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EPAR summary for the public

Portrazza

necitumumab

This is a summary of the European public assessment report (EPAR) for Portrazza. 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 Portrazza.

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

What is Portrazza and what is it used for?

Portrazza is a medicine for treating advanced stages of a type of lung cancer known as squamous non-small cell lung cancer.

Portrazza is only used in adults whose cancer cells have a specific protein (EGFR) on their surface and it is used together with gemcitabine and cisplatin chemotherapy.

Portrazza contains the active substance necitumumab.

How is Portrazza used?

Portrazza is given as a one hour infusion (drip) into a vein. The recommended dose is 800 mg on days 1 and 8 of each 3-week cycle. For the first 6 cycles, Portrazza is given together with gemcitabine and cisplatin chemotherapy, after which it is given on its own for as long the disease remains stable and the patient can tolerate it.

During infusions, resources should be available to deal with reactions that may occur. In case of a severe infusion or skin reaction, treatment may have to be stopped permanently. The risk of reactions can be reduced by adjusting the dose or infusion rate or by using preventive medicines. For more information, see the summary of product characteristics (also part of the EPAR).

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Portrazza is available as a concentrate for making a solution and can only be obtained with a prescription.

How does Portrazza work?

The active substance in Portrazza, necitumumab, is a monoclonal antibody (a type of protein) designed to recognise and attach to EGFR on the surface of the cancer cells. EGFR normally controls the growth and division of cells, but in cancer cells EGFR is often overactive, causing them to divide uncontrollably. By attaching to and blocking EGFR, necitumumab helps to reduce the growth and spread of the cancer.

What benefits of Portrazza have been shown in studies?

A main study of 1,093 patients with advanced squamous non-small cell lung cancer showed that adding Portrazza to gemcitabine and cisplatin chemotherapy can lead to a modest improvement in survival. In this study, patients treated with Portrazza in addition to chemotherapy lived on average 1.6 months longer than those treated with chemotherapy alone (11.5 months versus 9.9 months).

Most of the patients (95%) had cancer cells with EGFR. There was no improved survival in patients with non-EGFR cancer cells.

What are the risks associated with Portrazza?

The most common side effects with Portrazza (which may affect more than 1 in 10 people) are skin reactions, vomiting, stomatitis (inflammation of the lining of the mouth), fever, weight loss and low blood measurements of various minerals (magnesium, calcium, phosphate and potassium). The most common serious side effects are severe skin reactions (6% of patients) and blood clots (4% of patients). For the full list of all side effects reported with Portrazza, see the package leaflet.

Portrazza must not be used in patients who have had a severe or life-threatening reaction to any of the ingredients of the medicine.

Why is Portrazza approved?

In the main study, adding Portrazza to gemcitabine and cisplatin chemotherapy improved survival by a modest one and a half months without causing significant worsening in overall patient health. The Agency's Committee for Medicinal Products for Human Use (CHMP) therefore concluded that Portrazza's benefits are greater than its risks and recommended that it be approved for use in the EU.

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

A risk management plan has been developed to ensure that Portrazza is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Portrazza, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that markets the medicine will provide doctors with educational material with information on risk of blood clots and on the small number of cardiac arrest cases seen in studies.

Further information can be found in the summary of the risk management plan.

Other information about Portrazza

The European Commission granted a marketing authorisation valid throughout the European Union for Portrazza on 15 February 2016.

The full EPAR and risk management plan summary for Portrazza 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 Portrazza, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 02-2016.