

FIRST AND ONLY
FDA-APPROVED

oral medicine for children with
pediatric low-grade glioma
(pLGG) who have certain
changes in the BRAF gene,
that has returned or did not
respond to treatment



ojemda™
(tovorafenib)

100 mg tablets
25 mg/mL for oral suspension

About This Guide

Possible
Side Effects

Impact on
Physical Growth

Skin
Reactions

Hair Color
Changes

Notes

THIS CHILD HAS A BRAIN TUMOR

How to prepare for
side effects and help
manage them

*Holmes,
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 patients 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 accompanying [Patient Information](#), including [Instructions for Use](#).

Confidence comes from knowing what to expect

A letter of support from Reeba, mother of Myla, who took OJEMDA

As you raise your children, there are a lot of things you worry about, but my daughter getting a brain tumor was not something I could have ever imagined. Starting treatment for your child is overwhelming and terrifying. You must stay strong, but also informed about the side effects and how you can manage them.

Being an advocate for your child and making sure they communicate with you and their care team about what is not comfortable can help things go smoother. Finding ways to help make their quality of life as strong as possible could make treatment just a bit easier. It's OK to be vulnerable and be sad about the bad news, but make sure you also celebrate the wins, no matter how small! Your positive attitude and support will make a world of difference as you navigate this journey together.

With love,
Reeba, Myla's mom



In this guide, you will meet some of the children from FIREFLY-1, the clinical trial for OJEMDA

Parents of children participating in the clinical trial for OJEMDA (oh-JEM-dah) documented their journey through photos. You'll find some of their experiences in this guide. **Your child's experience with OJEMDA may be different.**

By preparing for potential side effects, you can have an important impact on your child's journey with OJEMDA

Every child's experience is different. But seeing and hearing what others have gone through may help you navigate the journey ahead.

This guide includes:

- Overview of side effects of OJEMDA
- What to look for and expect
- Tips to manage side effects

Remember, your child's care team, including your specialty pharmacist, is there to support you every step of the way.



See how OJEMDA was studied in 137 patients—the largest clinical trial of children with BRAF gene changes at [OJEMDA.com](https://www.ojemda.com)



Ben at age 14

Olive at age 11

Gabby at age 16

Myla at age 11

Sam at age 11

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



OJEMDA may cause serious side effects



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
- Vomiting blood or vomit that looks like coffee grounds
- Coughing up blood or blood clots
- 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
- Tiredness
- Dark or brown (tea-colored) urine
- Bruising
- Nausea or vomiting
- Bleeding
- Loss of appetite
- Pain in the upper right stomach area



Slowed growth

- Your child's growth (height) will be checked routinely during treatment with OJEMDA
- Rate of growth resumed after children took a break from OJEMDA

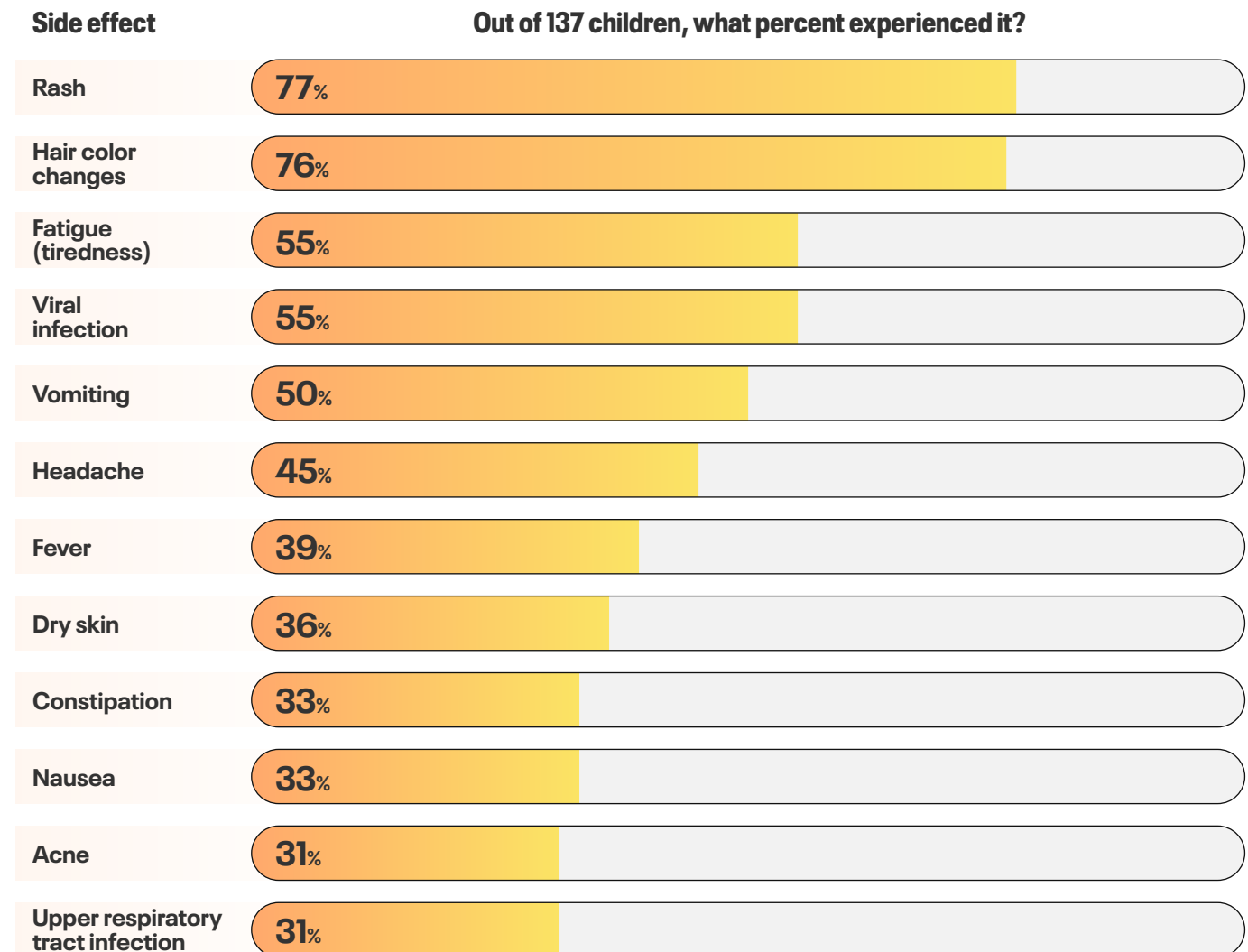
Other safety considerations

OJEMDA may cause fertility problems in female and male children, which can affect their ability to have children. If you have concerns about your child's fertility, you should discuss their family planning goals with their care team. Remember, your care team is there to support you every step of the way.

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

What are the most common side effects?

Children mostly experience mild to moderate side effects while taking OJEMDA, with 74% of children (102 out of 137) staying on treatment.



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.



Impact on physical growth

Children with pLGG may have growth-related conditions. Treatments for childhood cancer (like chemotherapy, radiation, extended steroid use, or targeted treatment) can also affect growth.

How common is slowed growth in children taking OJEMDA?

An initial analysis conducted in June 2023 showed that 15% of children 18 years or younger had slowed growth in the clinical trial.

In May 2024, additional data was collected and studied. These results are not in the OJEMDA Prescribing Information.

In the updated data analysis,

46% (61 out of 133) of children 18 years or younger had slowed growth



- Children who participated in the FIREFLY-1 clinical study are being monitored for long-term observation, and further analysis may become available

When does growth typically slow in children taking OJEMDA?

Every child is different, and depending on their age (and other factors), growth changes may be noticed at varying times, or sometimes not at all. You can monitor your child's growth at home, and check in with your child's healthcare team to see how their growth is tracking.

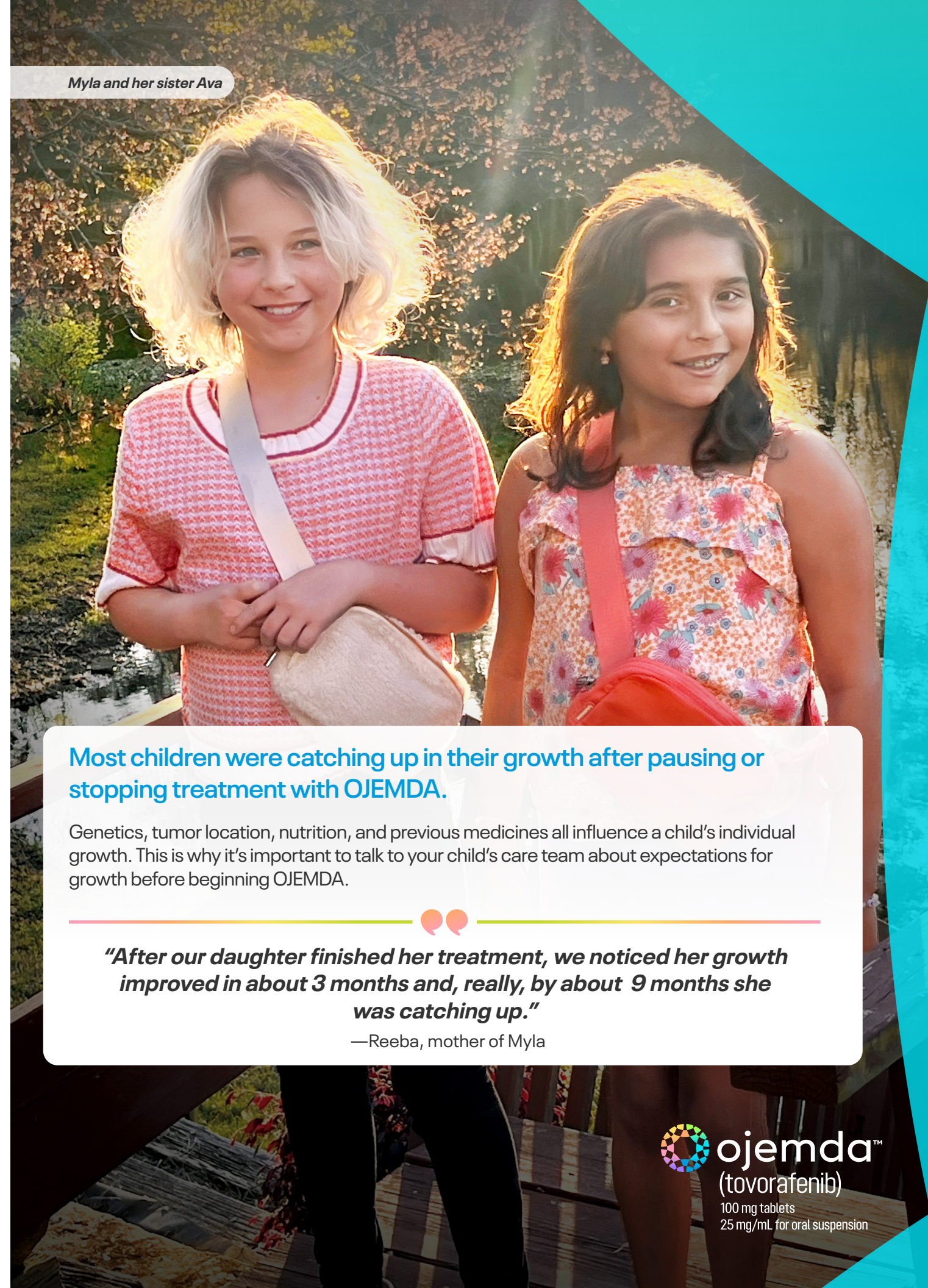
Is slowed growth reversible?



Improvement in growth was seen as early as 3 months after stopping OJEMDA in the clinical trial.

- This data is based on the results of the updated analysis in May 2024 and is also not included in the OJEMDA Prescribing Information

Myla and her sister Ava




Most children were catching up in their growth after pausing or stopping treatment with OJEMDA.

Genetics, tumor location, nutrition, and previous medicines all influence a child's individual growth. This is why it's important to talk to your child's care team about expectations for growth before beginning OJEMDA.

"After our daughter finished her treatment, we noticed her growth improved in about 3 months and, really, by about 9 months she was catching up."

—Reeba, mother of Myla

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

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

Skin reactions

How common are they?

Skin reactions are common side effects in lots of cancer treatments, including OJEMDA. Some of the common skin reactions for OJEMDA were rash, acne, dry skin, and sensitivity to sunlight.



In the clinical trial of OJEMDA,

77% (105 out of 137) of children had rash



The majority of children experienced mild to moderate rash. 12% of children (16 out of 137) had serious rash.

14% (19 out of 137) of children had sensitivity to sunlight



When did children in the clinical trial first notice rash?



In the clinical trial for OJEMDA, children experienced rash as early as 2 weeks after taking the first dose and up to 16 months after.

How can rash, dry skin, or acne be managed?

Here are a few tips to help make your child more comfortable. Be sure to work with your child's care team to come up with the right plan to manage side effects.



Avoid irritation

- Use unscented creams and gentle soaps; avoid products with alcohol or retinoids
- Wash clothing with gentle (hypoallergenic) laundry detergent



Soothe

- Take short, warm baths or showers (see [page 6](#) for details)
- Talk to your child's doctor about steroids for dry skin:
 - 2% ketoconazole shampoo or steroid oil for the scalp
 - Low-strength steroid ointment for the face, elbows, and knees
 - Regular strength ointment for the legs, arms, stomach, and back



Protect

- Apply unscented, thick moisturizers (creams over lotions) to dry skin right after bathing
- Wear sunscreen when outside

"Ben's doctors told us there were going to be rashes. There were, and the team was great about helping us handle it."

—David, father of Ben

Additional information on skin reactions

What are some home remedies that can help?

Different types of home remedies have been shown to help soothe irritated skin, including rashes. Talk to your child's care team about options, from more natural (oatmeal baths or aloe vera for sun sensitivity) to more medicinal (diluted bleach bath for rash). Below are instructions for 2 popular remedies:



Oatmeal bath instructions

- 1 Fill the bathtub ½ full with lukewarm water while sprinkling in 1 cup of finely ground oatmeal
- 2 Soak for 10-15 minutes
- 3 Gently pat skin dry following bath and apply moisturizer



Bleach bath instructions

- 1 Fill the bathtub ½ full with warm water with ¼ cup of bleach
- 2 Soak for 10 minutes
- 3 Gently pat skin dry following bath and apply moisturizer

Ask your child's care team about what skincare products to use (or avoid!) after bleach baths



"We found bleach baths intimidating at first, but our nurse explained that it was similar to swimming in a chlorine-treated pool."

—Mandy, mother of Gabby

What else should you know?

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

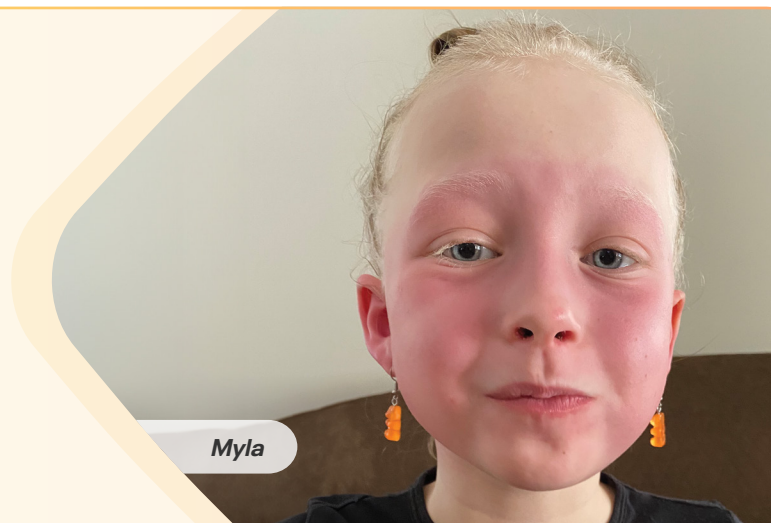
- Rash
- Acne
- Peeling, redness, or irritation
- Bumps
- Blisters

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

How can sensitivity to sunlight be managed?

Some children experience skin reactions when exposed to sunlight.

This photosensitivity, or sensitivity to sunlight, may be managed. In addition to the tips below, be sure to ask your child's care team for help.



Always use sunscreen (even if it's not sunny outside)

- Before putting on clothes, apply sunscreen to your child (SPF 50+)
- Reapply to exposed skin as needed
- Keep extra sunscreen with you, and in your children's backpack



When dressing, cover legs, arms, and face

- Make sure clothing is sun protective (dark colors, thick fabric, or labeled "UV protective")
- Use sunglasses and brimmed hats to cover the head and neck

"It's a sun reaction, and it would puff up for hours. It would look like a sunburn, and then it would just kind of fade away."

—Trista, mother of Olive

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

Hair color changes

How common is hair color change?

Certain cancer treatments, especially targeted therapies, commonly can lead to changes in hair color. Eyelashes, eyebrows, and body hair may change, too.

In the clinical trial of OJEMDA,

76% (104 out of 137) of children had hair color changes

Hair color changes consisted of lightening, graying, or turning white.

"My mom asked if I wanted to dye my hair, but I said no! This is who I am, and I love who I am."

—Gabby

Gabby

When do children usually first notice hair color change?

Hair color changes may appear soon after treatment, but timing varies among children based on factors such as how fast their hair grows.

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

How can hair color change be managed?

Each person experiences hair color changes differently. Depending on your child's age, these changes may be unwanted.

Older children, like pre-teens and teenagers, may find color changes to be a burden, so it could be helpful to manage expectations through open and supportive conversations.

Before OJEMDA When discussing the potential for hair color changes, focus on the positives

Conversation starter:

"After you take OJEMDA to treat your brain tumor, your hair might change color. How would that make you feel?"

During OJEMDA Empower children to make their own hair decisions, including hair dye, hair chalk, or makeup as appropriate

Conversation starter:

"What would help you feel more confident about your hair color changes?"

After OJEMDA Talk to them to prepare them for two-toned hair as their original hair color grows in

Conversation starter:

"When you see your natural roots, that means your old hair color is coming back. What does that mean for you?"

"There were times our daughter felt special and unique. She never wanted to dye her hair or change it in any way. She loved it."

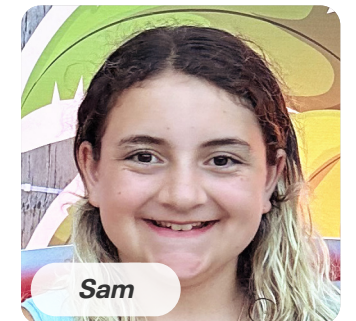
—Trista, parent of Olive




Myla



Olive



Sam

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

Notes

If you found any of these tips helpful or have questions for your child’s care team, write them here:

IMPORTANT SAFETY INFORMATION (cont’d)

Before taking or giving OJEMDA, tell your healthcare provider about all of your or your child’s medical conditions, including: (cont’d)

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.

IMPORTANT SAFETY INFORMATION (cont’d)

Before taking or giving OJEMDA, tell your healthcare provider about all of your or your child’s medical conditions, including: (cont’d)

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

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.

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
 - vomiting blood or your vomit looks like “coffee grounds”
 - coughing up blood or blood clots
 - 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
 - acne
 - blisters
 - bumps or tiny papules
 - peeling, redness, or irritation
- **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
 - nausea or vomiting
 - bleeding
 - dark or brown (tea-colored) urine
 - loss of appetite
 - pain in your upper right stomach area
 - tiredness
 - bruising
- **slowed growth in children.** Growth will be checked routinely during treatment with OJEMDA.

The most common side effects of OJEMDA include:

- rash
- headache
- nausea
- hair color changes
- fever
- acne
- tiredness
- dry skin
- upper respiratory tract infection
- viral infection
- constipation
- vomiting

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.

Please see accompanying full Patient Information, including Instructions for Use, for more information.



Help shrink your child's tumor with OJEMDA

The clinical study **FIREFLY-1** studied safety, and also showed meaningful tumor shrinkage



51% of children (39 out of 76) experienced tumor shrinkage of at least 25%



Children experienced mostly mild to moderate side effects, with 74% of children (102 out of 137) staying on treatment

Serious side effects include bleeding problems, skin reactions, liver problems, and slowed growth in children.

Most children's growth rate returned to normal after taking a break from treatment. During treatment with OJEMDA, growth will be checked often.

The FIREFLY-1 main phase concluded at the end of 2024. Patients are being followed for longer-term observation.



Once-weekly oral dosing in tablet or liquid form that can be taken with or without food conveniently from home



Comprehensive patient support to help your child start and stay on treatment at [EveryDaySupport.com](https://www.everydaysupport.com)

For more information, visit [OJEMDA.com](https://www.OJEMDA.com)



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



Day One, the Day One logo, OJEMDA, and the OJEMDA logo are trademarks or registered trademarks of Day One Biopharmaceuticals, Inc. All other trademarks are the property of their respective owners.

©2025 Day One Biopharmaceuticals, Inc. All rights reserved. TOVO-US-0378, 04/25 (v1.0).

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