



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EPAR summary for the public

Erivedge

vismodegib

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

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

What is Erivedge and what is it used for?

Erivedge is a cancer medicine that contains the active substance vismodegib. It is used to treat adults with basal cell carcinoma (a slow-growing form of skin cancer) in advanced stages: when the cancer is metastatic (has spread to other parts of the body) and is causing symptoms, or when it is locally advanced (has started to spread to nearby areas) and is not suitable for surgery or radiotherapy (treatment with radiation).

How is Erivedge used?

Erivedge can only be obtained with a prescription. It should only be prescribed by or under the supervision of a specialist doctor experienced in managing basal cell carcinoma. It is available as capsules (150 mg). The recommended dose is one capsule once a day. The benefits of continuing treatment should be regularly assessed and the best duration of treatment will vary based on the benefit and side effects experienced by each patient. For further information, see the package leaflet.

How does Erivedge work?

The active substance in Erivedge, vismodegib, disrupts the so-called 'Hedgehog signalling pathway', which is normally involved in regulating the early stages of cell development in unborn babies and certain cell processes in adults. In basal cell carcinoma, the Hedgehog signalling pathway becomes abnormally active and leads to the growth and spread of the cancerous cells. Vismodegib attaches to a



protein called 'SMO', which is involved in activating the Hedgehog signalling pathway. By attaching to SMO, vismodegib blocks this pathway, thereby slowing down the growth and spread of the cancer cells in basal cell carcinoma.

What benefits of Erivedge have been shown in studies?

Erivedge was studied in one main study involving 104 patients with either metastatic or locally advanced basal cell carcinoma. The patients were given Erivedge until their disease got worse or they could no longer tolerate treatment or withdrew from the study. Erivedge was not compared with another treatment. The main measure of effectiveness was the response to treatment, based on reduction by at least 30% in tumour size or disappearance of all signs of cancer (the objective response rate). Around 33% (11 out of 33) of patients with metastatic disease and 48% (30 out of 63) of patients with locally advanced disease responded to treatment.

What are the risks associated with Erivedge?

The most common side effects with Erivedge (seen in more than 3 in 10 people) are muscle spasms, hair loss, taste disturbances, weight loss, tiredness, nausea (feeling sick) and diarrhoea. For the full list of all side effects reported with Erivedge, see the package leaflet.

Erivedge must not be used in women who are pregnant or breast-feeding, or who could potentially have children and do not comply with the special pregnancy prevention programme for Erivedge. It must not be used together with St John's wort (a herbal medicine used to treat depression). For the full list of restrictions, see the package leaflet.

Why is Erivedge approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Erivedge'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 Erivedge had been shown for patients with locally advanced and metastatic disease. It also considered that the side effects were manageable. Since Erivedge disrupts the mechanism involved in the early development stages of unborn babies, the CHMP concluded that appropriate measures were needed for both men and women treated with Erivedge to prevent pregnancy during and after stopping treatment.

Erivedge was originally given 'conditional approval' because there was more evidence to come about the medicine. As the company has supplied the additional information necessary, the authorisation has been switched from conditional to full approval.

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

The company will implement a pregnancy prevention programme, by providing educational materials on the risks to the unborn baby, including a reminder card, to patients and healthcare professionals who prescribe and dispense Erivedge. The company will report any pregnancies that occur during treatment with Erivedge and will monitor their outcome.

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

Other information about Erivedge

The European Commission granted a marketing authorisation valid throughout the European Union for Erivedge on 12 July 2013.

The full EPAR for Erivedge can be found on the Agency's website: [ema.europa.eu/Find/medicine/Human medicines/European public assessment reports](http://ema.europa.eu/Find/medicine/Human%20medicines/European%20public%20assessment%20reports). For more information about treatment with Erivedge, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 10-2016.