EMA/635489/2015
EMEA/H/C/003960

EPAR summary for the public

Cotellic

cobimetinib

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

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

What is Cotellic and what is it used for?

Cotellic is a cancer medicine used to treat adults with melanoma (a type of skin cancer) that has spread to other parts of the body or cannot be surgically removed. Cotellic is used in combination with another medicine called vemurafenib. It is only for patients whose melanoma tumour cells have been shown to have a specific mutation (change) in the BRAF gene called 'BRAF V600'.

Cotellic contains the active substance cobimetinib.

How is Cotellic used?

Treatment with Cotellic must be started and supervised by a doctor experienced in the use of cancer medicines. Before starting treatment, patients must be tested for the BRAF V600 mutation. The medicine can only be obtained with a prescription.

Cotellic is available as tablets (20 mg). It is given at a recommended dose of 60 mg a day (3 tablets of 20 mg). Treatment with Cotellic is given in 28 day cycles: the tablets are taken for 21 consecutive days, followed by a 7-day break. The doctor may need to interrupt or stop treatment, or reduce the dose, if the patient experiences certain side effects.Treatment should continue for as long as the disease improves or remains stable and side effects are tolerable. For more information, see the summary of product characteristics.

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How does Cotellic work?

The active substance in Cotellic, cobimetinib, is an inhibitor of MEK, a protein involved in stimulating normal cell division. In melanoma with the BRAF V600 mutation, an abnormal form of the protein BRAF is produced, which switches on the protein MEK. This encourages the cancer to develop by allowing uncontrolled division of the cancer cells. Cotellic works by blocking MEK directly and by preventing its activation by the abnormal form of BRAF, thereby slowing down the growth and spread of the cancer. Cotellic is only given to patients whose melanoma is caused by the BRAF V600 mutation and must be used in combination with vemurafenib, which is a BRAF inhibitor.

What benefits of Cotellic have been shown in studies?

Cotellic has been studied in one main study involving 495 patients with melanoma that had spread or that could not be surgically removed, and whose melanoma had a BRAF V600 mutation. Patients had not been previously treated and were given either Cotellic with vemurafenib or placebo (a dummy treatment) with vemurafenib; the main measure of effectiveness was how long patients lived without their disease getting worse (progression-free survival). In this study, adding Cotellic to vemurafenib was more effective than adding placebo to vemurafenib: it took on average 12.3 months before the disease got worse in patients given Cotellic, compared with 7.2 months in patients given placebo.

What are the risks associated with Cotellic?

The most common side effects with Cotellic (which may affect more than 1 in 5 people) are diarrhoea, rash, nausea (feeling sick), vomiting, pyrexia (fever), photosensitivity (light sensitivity) reaction, abnormal results for certain liver function tests (increased levels of alanine aminotransferase, aspartate aminotransferase) and abnormal results for an enzyme related to muscle breakdown (creatine phosphokinase).

For the full list of all side effects and restrictions reported with Cotellic, see the package leaflet.

Why is Cotellic approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Cotellic's benefits are greater than its risks and recommended that it be approved for use in the EU. The Committee noted that Cotellic in combination with vemurafenib had shown a clinically relevant benefit in patients whose melanoma had a BRAF V600 mutation, when compared with vemurafenib alone. Because Cotellic and vemurafenib work by blocking different proteins important for cancer growth, combining them results in a better response and could delay cancer cells becoming resistant to vemurafenib. Although a supportive study showed that patients who were not previously treated with BRAF or MEK inhibitor medicines (such as vemurafenib) seemed to benefit the most from the therapy, the Committee considered that patients who previously received BRAF inhibitors may still benefit from treatment with Cotellic and vemurafenib. In terms of safety, the side effects were considered acceptable and manageable with appropriate measures.

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

A risk management plan has been developed to ensure that Cotellic 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 Cotellic, including the appropriate precautions to be followed by healthcare professionals and patients.

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

Other information about Cotellic

The European Commission granted a marketing authorisation valid throughout the European Union for Cotellic on 20 November 2015.

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

This summary was last updated in 11-2015.