ojemda™
(tovorafenib)
100 mg tablets
25 mg/mL for oral suspension

OJEMDA™ (tovorafenib) Product Information

INDICATION

OJEMDA™ (tovorafenib) is indicated for the treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (LGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation.

This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

The OJEMDA Prescribing Information includes warnings and precautions for hemorrhage, skin toxicity including photosensitivity, hepatotoxicity, effect on growth, embryo-fetal toxicity, and NF1 associated tumors.

4 blister cards (16 tablets)

NDC: 82950-001-16
Description: Tovorafenib 100-mg tablets, 16 tablets
BSA Band: 0.90 m^2–1.12 m^2
Dosing: 400 mg once per week (4 tablets × 100 mg)
Days Supplied: 28-day supply

5 blister cards (20 tablets)

NDC: 82950-001-20
Description: Tovorafenib 100-mg tablets, 20 tablets
BSA Band: 1.13 m^2–1.39 m^2
Dosing: 500 mg once per week (5 tablets × 100 mg)
Days Supplied: 28-day supply

4 blister cards (24 tablets)

NDC: 82950-001-24
Description: Tovorafenib 100-mg tablets, 24 tablets
BSA Band: ≥1.40 m^2
Dosing: 600 mg once per week (6 tablets × 100 mg)
Days Supplied: 28-day supply

OJEMDA for oral suspension

NDC: 82950-012-01
Description: Each bottle delivers 300 mg of tovorafenib in 12 mL
BSA Band: 0.30 m^2–0.89 m^2
Dosing: 380 mg/m^2 once per week, according to BSA
Days Supplied: 7-day supply per bottle (order 4 bottles for 28-day supply)

Dosing and Administration

Recommended Dosage:
The recommended dosage of OJEMDA based on body surface area (BSA) is 380 mg/m^2 orally once weekly (the maximum recommended dosage is 600 mg orally once weekly) with or without food until disease progression or intolerable toxicity. OJEMDA may be administered as an immediate release tablet or as an oral suspension. A recommended dosage for patients with BSA less than 0.3 m^2 has not been established.

Dispense the product in the original package. Tablets should not be removed from blisters until immediately before use.

Storage: Store at 20 °C to 25 °C (68 °F to 77 °F); excursions permitted between 15 °C and 30 °C (59 °F and 86 °F).

Note: Suspension must be used immediately after reconstitution.

OJEMDA Ordering

OJEMDA is available through a limited network of specialty pharmacies.*

Biologics By McKesson

Phone number: 800-850-4306
Fax number: 800-823-4506
Website: www.biologicsinc.com
Available 8 AM to 8 PM ET, Monday through Friday.

Onco360 ONCOLOGY PHARMACY

Phone number: 877-662-6633
Fax number: 877-662-6355
Website: www.onco360.com
Available 8 AM to 8 PM ET, Monday through Friday.

*Day One Biopharmaceuticals does not influence or advocate for the use of either specialty pharmacy and makes no representation or guarantee of services or coverage.

Please see additional Important Safety Information on the next page and full Prescribing Information.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Hemorrhage

Hemorrhage, including major hemorrhage defined as symptomatic bleeding in a critical area or organ, can occur with OJEMDA. Advise patients and caregivers of the risk of hemorrhage during treatment with OJEMDA. Monitor for signs and symptoms of hemorrhage and evaluate as clinically indicated. Withhold and resume at reduced dose upon improvement, or permanently discontinue based on severity.

Skin Toxicity Including Photosensitivity

OJEMDA can cause rash, including maculopapular rash and photosensitivity. Monitor for new or worsening skin reactions. Consider dermatologic consultation and initiate supportive care as clinically indicated. Withhold, reduce the dose, or permanently discontinue OJEMDA based on severity of adverse reaction.

Photosensitivity

Advise patients to use precautionary measures against ultraviolet exposure such as use of sunscreen, sunglasses, and/or protective clothing during treatment with OJEMDA. Withhold, reduce the dose, or permanently discontinue OJEMDA based on severity of adverse reaction.

Hepatotoxicity

OJEMDA can cause hepatotoxicity. Monitor liver function tests, including ALT, AST and bilirubin, before initiation of OJEMDA, one month after initiation and then every three months thereafter and as clinically indicated. Withhold and resume at the same or reduced dose upon improvement, or permanently discontinue OJEMDA based on the severity.

Effect on Growth

OJEMDA can cause reductions in growth velocity. Growth velocity recovered after interruption of treatment with OJEMDA. Routinely monitor patient growth during treatment with OJEMDA.

Embryo-Fetal Toxicity

Based on findings from animal studies and its mechanism of action, OJEMDA may cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus.

Advise females of reproductive potential to use effective nonhormonal contraception during treatment with OJEMDA and for 28 days after the last dose, since OJEMDA can render some hormonal contraceptives ineffective. Advise male patients with female partners of reproductive potential to use effective nonhormonal contraception during treatment with OJEMDA and for 2 weeks after the last dose.

NF1 Associated Tumors

Based on nonclinical data in NF1 models without BRAF alterations, tovorafenib may promote tumor growth in patients with NF1 tumors. Confirm evidence of a BRAF alteration prior to initiation of treatment with OJEMDA.

Adverse Reactions

The most common adverse reactions (≥30%) were rash, hair color changes, fatigue, viral infection, vomiting, headache, hemorrhage, pyrexia, dry skin, constipation, nausea, dermatitis acneiform, and upper respiratory tract infection.

Please see full Prescribing Information.

For More Information on OJEMDA

Call **855-DAY-1BIO/855-329-1246**

Visit **OJEMDAHCP.com**

Day One BIOPHARMACEUTICALS

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