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Ojemda (*tovorafenib*)

A plain-language overview of Ojemda and why it is authorised in the EU

What is Ojemda and what is it used for?

Ojemda is a medicine used to treat patients aged six months and older with paediatric low-grade glioma (a type of brain tumour). It can be used when the tumour has certain changes in the *BRAF* gene (such as a *BRAF* fusion or rearrangement or V600 mutation) in patients whose disease has worsened despite previous treatment with one or more systemic medicines (medicines affecting the whole body).

Glioma is rare, and Ojemda was designated an 'orphan medicine' (a medicine used in rare diseases) on 20 May 2021. Further information on the orphan designation can be found on the EMA website.

Ojemda contains the active substance tovorafenib.

How is Ojemda used?

Ojemda can only be obtained with a prescription, and treatment should only be started and supervised by a doctor experienced in the use of cancer medicines. Before starting treatment, patients must have a test to confirm their cancer cells have a *BRAF* fusion or rearrangement or V600 mutation.

Ojemda is available as tablets and as a powder to be made up into an oral suspension (a liquid to be drunk). It is to be taken by mouth once weekly, with or without food.

Treatment with Ojemda should continue as long as the patient benefits from it or until unacceptable side effects occur.

For more information about using Ojemda, see the package leaflet or contact your doctor or pharmacist.

How does Ojemda work?

In patients with paediatric low-grade glioma whose tumour has certain changes in the *BRAF* gene, including *BRAF* V600 mutations, *BRAF* fusions and rearrangements, RAF proteins cause tumour cells to grow and multiply. The active substance of Ojemda, tovorafenib, works by blocking RAF proteins. By targeting these proteins, tovorafenib helps slow down or stop the messages inside cells that cause tumour growth.

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What benefits of Ojemda have been shown in studies?

A main study showed that Ojemda is effective in patients with paediatric low-grade glioma whose tumour had changes in the *BRAF* gene and whose disease had worsened despite previous treatment with one or more systemic medicines.

The study involved 77 patients and did not compare Ojemda with another medicine or placebo (a dummy treatment). Forty patients (52.6%) achieved a response at some point during once-weekly treatment with Ojemda, and the response lasted on average for 18 months. No patient achieved a complete response (disappearance of the tumour and no new lesions), 29 patients achieved a partial response (at least 50% decrease in tumour size and no new lesions), and 11 achieved a minor response (25–49% decrease in tumour size and no new lesions).

Studies carried out with Ojemda are described in more detail in the medicine's assessment report.

What are the side effects and restrictions with Ojemda?

For the full list of side effects and restrictions with Ojemda, see the package leaflet.

The most common side effects with Ojemda (which may affect more than 1 in 10 people) include hair colour changes, increased blood creatine phosphokinase (enzyme released into the blood when muscle is damaged), tiredness, anaemia (low levels of red blood cells), vomiting, low blood levels of phosphates, headache, rash, fever, growth retardation, dry skin, increased levels of liver enzymes (aspartate aminotransferase and lactate dehydrogenase), nausea, constipation, upper respiratory tract (nose and throat) infection, dermatitis acneiform (inflammation of the skin resembling acne), nosebleed, decreased appetite and paronychia (nail bed infection).

Why is Ojemda authorised in the EU?

At the time of the approval of Ojemda, there were limited treatment options for patients with paediatric low-grade glioma, including surgery and chemotherapy. In addition, targeted therapy was available only to patients whose tumours had a *BRAF* V600E mutation, and no further treatment options were available for those patients whose disease had worsened after this treatment. Although data were derived from a study in which Ojemda was not compared to another treatment, the medicine was shown to be effective in patients with paediatric low-grade glioma whose tumour had changes in the *BRAF* gene and whose disease had worsened despite previous treatment with one or more systemic medicines. Concerning safety, side effects were considered manageable with appropriate monitoring and dose modifications.

Ojemda has been given conditional authorisation for use in the EU. This means that it has been authorised on the basis of less comprehensive data than are normally required, because it fulfils an unmet medical need. The European Medicines Agency considers that the benefit of having the medicine available earlier outweighs any risks associated with using it while awaiting further evidence.

The company must provide further data on Ojemda. It must submit final results from an ongoing clinical study in patients with paediatric low-grade glioma from six months of age comparing the effectiveness and safety of Ojemda with chemotherapy. Every year, the Agency will review any new information that becomes available.

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

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

As for all medicines, data on the use of Ojemda are continuously monitored. Suspected side effects reported with Ojemda are carefully evaluated and any necessary action taken to protect patients.

Other information about Ojemda

Ojemda received a conditional marketing authorisation valid throughout the EU on 20 April 2026.

Further information on Ojemda, including the package leaflet and assessment report, can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/ojemda.

For information about the availability of this medicine in your country, contact your national competent authority.

This overview was last updated in 04-2026.