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EPAR summary for the public

Odomzo

sonidegib

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

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

What is Odomzo and what is it used for?

Odomzo is a cancer medicine used to treat adults with basal cell carcinoma (a type of skin cancer) which is locally advanced (has started to spread nearby) and which cannot be treated either by surgery or by radiotherapy (treatment with radiation).

Odomzo contains the active substance sonidegib.

How is Odomzo used?

Odomzo can only be obtained with a prescription. It should only be prescribed by a specialist doctor experienced in the treatment of advanced basal cell carcinoma or under the supervision of such a doctor.

Odomzo is available as capsules (200 mg) and the recommended dose is one capsule taken once a day at least two hours after the last meal and an hour before the next. Odomzo is continued as long as it has a beneficial effect or until it can no longer be taken because of side effects.

For further information, see the package leaflet.

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How does Odomzo work?

Some cancers, including basal cell carcinoma, result from overactivity of a specific set of cell processes called the Hedgehog signalling pathway. This pathway normally controls a number of cell activities including cell growth and how cells develop correctly to make up different body organs in unborn babies. Sonidegib, the active substance in Odomzo, attaches to a protein that controls the Hedgehog signalling pathway. By attaching to this protein, sonidegib blocks the Hedgehog signalling pathway and thereby reduces the growth and spread of cancer cells.

What benefits of Odomzo have been shown in studies?

Odomzo was studied in one main study involving 230 patients with basal cell carcinoma which was either locally advanced or metastatic (spread to other parts of the body). Patients were started on two different doses of Odomzo: 200 or 800 mg once a day. The main measure of effectiveness was the response to treatment, based on a reduction in tumour size and improvement in other signs of cancer; treatment was considered sufficiently effective if the response rate was at least 30%.

Of those with locally advanced basal cell carcinoma, around 56% (37 of 66 patients) on the 200-mg dose and 45% (58 of 128 patients) started on the 800-mg dose responded to treatment. Response rates were less than 20% in patients with metastatic cancer started on either 200 or 800 mg Odomzo and the company withdrew its application for use in metastatic basal cell carcinoma.

What are the risks associated with Odomzo?

The most common side effects with Odomzo (which may affect more than 1 in 10 people) are muscle spasms, hair loss, taste disturbance, tiredness, nausea, vomiting, muscle and bone pain, belly ache, headache, diarrhoea, weight loss, loss of appetite, and itching. For the full list of all side effects reported with Odomzo, see the package leaflet.

Women who are pregnant or who are breastfeeding must not take Odomzo. Women who could potentially become pregnant must not take Odomzo unless they comply with the Odomzo pregnancy prevention programme. For the full list of restrictions, see the package leaflet.

Why is Odomzo approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Odomzo's benefits are greater than its risks and recommended that it be approved for use in the EU. The Committee considered that the benefits of Odomzo had been shown for patients with locally advanced disease. It also considered that the side effects were manageable.

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

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

In addition, the company will send a letter to doctors when Odomzo is launched. It will also supply educational material to doctors and to patients, including a reminder card about the risks of the medicine and, in particular, the possibility of serious harm to the unborn baby if Odomzo is taken during pregnancy. Substances that affect the Hedgehog pathway can result in serious harm to an

unborn baby. Therefore, women taking Odomzo must take effective measures to prevent pregnancy during treatment and for 20 months after stopping it. Men taking Odomzo must always use condoms for sex with female partners and for 6 months after stopping treatment.

Furthermore, the company is to supply further analysis from its main study on the effectiveness and safety of Odomzo, including its effectiveness in rapidly growing and slow-growing basal cell carcinoma. The company is also required to analyse available tumour material from patients whose cancer worsened despite treatment, in order to determine why the treatment did not work.

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

Other information about Odomzo

The European Commission granted a marketing authorisation valid throughout the European Union for Odomzo on 14 August 2015.

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

This summary was last updated in 08-2015.