and of assessing electrocardiograms (ECG, a test that measures the electrical activity of the heart). Patients must be given a patient alert card containing important safety information and they must be informed by their doctor about the risks of Caprelsa.

Caprelsa is available as tablets (100 mg and 300 mg) and the recommended dose for adults is 300 mg once a day, taken at around the same time each day. The dose for children aged 5 years or older is calculated using the child's weight and height. Patients who cannot swallow tablets can mix the tablet in plain (non-sparkling) water.

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The doctor may temporarily stop Caprelsa treatment and reduce the dose if the patient has abnormal ECG or severe side effects. Treatment is continued for as long as the patient benefits from it.

Caprelsa may work less well in patients without a mutation (change) in a gene called the 'rearranged during transfection' (RET) gene. It is recommended that the doctor checks for RET mutation at the start of Caprelsa treatment.

How does Caprelsa work?

The active substance in Caprelsa, vandetanib, is a 'protein tyrosine kinase inhibitor'. This means that it blocks the activity of enzymes known as tyrosine kinases. These enzymes are needed by certain receptors (such as VEGF, EGF and RET receptors) on the surface of cancer cells, where they activate several processes including cell division and the growth of new blood vessels. By blocking the activity of VEGF receptors, the medicine reduces the blood supply to the cancer cells, slowing down the cancer's growth. By blocking the activity of EGF receptors, the cancer cells no longer receive the messages needed for growth and multiplication. Vandetanib also blocks the activity of RET receptors, which play a role in the growth of medullary thyroid cancer cells.

What benefits of Caprelsa have been shown in the studies?

In a main study, Caprelsa was more effective than placebo (a dummy treatment) in adults with medullary thyroid cancer that could not be removed by surgery or had spread to other parts of the body. The study involved 331 patients and the main measure of effectiveness was progression-free survival (how long the patients lived without their disease getting worse). On average, patients taking Caprelsa lived for 30.5 months without their disease getting worse, compared with 19.3 months for patients taking placebo.

In a second main study, Caprelsa was given to children aged between 9 and 17 years with hereditary medullary thyroid cancer. The main measure of effectiveness was 'overall response rate' (ORR) which considers several features of the disease. Of the 16 children treated with Caprelsa, 7 (44%) had partial response on the ORR scale, which was comparable to the response rate in adults. On average children taking Caprelsa lived for 46 months without their disease getting worse.

What are the risks associated with Caprelsa?

The most commonly reported side effects with Caprelsa are diarrhoea, rash, nausea (feeling sick), high blood pressure and headache. For the full list of all side effects reported with Caprelsa, see the package leaflet.

Caprelsa can affect the electrical activity of the heart including a measurement called QTc interval. It must not be used in people with a problem called 'congenital long QTc syndrome' or who have a QTc interval longer than 480 milliseconds. Caprelsa must not be used with other medicines that can prolong the QTc interval. It must also not be used in women who are breast-feeding. For the full list of restrictions, see the package leaflet.

Why is Caprelsa approved?

The CHMP concluded that Caprelsa was shown to be effective in the treatment of medullary thyroid cancer in patients aged 5 years and older. However, it was uncertain how well it works in patients without a mutation (change) in a gene called the 'rearranged during transfection' (RET) gene or in patients whose RET mutation status is not known. The Committee noted the potential risk for QTc

interval prolongation, and measures were introduced to minimise this risk. The CHMP concluded that the benefits of Caprelsa outweigh its risks in patients whose disease is spreading quickly and is causing symptoms, since they are in urgent need of treatment. Therefore, the Committee recommended that Caprelsa be granted marketing authorisation.

Caprelsa has been given 'conditional approval'. This means that there is more evidence to come about the medicine, in particular on the size of the benefit in patients without the RET mutation. Every year, the European Medicines Agency will review any new information that becomes available and this summary will be updated as necessary.

What information is still awaited for Caprelsa?

The company that markets Caprelsa will carry out a study in patients with medullary thyroid cancer to compare the effects of Caprelsa in patients with and without the RET mutation.

What measures are being taken to ensure the safe and effective use of Caprelsa?

The company that markets Caprelsa will ensure that doctors who are expected to prescribe Caprelsa receive educational material containing important safety information about Caprelsa, including measures to manage the risk of QTc prolongation and other potential side effects, and a patient alert card and guidance for children or their carers.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Caprelsa have also been included in the summary of product characteristics and the package leaflet.

Other information about Caprelsa

The European Commission granted a marketing authorisation valid throughout the European Union for Caprelsa on 17 February 2012.

The full EPAR for Caprelsa can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Caprelsa, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2016.