

STEP-BY-STEP GUIDE FOR

preparing a liquid dose of OJEMDA™ (tovorafenib)



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 on pages 24-25, and accompanying [Patient Information](#).

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

Before
you begin

1: Prep

2: Mix

3: Fill

4: Give

FAQs

Important Safety
Information



Hana, lives with pLGG

What's inside

This step-by-step guide was created to empower you with the knowledge and confidence needed to prepare and give a liquid dose of OJEMDA to your child.

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Please see Important Safety Information on pages 24-25, and accompanying [Patient Information](#).


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

Before you begin

Important safety tips to remember before you get started

1. Check your child's prescribed dose

- If your child's prescribed dose is more than 300 mg or 12 mL, you'll need to prepare 2 bottles. Split the dose as equally as possible between 2 bottles. Prepare and give each bottle one at a time.

2. Timing is key

- Set aside several minutes for this process, and read through all instructions before you start.
- OJEMDA must be taken **within 15 minutes after mixing, or the medicine will start to thicken.**
- If you made a mistake, we can help get you a replacement dose. Call your child's pharmacist, care team, or Patient Navigator at EveryDay Support From Day One™ at 855-DAY1-BIO/855-329-1246 Monday-Friday, from 8 AM-8 PM ET

3. Wash and dry your hands

- Make sure you wash and dry your hands before you start.

4. Get your surface and supplies ready

- Prepare the dose on a clean flat surface.
- Always use the supplies in the OJEMDA™ (tovorafenib) box or those provided by your pharmacist. This ensures you can measure and give your child's dose correctly.

5. Dispose of items after use

- After you give your child the medicine, throw away all of the used supplies.
- Unused medicine must be thrown away too.

6. Do not reuse

- Each bottle of OJEMDA and supplies are for single use only.

Have questions along the way?

Look for reminders on this side of the page throughout the guide for helpful information.

What you'll need

Here are items you'll find in each OJEMDA™ (tovorafenib) box.
Supplies are for single use.



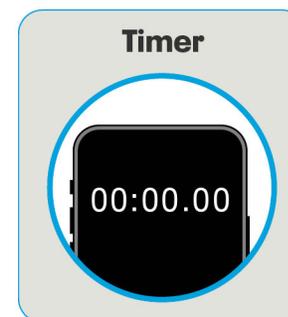
Does your child's dose require 2 bottles?

If their dose requires 2 bottles, prepare and give each bottle 1 at a time.

Does your child have a feeding tube?

You will need additional supplies. See page 5 for details.

Items NOT included in the OJEMDA box that you'll need



Giving OJEMDA by feeding tube?

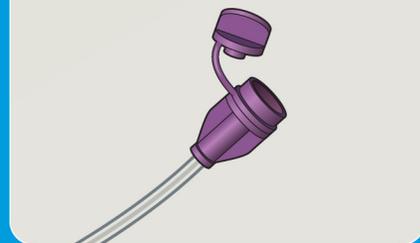
OJEMDA™ (tovorafenib) may be given through a feeding tube. **Here are the additional items you will need.**

The supplies below are NOT included in the OJEMDA box. Reach out to your pharmacist or care team if you need them.

Regardless of the feeding tube your child has, you will need 2 different syringes to administer OJEMDA:

1. The syringe in the OJEMDA box to **prepare** and **mix**
2. A 20 mL ENFit syringe and bottle adapter to **fill** and **give** the medication

**Feeding tube
(minimum size 12 French)**



ENFit® bottle adapter



20 mL ENFit® syringe



Review the instructions with your child's care team to make sure you have all the supplies you need, and you're comfortable giving this medication at home.

Before and after each dose of OJEMDA, flush the feeding tube according to the manufacturer's instructions.



Joseph, lives with pLGG

EveryDay Support From Day One™ is here for you

Your Patient Navigator and specialty pharmacy work together with your child's doctor to help your child get OJEMDA™ (tovorafenib)

Patient Navigators

A Patient Navigator will be your main point of contact at EveryDay Support From Day One. Our Patient Navigator team has extensive expertise in helping patients and their caregivers get the medicine they need.

Specialty pharmacies

Our specialty pharmacy partners have nurses and pharmacists who can answer your questions and address any concerns you might have about the treatment.

For more information, call a Patient Navigator at **855-DAY1-BIO/855-329-1246**
Monday–Friday, from 8 AM–8 PM ET

The specialty pharmacy will offer:

- Counseling with a pharmacist on how to give your child their medicine
- Advice on how to prepare, measure, and give a liquid formulation of the medicine, if needed
- Tips and assistance to manage side effects, if needed
- Call or text reminders to schedule the next shipment
- Ongoing support as needed



Holmes, lives with pLGG

Summary of steps

This guide will cover how to prepare and administer a liquid dose of OJEMDA™ (tovorafenib), including:



1

Prep

Prepare your surface, wash and dry your hands, gather your supplies, and fill the syringe with 14 mL of water.

3

Fill

Use your syringe to push air into the bottle. Flip it upside down, and fill the syringe with your child's dose.

2

Mix

Inject water into the bottle, and mix with the powder to make the solution.

4

Give

Give your child the medication and throw away all of the used supplies.

Ready to begin? Let's get started!

Turn the page to begin the full step-by-step instructions

Please see Important Safety Information on pages 24-25, and accompanying [Patient Information](#). 7

Prep

Using a feeding tube?

You may need additional equipment not included in your box of OJEMDA™ (tovorafenib).

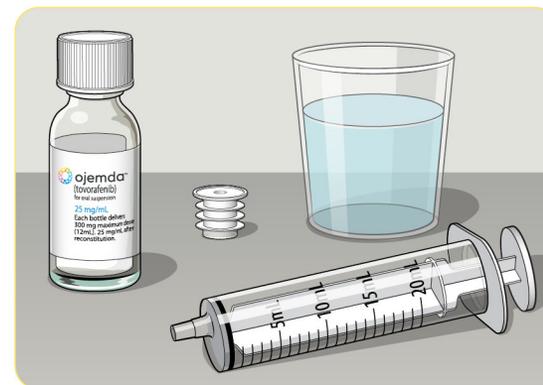
- Feeding tube (minimum size 12 French)
- ENFit bottle adapter
- 20 mL ENFit syringe

See page 5 for details.



Step 1

To start, clear off and clean a flat surface. Then, wash and dry your hands.



Step 2

Lay out all the supplies:

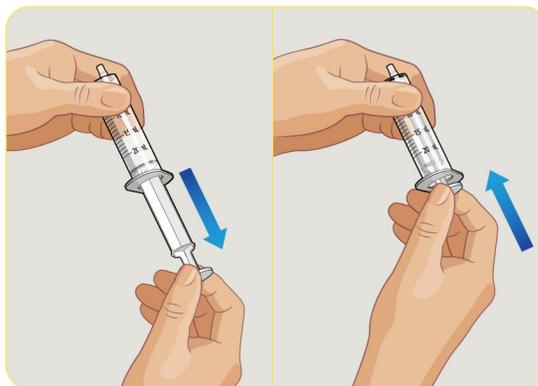
- Syringe
- Bottle of OJEMDA
- Bottle adapter
- Cup filled halfway with room-temperature water.
DO NOT use cold water
- Timer

Prep

1

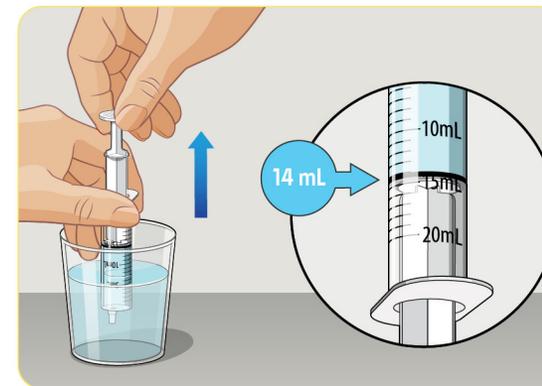
IMPORTANT

You are adding 14 mL of water no matter what dose your doctor prescribed. The extra water is to ensure the right concentration of medicine.



Step 3

- Next, pick up the syringe.
- Pull the plunger up to the top of the syringe, and push it back down to remove all the air inside.

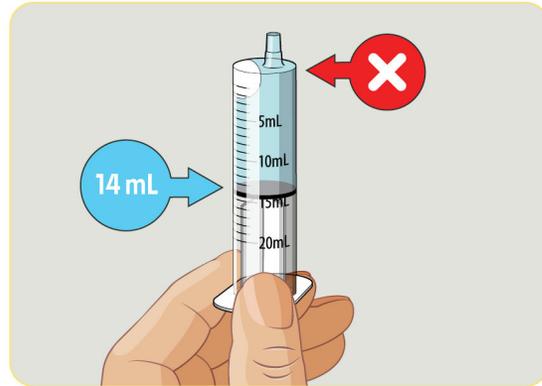


Step 4

- Place the tip of the syringe into the water.
- Regardless of the dose your doctor prescribes, **pull the plunger up to draw exactly 14 mL of water into the syringe.**

Prep

1



Step 5

Turn the syringe upward to check for large air bubbles. (Small air bubbles are OK.)

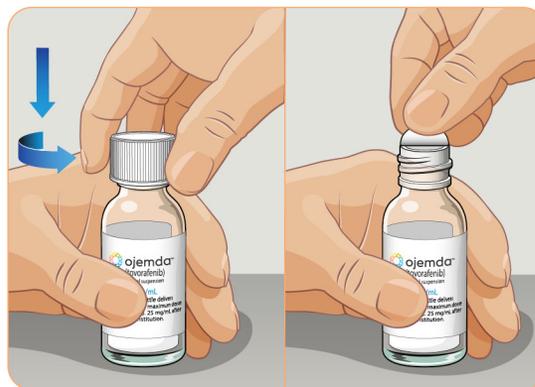
- If you see large air bubbles, push on the plunger to release them.
- **Then, draw more water back into the syringe so you have exactly 14 mL.**
- Repeat this step until there are no large air bubbles.
- Set the syringe aside.

2

Mix

Reminder

Once prepared, OJEMDA™ (tovorafenib) must be **taken within 15 minutes**.



Step 6

- Open the bottle by pushing down on the cap and twisting counter-clockwise.
- Set the bottle cap aside. **DO NOT throw the cap away just yet.**
- Remove the safety seal from under the cap.
- **DO NOT** use the bottle with powder if the safety seal is broken or missing. Call your child's care team or pharmacist if the safety seal is broken.



Step 7

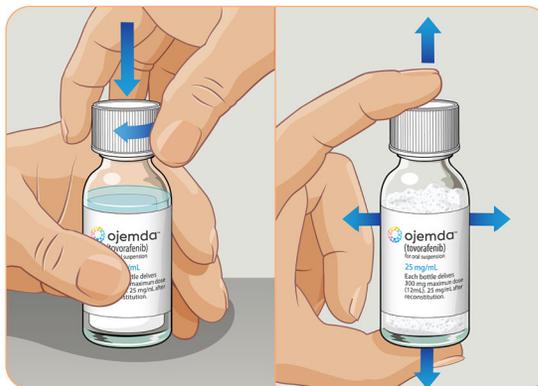
- While holding the bottle in place, insert the tip of the syringe into the bottle and carefully inject all 14 mL of water.
- Set the now-empty syringe aside.

Mix

2

Reminder

DO NOT shake the bottle for more than **2 minutes** total time.



Step 8

- Right away, put the cap back onto the bottle and close it.
- Start your timer and shake the bottle well for **60 seconds**.



Step 9

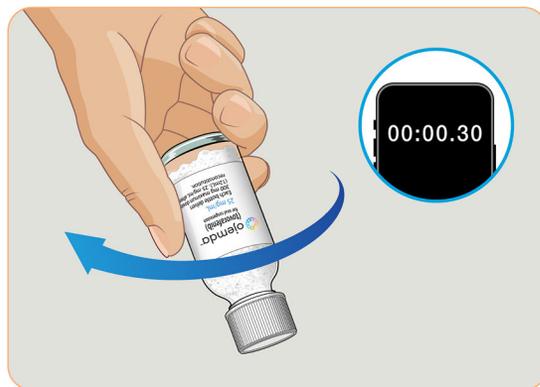
- Flip the bottle to check for any extra powder stuck to the bottom.
- If you still see powder, continue to shake for another 15 seconds.
- Check the bottle to make sure all of the powder is no longer visible.
- If you still see powder after 2 minutes, contact your child's pharmacist, care team, or your Patient Navigator at EveryDay Support From Day One™ and ask for a replacement bottle.

Mix

2

Made a mistake?

Call your child's care team, pharmacist, or your Patient Navigator at EveryDay Support From Day One™ to ask for a new bottle of OJEMDA™ (tovorafenib).



Step 10

Turn the bottle upside down again, and swirl for an additional **30 seconds**.

- Swirling the bottle ensures that any final bits of powder that may be stuck in the bottle neck mix thoroughly.



Step 11

Open the bottle, and check to see that no clumps are stuck in the bottle neck or under the cap.

- If you see clumps of powder in the bottle, put the cap back on, turn the bottle upside down, and swirl it for another 15 seconds.

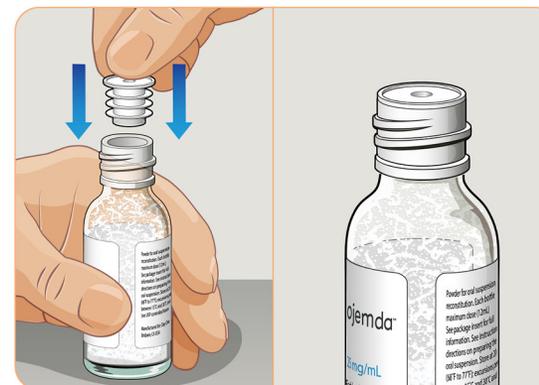
Mix

2



Step 12

Foam is OK! The appearance of the mixed medicine will be foamy and milky. Let the bottle sit for **60 seconds** to allow most of the foam to settle.



Step 13

Remove the cap, take the bottle adapter, and press it firmly into the bottle.

- The top edge of the bottle adapter should be even with the bottle top.

Giving OJEMDA™ (tovorafenib) by feeding tube?

When you complete step 13, skip to page 16.

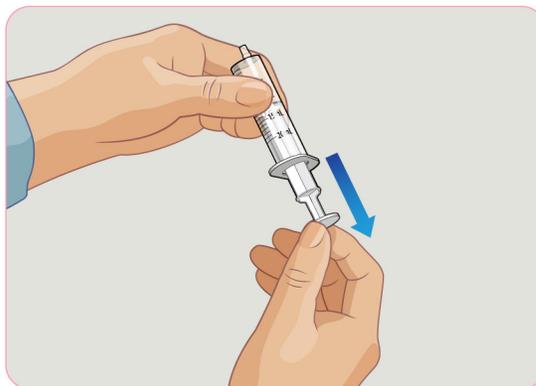
Fill (For administration by mouth)

3

Reminder

If your child's dose is over 12 mL, **split the dose as evenly as possible** between 2 bottles.

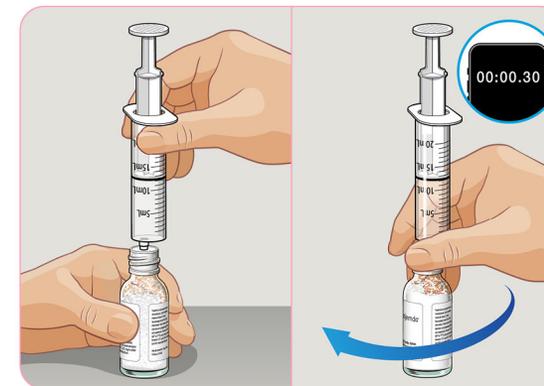
For example, a 13 mL dose would use 6 mL from 1 bottle and 7 mL from another.



Step 14

Take your syringe, and pull the plunger down to draw air to the prescribed dose amount.

- For example, if your child's prescribed dose is 12 mL, you would draw the syringe back to the 12 mL mark.



Step 15

- Push the entire tip of the syringe into the bottle adapter.
- With the syringe still in the adapter, hold the bottle at the neck and swirl the bottle for **30 seconds**.

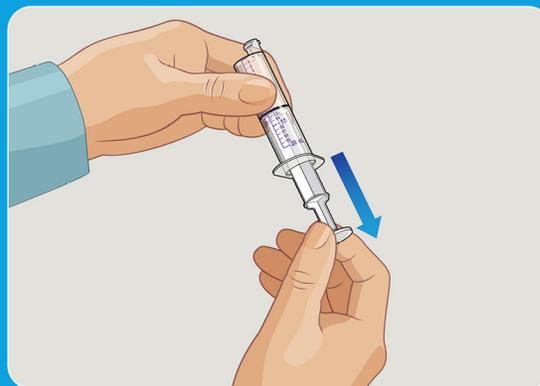
Fill (For administration by feeding tube)

3

Reminder

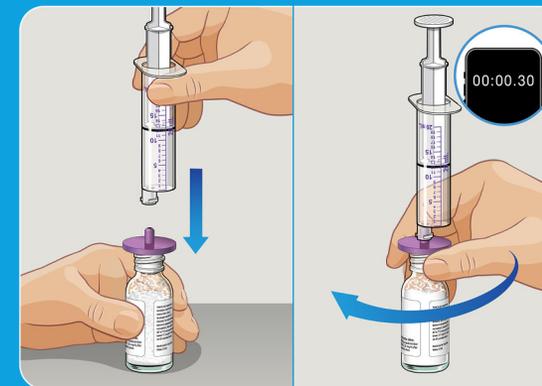
If your child's dose is over 12 mL, **split the dose as evenly as possible** between 2 bottles.

For example, a 13 mL dose would use 6 mL from 1 bottle and 7 mL from another.



Step 14

- Take your 20 mL ENFit syringe, and pull the plunger down to draw air to the prescribed dose amount.
- For example, if your child's prescribed dose is 12 mL, you would draw the ENFit syringe back to the 12 mL mark.



Step 15

- Take the ENFit bottle adapter and press it firmly into the OJEMDA™ (tovorafenib) bottle adapter.
- Connect the ENFit syringe to the ENFit bottle adapter.
- With the ENFit syringe still in the ENFit bottle adapter, hold the bottle at the neck and swirl the bottle for **30 seconds**.

Next, follow steps 16 through 20. The steps are the same if you are giving OJEMDA by mouth or by feeding tube.

3

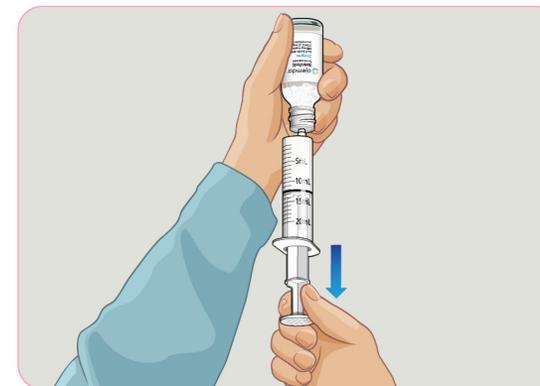
Fill

Wondering why you need to add air to the bottle?

Forcing air into the bottle helps you to withdraw the liquid medicine into the syringe.

**Step 16**

Force the air from the syringe into the bottle and keep pushing the plunger down.

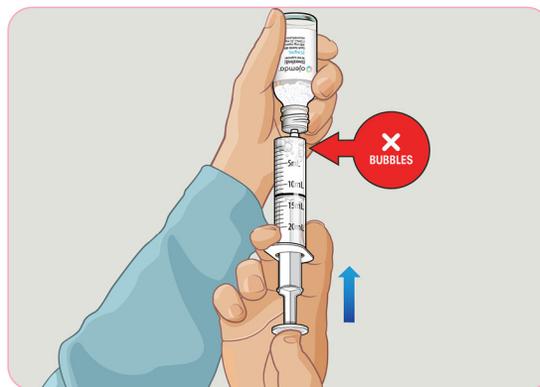
**Step 17**

With the plunger down and the syringe still inserted into the bottle, flip the bottle upside down.

- Pull the plunger to fill the syringe to the line of the prescribed dose amount.

Fill

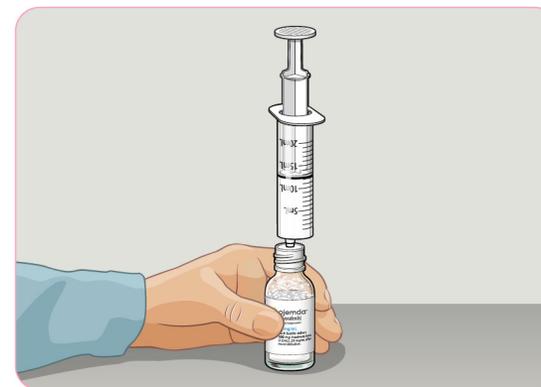
3



Step 18

Before removing the syringe, **check for any bubbles in it.**

- To remove bubbles, slowly push some liquid medicine back into the bottle to gently push them out.
- If necessary, draw in more medicine to the prescribed dose.

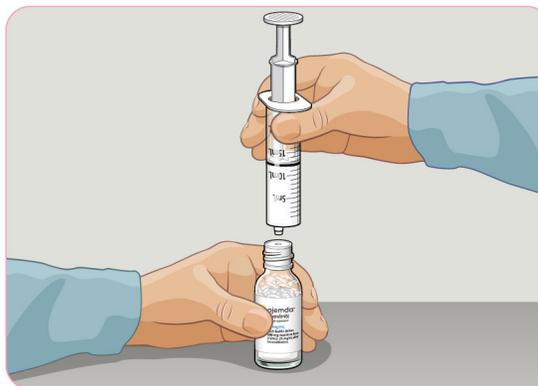


Step 19

Next, while holding the plunger in place, carefully turn the bottle upright, and put it down onto your work surface.

3

Fill



Step 20

- Release the plunger and hold the body of the syringe, pulling straight up to remove it.
- Holding the plunger could cause it to come off.
- Check the solid black line again to ensure you've drawn the prescribed dose into the syringe.

IMPORTANT

If you are giving a dose of OJEMDA™ (tovorafenib) by mouth, continue to page 20.

If you are giving a dose of OJEMDA by feeding tube, go to page 21.

Give (For administration by mouth)

4

Reminder

Have your child sit upright when taking their dose of OJEMDA™ (tovorafenib).

Your child can drink and eat immediately before or after taking OJEMDA.



Step 21

Give your child the syringe if they are able to take the medication on their own.

- If not, put the syringe inside your child's mouth, against the cheek.
- This position is important to prevent a gag reflex.



Step 22

Slowly push the medicine into your child's mouth.

- **DO NOT** forcefully push on the plunger as it may cause choking.
- Be sure to give the entire dose by pressing the plunger down completely.
- If your child's prescribed dose is more than 12 mL, you will need to prepare another bottle. Immediately repeat **Prep, Mix, Fill, and Give** instructions to give the remaining dose.

Throw away the bottle, including any unused medicine and supplies, in your household trash.

Give (For administration by feeding tube)

4

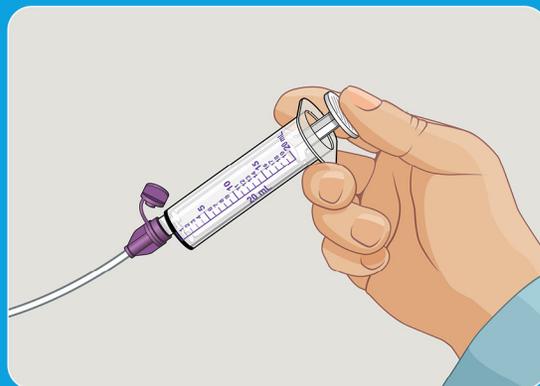


Step 21

Flush the feeding tube with water before giving each dose according to the manufacturer's instructions.

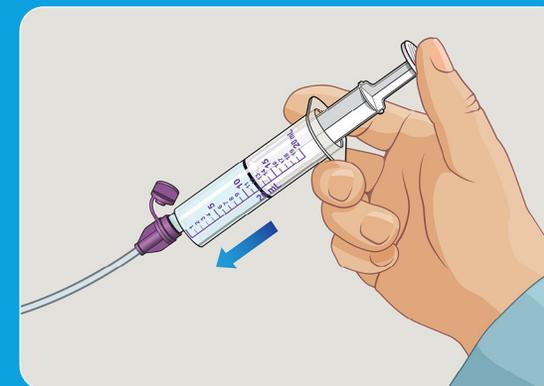
- Connect the 20 mL ENFit syringe filled with OJEMDA™ (tovorafenib) to the feeding tube.

Throw away the bottle, including any unused medicine and supplies, in your household trash.



Step 22

Apply steady pressure to the plunger to give the entire dose of OJEMDA through the feeding tube.



Step 23

Flush the tube after giving each dose according to the manufacturer's instructions to ensure that no medicine remains inside the tube.

- If your child's prescribed dose is more than 12 mL, you will need to prepare another bottle. Immediately repeat **Prep**, **Mix**, **Fill**, and **Give** instructions to give the remaining dose.

Frequently asked questions (FAQs)

What does the medicine taste like?

OJEMDA™ (tovorafenib) is strawberry flavored.

What should I do if my child vomits?

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

What should I do if OJEMDA gets on my child's skin or in my child's eyes?

If it gets on your or your child's skin, wash the area well with soap and water. If at any time it gets in your or your child's eyes, rinse the eyes well with cool water.

What should I do if I make a mistake in one of the steps or if the medicine solidifies?

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

Can I shake the bottle for more than 2 minutes (steps 8 and 9)?

No. Be sure you don't shake for more than 2 minutes. It's important that you give your child the medicine within 15 minutes of mixing it.

Why should I "swirl" instead of shake the bottle (step 10)?

Swirling allows you to get any excess powder that might be stuck in the neck of the bottle.

Why should I push air into the bottle (steps 14-16)?

Pushing air into the bottle makes it easier to draw medicine into the syringe.

Can I still give my child the medicine if 15 minutes have passed?

Once 15 minutes have passed, the mixed medicine will thicken into a gel. Please do not give your child the dose if 15 minutes have passed. Call your child's care team, pharmacist, or EveryDay Support From Day One to get a replacement dose.

Frequently asked questions (FAQs)

What if my child misses a dose of OJEMDA™ (tovorafenib)?

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.

Can OJEMDA be taken with other medications?

OJEMDA may affect the way other medicines work, and other medicines may affect how OJEMDA works. Tell your child's doctor about all the medicines your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements, and they can help determine if there is a likelihood of an interaction.

What should I do if my bottle breaks, gets dropped, or goes past its expiration date?

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

How is my child's dosage determined?

Your child's dose is unique. Their doctor will prescribe the right dose based on your child's body surface area. Body surface area is a way to measure your child's body to make sure they get the right amount of medicine. Depending on your child's body surface area, you may need 2 bottles to prepare the prescribed dose. Each bottle offers a maximum dose amount of 12 mL (or 300 mg). Prepare and give 1 bottle at a time. Each dose must be given within 15 minutes after being prepared.

How should OJEMDA be stored?

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

How should I dispose of OJEMDA?

After giving a dose, throw away the bottle, including any unused medicine and syringe, in your household trash.

Important Safety Information

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.

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.

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.

Important Safety Information (cont'd)

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
 - bumps or tiny papules
 - acne
 - peeling, redness, or irritation
 - blisters
- **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
 - dark or brown (tea-colored) urine
 - nausea or vomiting

- loss of appetite
- tiredness
- bruising
- bleeding
- 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
- hair color changes
- tiredness
- viral infection
- vomiting
- headache
- fever
- dry skin
- constipation
- nausea
- acne
- 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.

Have questions or concerns?

EveryDay Support.

FROM DAY ONE

To learn about video consultations with the specialty pharmacy, call a Patient Navigator at the number below.



Call 855-DAY1-BIO / 855-329-1246

Monday–Friday, 8 AM–8 PM ET

Please see Important Safety Information on pages 24-25, and accompanying [Patient Information](#).

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