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Summary report on authorisation dated 25 August 2026

# Ojemda® (active substance: tovorafenib)

## Temporary authorisation in Switzerland: 5 May 2026

## Powder for oral suspension for the treatment of paediatric low-grade glioma (LGG) with BRAF alteration after prior therapy

## About the medicinal product

Ojemda contains the active substance tovorafenib.

Ojemda is a medicinal product for the treatment of paediatric low-grade glioma, a rare form of brain cancer in children. The cancer arises from certain cells in the brain (glial cells) that support and protect the nerve cells.

The medicinal product is used in patients aged 6 months and older whose cancer exhibits a certain genetic alteration in the BRAF gene (BRAF fusion, BRAF rearrangement or BRAF mutation) and which has recurred after earlier treatment or has not responded to prior treatment.

Since this is a rare and life-threatening or chronically debilitating disease, the medicinal product Ojemda has been authorised as an orphan drug. The term "orphan drug" refers to medicinal products used to treat patients with rare diseases.

## Mode of action

Ojemda acts specifically on certain alterations in the tumour cells. Some of these tumours exhibit an alteration in the BRAF gene. As a result, signals in the cells that control growth are constantly active. This means that the tumour cells can proliferate uncontrolled.

The medicinal product intervenes in these growth processes and inhibits the overactive signals that drive tumour growth. This may slow down or even stop tumour cell growth.

## Administration

Ojemda is a prescription only medicine.

It is available as a powder for oral suspension and as film-coated tablets. The suspension is prepared with water, then taken orally.

The recommended dosage is determined by the patient's size (body surface area). Ojemda is taken once per week.

Treatment continues for as long as a benefit can be observed and no serious side effects occur.

Before treatment starts, patients must be tested to confirm their tumour exhibits an appropriate alteration in the BRAF gene.

Treatment should be initiated and supervised by professionals experienced in the treatment of cancer.

## Efficacy

The efficacy of Ojemda was investigated in a study (FIREFLY-1) that enrolled 137 patients aged between 6 months and 25 years whose brain tumour had recurred after earlier treatment or had failed to respond to prior treatment.

All study participants received Ojemda; there was no comparator group receiving a different treatment.

The results showed that the cancer responded to treatment in a large proportion of patients. These patients' tumours either shrank or did not display signs of further growth.

Many patients experienced a durable response to treatment.

## Precautions, undesirable effects, & risks

Ojemda must not be used in those who are hypersensitive to the active substance or any of the excipients.

Various risks may occur during treatment. In particular, these include bleeding (including bleeding in the tumour), retarded growth in children, liver problems and skin reactions including increased sensitivity to sunlight. Regular medical check-ups are necessary throughout treatment for this reason.

The most common undesirable effects (affecting more than 1 in 10 patients treated) include hair colour changes, fatigue, vomiting, headache, skin rash, fever, dry skin, growth retardation, anaemia and various changes in blood values (e.g. elevated levels of a muscle enzyme or changes in liver enzyme levels).

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

## Why the medicinal product has been authorised

Paediatric low-grade glioma accounts for some childhood brain cancer. There is a need for additional treatment options for patients who experience a recurrence of the disease after prior treatment or who do not respond to treatment.

The study showed that a large proportion of patients responded to treatment with Ojemda and their tumour shrank or displayed no signs of further growth.

The safety and efficacy data for children under two years of age are currently limited. Additional data on the possible long-term effects, particularly on growth and development, are also needed. These additional data are expected from ongoing studies.

Taking all the risks and precautions into account, and based on the available data, the benefits of Ojemda outweigh the risks.

The medicinal product Ojemda has been authorised in Switzerland on a temporary basis (in accordance with Art. 9a of the Therapeutic Products Act) since not all clinical trials

data were available at the time of authorisation.

The temporary authorisation is contingent on the outstanding clinical data requested by Swissmedic being submitted on schedule. The data in question are from clinical trials that are still ongoing or have yet to be concluded. Once these authorisation conditions have been met, the temporary authorisation can be converted into an authorisation without special conditions in the event of a positive benefit-risk assessment of the results.

## Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Ojemda®

Information for patients (package leaflet): Information for patients Ojemda®
Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.