

FIRST AND ONLY FDA-APPROVED

oral medicine for
children with pediatric
low-grade glioma (pLGG)
that returned or did not
respond to treatment and
who have a certain type
of abnormal *BRAF* gene

What to know when starting OJEMDA™



ojemda™
(tovorafenib)

100 mg tablets
25 mg/mL for oral suspension

THIS CHILD HAS A BRAIN TUMOR

Getting started with
OJEMDA: What's ahead

Sawyer,
lives with pLGG

INDICATION

What is OJEMDA™ (tovorafenib)?

OJEMDA is a prescription medicine used to treat certain types of brain tumors (cancers) called gliomas in people 6 months and older:

- that is a pediatric low-grade glioma (LGG), **and**
- that has come back after previous treatment or has not responded to previous treatment **and**
- that has a certain type of abnormal *BRAF* gene.

IMPORTANT SAFETY INFORMATION

Before taking or giving OJEMDA, tell your healthcare provider about all of your or your child's medical conditions, including if you:

- have bleeding, skin, or liver problems
- are pregnant or plan to become pregnant. OJEMDA can harm your unborn baby.

Please see Important Safety Information throughout and Patient Information, including Instructions for Use for more information.

How to take
OJEMDA

Common questions

Side effects

Tips for starting

Resources

Important Safety
Information

What you'll find in this guide

Everything you need to get started with OJEMDA

How to take OJEMDA	4
Common questions	6
Side effects and management tips	8
Tips for starting a treatment routine	14
How to enroll in EveryDay Support From Day One™	16
Notes	17
Important Safety Information	18

Hana, lives with pLGG, and Kibebew, her brother

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Once-weekly oral dosing can mean fewer daily interruptions



Give OJEMDA **once a week** on the same day and time



OJEMDA is available in **2 forms**



Flexibility to take **with or without food**



Can be taken **conveniently from home**



Tablets

Swallow whole with water. **Do not cut, chew, or crush.**



Product images are not shown at actual size.



Oral suspension

Before preparing a liquid dose, read the Step-by-Step Guide for Preparing a Liquid Dose of OJEMDA, available online at **[OJEMDA.com/step-by-step](https://www.ojemda.com/step-by-step)**. Work with your child's care team to learn how to prepare the first dose together.

Product images are not shown at actual size.

For specific liquid dose instructions, visit **[OJEMDA.com/step-by-step](https://www.ojemda.com/step-by-step)** or scan this QR code

Scan



How to take OJEMDA

Oral suspension vs tablets: Which is right for my child?

You and your child's care team will decide which form of OJEMDA is right for your child.

You and your child's care team will determine if OJEMDA is right for your child and decide which form may be appropriate based on factors such as your child's ability to swallow tablets. Your child's care team will determine the dosage of OJEMDA based on a measurement of the size of your child's body called body surface area (BSA), ensuring your child receives the right amount of medicine.

OJEMDA should be taken exactly as your child's doctor instructs. Do not change your child's dose or stop OJEMDA unless your child's doctor tells you to.

How to store OJEMDA

Store OJEMDA at room temperature 68°F to 77°F (20°C to 25°C) and in a dry, safe place, out of the reach of children.

How to handle OJEMDA

Tablets: Keep tablets in the original package. Tablets should not be removed from the package until immediately before use.

Oral suspension: The prepared liquid dose must be used within 15 minutes once prepared. Throw away the bottle, including any unused medicine and syringe, after giving your child OJEMDA.

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Holmes, lives with pLGG, and Clare, his mom

What to do if...

Your child misses a dose of OJEMDA

If a dose is missed by:

- 3 days or less, the missed dose should be taken as soon as possible, and the next dose should be taken on its regularly scheduled day
- More than 3 days, the missed dose should be skipped and the next dose should be taken on its regularly scheduled day

Your child vomits after taking OJEMDA

If your child vomits right after taking a dose, give them another dose. If you are not sure if you should give them another dose, contact your child’s care team.

OJEMDA tablets are chipped or the seal is broken

Do not give any chipped or broken OJEMDA tablets. Do not use OJEMDA for oral suspension if the safety seal under the cap is broken or missing. Call your specialty pharmacy if a replacement is needed.

Your child takes too much OJEMDA

Call your child’s care team right away.

You make a mistake while preparing a liquid dose of OJEMDA

Call your child’s care team, pharmacist, or your Patient Navigator at EveryDay Support From Day One™. If necessary, they can overnight a replacement dose.

You’re worried about side effects your child may be experiencing

Call your child’s care team. They can assess your individual situation and guide you on the best course of action.

5 R’s to remember about OJEMDA

- 1 Request:** Know that OJEMDA is available in tablets or oral suspension. Ask your child’s care team which option is best for your child.
- 2 Routine:** Give OJEMDA once a week on the same day and time.
Ready: Only remove the tablets once your child is ready to take them. Give the liquid dose within 15 minutes of preparing it. **Closely follow the Step-by-Step Guide for Preparing a Liquid Dose of OJEMDA at [OJEMDA.com/step-by-step](https://www.ojemda.com/step-by-step).**
- 3 Rubbish:** Throw away the prepared liquid dose if it is not used within 15 minutes.
- 4 Repeat:** Give OJEMDA as prescribed.

Please see Important Safety Information throughout and [Patient Information](#), including Instructions for Use for more information.





Sawyer, lives with pLGG, and Jordan, her dad

What are the possible side effects?

OJEMDA may cause serious side effects, including:



Bleeding problems, such as nose bleeds or bleeding from the tumor

Call your child's doctor immediately if they have any symptoms including:

- Headache, dizziness, or feeling weak
- Coughing up blood or blood clots
- Vomiting blood or vomit looks like coffee grounds
- Red or black stools that look like tar



Skin reactions, including sensitivity to sunlight (photosensitivity)

Call your child's doctor if your child gets new or worsening skin reactions, including:

- rash
- peeling, redness, or irritation
- bumps
- blisters
- acne



Liver problems

Your child's doctor will do blood tests to check your child's liver function before and during treatment with OJEMDA. Call your child's doctor right away if your child gets any of the following symptoms:

- yellowing of skin or eyes
- feeling tired
- dark or brown (tea-colored) urine
- bruising
- nausea or vomiting
- bleeding
- loss of appetite
- pain in the upper right stomach area



Slowing of growth (height)

- Your child's growth will be checked routinely during treatment with OJEMDA
- Growth was improved after children paused or stopped taking OJEMDA

Other safety considerations

OJEMDA may cause fertility problems in males and females. Talk to your healthcare provider if this is a concern for you.

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What are the most common side effects?

Side effects with OJEMDA were mostly mild to moderate. However, as you know, all children are different. So, if something concerns you, discuss side effect management with your care team.

The most common side effects of OJEMDA include:

Side effect	Out of 137 children, how many experienced it?*
Rash	83%
Hair	77%
Viral infection	63%
Feeling tired	61%
Vomiting	56%
Headache	53%
Fever	47%
Dry skin	47%
Acne	38%
Nausea	37%
Constipation	36%
Upper respiratory tract infection	36%

*Based on patients who completed up to 2 years of treatment with OJEMDA in the clinical trial. Additional analyses were conducted. These data are not reflected in the Prescribing Information.

These are not all the possible side effects of OJEMDA. Talk to your child’s care team for medical advice about side effects. They can determine if your child needs to change their dosage or stop treatment. You may report side effects to the FDA at 1-800-FDA-1088. You may also report side effects to Day One Biopharmaceuticals at 1-877-204-2820.

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Tips to help manage side effects

Make sure to work with your child's care team to build a plan that will make your child comfortable

Rash, acne, or dry skin

- Soothe with a warm bath; use unscented creams and gentle soaps
- Moisturize dry skin with lotions to help retain moisture

Hair color changes

- Discuss with your child how they’d like to handle their hair if it lightens or turns white
- Consider whether your child would like to dye their hair
- Once the treatment is stopped, the child’s hair, eyebrows, and eyelashes may grow back in their natural color

Feeling tired

- Allow more time for naps and reduce activity to conserve your child’s energy
- Help your child drink lots of fluids and eat well
- Encourage exercising when possible

Vomiting or nausea

- Feed your child frequent small snacks (empty stomachs can make nausea worse)
- Encourage your child to sip liquids slowly throughout the day

Headache

- Use a cold washcloth and place it on your child’s forehead or back of their neck
- Help your child rest in a darkened room

Viral or upper respiratory tract infection

- Call your child’s care team if your child is showing signs of a viral infection, or an upper respiratory infection, like a cold or bronchitis. Your child’s doctor can help choose the best treatment plan

Fever

- Contact your child’s care team right away if your child gets a fever
- Give your child plenty of liquids and place a cold cloth on their forehead

Constipation

- Give your child warm fluids often
- Feed your child high-fiber foods



Treatment that most children can stick with

In the study, most side effects reported in children were mild to moderate, and managed

89% of children did not stop taking OJEMDA due to side effects
(122 out of 137 children)



The side effects that caused 11% of children (15 out of 137) to stop taking OJEMDA were:

- bleeding from the tumor (4 out of 137)
- slowing of growth (4 out of 137)

If your child experiences any serious side effects during treatment with OJEMDA, your child's doctor may decrease dosage.

*The FIREFLY-1 main phase concluded in 2024. Patients are currently being followed for longer-term observation.

SELECT IMPORTANT SAFETY INFORMATION

Females who are able to become pregnant:

- You should use effective non-hormonal birth control (contraception) during treatment with OJEMDA and for 28 days after your last dose of OJEMDA.

Males with female partners who are able to become pregnant should use effective non-hormonal birth control (contraception) during treatment with OJEMDA and for 2 weeks after your last dose of OJEMDA.

- are breastfeeding or plan to breastfeed. Do not breastfeed during treatment and for 2 weeks after your last dose of OJEMDA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Taking certain other medicines can affect how OJEMDA works and may increase your risk of side effects. OJEMDA may also affect how other medicines work.

“Side effects can happen with any medication. It is important to discuss any symptoms your child may experience while taking OJEMDA so that your doctor can advise on the appropriate course of action.”

— Dr Peter Manley, Vice President at Day One Biopharmaceuticals



Breslyn, lives with pLGG, and Noelle, her sister

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Holmes, lives with pLGG

Tips for starting a treatment routine

How to begin with OJEMDA

Thinking about how to introduce OJEMDA into your child's life? What's the right time and the right way to involve them? Your child's care team can also help to establish a new routine.

SELECT IMPORTANT SAFETY INFORMATION

What should I avoid while taking OJEMDA?

Limit the amount of time you spend in sunlight. OJEMDA can make your skin sensitive to the sun (photosensitivity). Use sun protection measures, such as sunscreen, sunglasses and wear protective clothes that cover your skin during your treatment with OJEMDA.

Stay on track: Set a routine

It's important that your child takes their OJEMDA once a week, on the same day and time.

Consider following these tips based on their age group.

Infants/Toddlers (6 months-2 years)

Repetition can be helpful when creating a routine with tots. Try to pair their treatment with another activity they are familiar with, like playing their favorite song or TV show.

Toddlers/Preschoolers (2-5 years)

Children can be motivated by rewards, such as receiving stickers or collecting points. See if your child would like to try a sticker chart to encourage them. Consider hanging a calendar or dry-erase board with their treatment day marked up in a visible place.

School-Age Children (6-11 years)

Children in this age group like to feel involved. Consider talking with your child to find a time and day they'd prefer.

Adolescents (12-17 years)

As your child approaches adulthood, check in with them about how much they want to manage on their own. Encourage independence where it makes sense, like setting a dose reminder alert on their phone.

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- are breastfeeding or plan to breastfeed. Do not breastfeed during treatment and for 2 weeks after your last dose of OJEMDA.

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What are the possible side effects of OJEMDA?

OJEMDA may cause serious side effects, including:

- **bleeding problems (hemorrhage)** are common and can also be serious. Tell your healthcare provider if you develop any signs or symptoms of bleeding, including:
 - headache, dizziness or feeling weak
 - coughing up blood or blood clots
 - vomiting blood or your vomit looks like "coffee grounds"
 - red or black stools that look like tar
- **skin reactions, including sensitivity to sunlight (photosensitivity)**. OJEMDA can cause skin reactions that can become severe. Tell your healthcare provider if you get new or worsening skin reactions, including:
 - rash
 - peeling, redness, or irritation
 - bumps or tiny papules
 - blisters
 - acne
- **liver problems**. Your healthcare provider will do blood tests to check your liver function before and during treatment with OJEMDA. Tell your healthcare provider right away if you develop any of the following symptoms:
 - yellowing of your skin or your eyes
 - feeling tired
 - dark or brown (tea-colored) urine
 - bruising
 - nausea or vomiting
 - bleeding
 - loss of appetite
 - pain in your upper right stomach area
- **slowed growth in children**. Growth will be checked routinely during treatment with OJEMDA.

The most common side effects of OJEMDA include:

- | | | |
|----------------------|------------|-------------------------------------|
| • rash | • vomiting | • constipation |
| • hair color changes | • headache | • nausea |
| • feeling tired | • fever | • acne |
| • viral infection | • dry skin | • upper respiratory tract infection |

OJEMDA may cause fertility problems in males and females, which may affect your ability to have children.

These are not all the possible side effects of OJEMDA. Call your healthcare provider for medical advice about side effects.

You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Day One Biopharmaceuticals at 1-877-204-2820.





Hana, lives with pLGG, and Kibebew, her brother

Thank you from Day One

Day One would like to thank the clinical study participants, their families, pediatric cancer advocacy foundations, and investigators who have given us feedback along this journey. We are inspired by the strength of children and families impacted by pLGG. That's why we put kids first in everything we do and are dedicated to supporting the community from Day One and every day after.



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