

Medication Guide
REVUFORJ (REV-you-forge)
(revumenib)
tablets, for oral use

What is the most important information I should know about REVUFORJ?

REVUFORJ may cause serious side effects including:

- **differentiation syndrome.** Differentiation syndrome is a serious, but common condition that affects your blood cells which may be life threatening or lead to death if not treated. Differentiation syndrome has happened as early as 3 days and up to 41 days after starting REVUFORJ. Tell any healthcare provider caring for you that you are taking a medicine that can cause differentiation syndrome. Call your healthcare provider or go to the nearest hospital emergency room right away if you develop any of the following symptoms of differentiation syndrome during treatment with REVUFORJ:
 - fever
 - cough
 - shortness of breath
 - severe headache
 - confusion
 - dizziness or lightheadedness
 - fast weight gain
 - swelling of arms, legs, neck, groin, or underarm area
 - decreased urination
 - rash

If you develop any of these symptoms of differentiation syndrome, your healthcare provider may start you on a medicine given through a vein (intravenous) called corticosteroids and may monitor you in the hospital.

- **changes in electrical activity of your heart called QT prolongation.** QT prolongation is a serious, but common side effect that can cause irregular heartbeats that can be life-threatening, such as a heart attack, and can lead to death. Your healthcare provider will check the electrical activity of your heart with a test called an electrocardiogram (ECG) and will also do blood tests to check your potassium and magnesium levels before and during treatment with REVUFORJ. Tell your healthcare provider right away if you feel faint, lightheaded, dizzy, or if you feel your heart beating irregularly or fast during treatment with REVUFORJ.

See “**What are the possible side effects of REVUFORJ?**” for more information about side effects.

What is REVUFORJ?

REVUFORJ is a prescription medicine used to treat adults and children 1 year and older with:

- acute leukemia with a lysine methyltransferase 2A gene (KMT2A) translocation whose disease has come back or has not improved after previous treatment(s).
- acute myeloid leukemia with a nucleophosmin 1 (NPM1) mutation whose disease has come back or has not improved after previous treatment(s) **and** who have no other satisfactory treatment options

Your healthcare provider will perform a test to make sure that REVUFORJ is right for you.

It is not known if REVUFORJ is safe and effective in children less than 1 year of age.

Before taking REVUFORJ, tell your healthcare provider about all of your medical conditions, including if you:

- have any heart problems, including a condition called long QT syndrome.
- have been told you have low blood levels of potassium or magnesium.
- are pregnant or plan to become pregnant. REVUFORJ can harm your unborn baby.

Females who are able to become pregnant:

- Your healthcare provider will perform a pregnancy test within 7 days before you start treatment with REVUFORJ.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with REVUFORJ.
- Use effective birth control (contraception) during treatment with REVUFORJ and for 4 months after the last dose of REVUFORJ.

Males who have female partners who are able to become pregnant:

- Use effective birth control during treatment with REVUFORJ and for 4 months after the last dose of REVUFORJ.
- Talk to your healthcare provider about birth control methods you can use during this time.
- are breastfeeding or plan to breastfeed. It is not known if REVUFORJ passes into your breast milk. **Do not** breastfeed during your treatment with REVUFORJ or for 1 week after your last dose of REVUFORJ.

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

REVUFORJ and other medicines may affect each other causing side effects.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take REVUFORJ?

- **Take REVUFORJ exactly as your healthcare provider tells you to. Do not** change your dose or stop taking REVUFORJ unless your healthcare provider tells you to.
- REVUFORJ tablets come in different strengths. Each strength is a different color. Your healthcare provider may prescribe more than 1 strength of REVUFORJ tablets for you, so it is important that you understand how to take your medicine the right way. Be sure that you understand exactly how many tablets you need to take, and what strengths to take.
- Take REVUFORJ 2 times a day at about the same time each day about 12 hours apart.
- Take REVUFORJ fasted (on an empty stomach) or with a low-fat meal (400 calories, 25% or less fat). Talk to your healthcare provider about examples of low-fat meals that you can eat.
- Swallow REVUFORJ tablets whole with a cup of water. **Do not** cut or chew tablets. If you are unable to swallow tablets, crush the tablets and break them apart in water. See the **Instructions for Use** for detailed instructions on how to prepare and give REVUFORJ tablets.
- If you miss a dose of REVUFORJ or did not take it at the usual time, take your dose as soon as possible and at least 12 hours before your next dose. **Do not** take 2 doses within 12 hours. Return to your normal scheduled dose the following day.

What are the possible side effects of REVUFORJ?

REVUFORJ may cause serious side effects including:

- see **“What is the most important information I should know about REVUFORJ?”**

The most common side effects of REVUFORJ include:

- infections, including bacterial and viral infections
- changes in liver function tests
- bleeding (hemorrhage)
- nausea and vomiting
- muscle pain
- low white blood cell counts with fever
- diarrhea
- tiredness
- swelling in the arms and legs
- decreased appetite
- constipation

Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with REVUFORJ if you develop certain side effects.

REVUFORJ may cause fertility problems in females and males, which may affect your ability to have children. Talk to your healthcare provider if this is a concern for you.

These are not all possible side effects of REVUFORJ.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store REVUFORJ?

- Store REVUFORJ at room temperature between 68°F to 77°F (20°C to 25°C).
- Store the tablets in the bottle that it comes in until you are ready to take it.
- The REVUFORJ bottle has a drying agent (desiccant) and child resistant closure.

Keep REVUFORJ and all medicines out of reach of children.

General information about the safe and effective use of REVUFORJ.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use REVUFORJ for a condition for which it is not prescribed. Do not give REVUFORJ to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or health professionals for information about REVUFORJ that is written for healthcare professionals.

What are the ingredients in REVUFORJ?

Active ingredient: revumenib

Inactive ingredients: microcrystalline cellulose, dicalcium phosphate, crospovidone, hypromellose, sodium bicarbonate, hydrophobic colloidal silica, magnesium stearate, polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, and red iron oxide.

The 110 mg tablet also includes yellow iron oxide.

The 160 mg tablet also includes FD&C blue #2/indigo carmine aluminum lake.

Manufactured for: Syndax Pharmaceuticals, Inc., New York, NY 10007
REVUFORJ ® is a registered trademark of Syndax Pharmaceuticals, Inc.
Copyright © 2025 Syndax Pharmaceuticals, Inc.
For more information, go to www.revuforj.com or call Syndax at 1-888-539-3REV.
218944-SYND-MG-003

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Revised: 10/2025

INSTRUCTIONS FOR USE
REVUFORJ (REV-you-forge)
revumenib tablets, for oral use

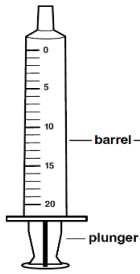
Read these Instructions for Use to prepare and take or give a dose of REVUFORJ tablets broken apart (dispersed) in water and each time you or your child get a prescription refill. There may be new information. This information does not take the place of talking with your healthcare provider about you or your child's medical condition or your treatment.

Important information you need to know before preparing to break apart the REVUFORJ tablets in water:

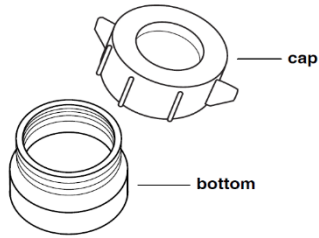
- For more information about REVUFORJ tablets, see the Medication Guide.
- **REVUFORJ tablets broken apart in water should be prepared for people who are unable to swallow whole REVUFORJ tablets. People who can swallow the tablets whole should not cut, chew, or break the tablets apart in water.**
- Take or give REVUFORJ tablets exactly as your healthcare provider tells you to. **Do not** change your dose or stop taking REVUFORJ unless your provider tells you to.
- REVUFORJ tablets come in different strengths. Each strength is a different color. Your healthcare provider may prescribe more than 1 strength of REVUFORJ tablets for you or your child, so it is important that you understand how to take or give the medicine the right way. Be sure that you understand exactly how many tablets you need to take, and what strengths to take.
- Check the expiration date on the REVUFORJ tablet bottles. **Do not** use REVUFORJ if the expiration date on the bottles have passed. Contact your healthcare provider or pharmacist.
- The REVUFORJ tablets should be crushed in a clean and dry pill crusher.
- Use room temperature water to dissolve the REVUFORJ tablets.
- Use a teaspoon to measure the room temperature water. Use a 20 mL oral syringe to administer the medicine.
 - Oral syringes can look different. Talk to your pharmacist if you are not sure if you have the correct oral syringe size.
 - Replace the oral syringe if there are signs of damage. **See Step 15.**

Supplies needed to prepare and break apart the REVUFORJ tablets in water. You will need to get the 20 mL oral syringe and pill crusher, which are available from your pharmacy.

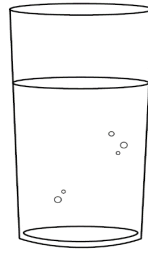
Figure A



20 mL Oral Syringe



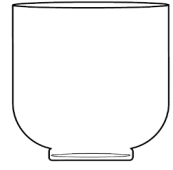
Pill Crusher



Room Temperature Water



1 Teaspoon



Small Plastic or Glass Cup

Preparing to dissolve the REVUFORJ tablets

Step 1: Gather and place the REVUFORJ bottles and supplies on a clean, flat surface.

Check your prescribed dose. Count out the strengths and number of REVUFORJ tablets needed for the prescribed dose.

Add all the REVUFORJ tablets to a clean and dry pill crusher. Screw the top of the pill crusher down until it touches the REVUFORJ tablets.

Turn the pill crusher cap back and forth to crush the REVUFORJ tablets. Continue turning the pill crusher cap back and forth, increasing the crushing pressure on the REVUFORJ tablets each time.

Repeat until all large REVUFORJ tablet pieces are broken up. The crushed REVUFORJ tablets should be like the consistency of flour.

Figure B

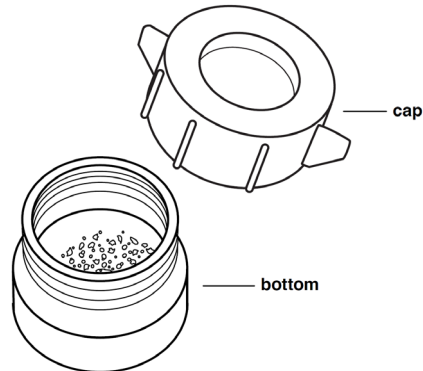


Figure C

Step 2: Use **two** teaspoons to measure 10 mL of room temperature water. Add the 10 mL of water to the small cup.

Add water to the cup first and then add the crushed REVUFORJ tablets.

Do not add the crushed REVUFORJ tablets first followed by the room temperature water.

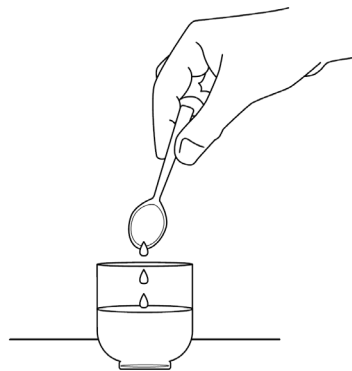


Figure D

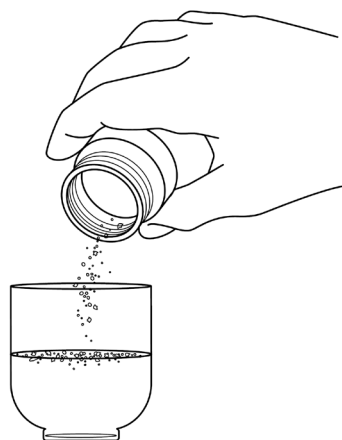
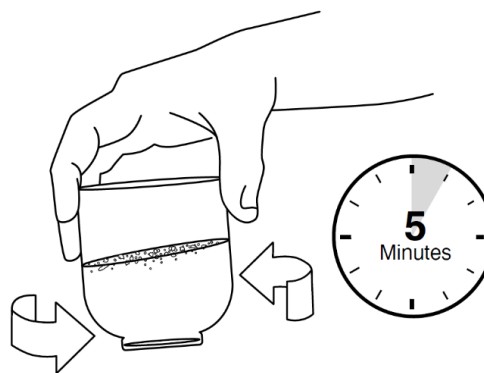


Figure E



Step 3: Tip the crushed REVUFORJ tablets from the pill crusher into the small cup that contains 10 mL of water. Carefully add all of the crushed REVUFORJ tablets to the small cup.

Hold the pill crusher upside down over the small cup. Tap the pill crusher to make sure no more crushed REVUFORJ tablet pieces are left in the pill crusher.

Step 4: Carefully swirl the cup right after adding the crushed REVUFORJ tablets to the small cup with water. Swirl the small cup every 30 seconds to 1 minute for a total of **5 minutes**.

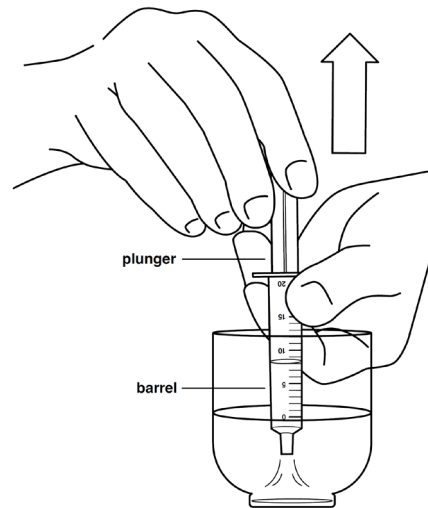
The crushed REVUFORJ tablets in water will look cloudy.

Step 5: Draw up the medicine into the 20 mL oral syringe right away.

Push the plunger of the oral syringe all the way up towards the tip. Place the tip of the oral syringe in the small cup. Pull the oral syringe plunger to draw up all of the medicine in the small cup.

The medicine must be taken within **2 hours** of preparation. Turn the oral syringe upside down and back several times before taking or giving the medicine.

Figure F



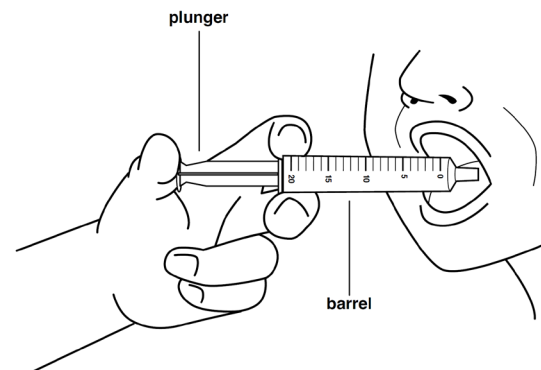
Step 6: The adult or child should sit up straight or stand before taking the medicine.

Place the tip of the oral syringe into the mouth against the inside of the cheek. Slowly and gently press down on the plunger to gently squirt the medicine into the mouth. Allow the adult or child to swallow the medicine. Make sure that no medicine is left in the mouth.

The adult or child should remain sitting up straight or standing for 2 to 3 minutes right after receiving a dose of the medicine.

If the medicine is vomited or all of the medicine is not swallowed, do not give another dose. Wait until the next scheduled dose.

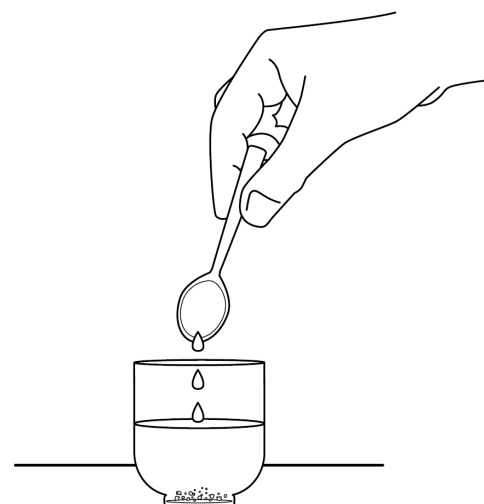
Figure G



Step 7: The small cup must be rinsed to make sure the adult or child receives the full dose of REVUFORJ tablets.

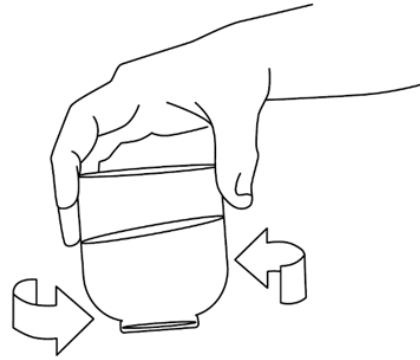
Place **two** teaspoons (10 mL) of room temperature water in the cup rinsing down the sides (Figure H)

Figure H



Swirl the water around the sides of the small cup to make sure any remaining crushed REVUFORJ tablets is mixed with the water (Figure I).

Figure I



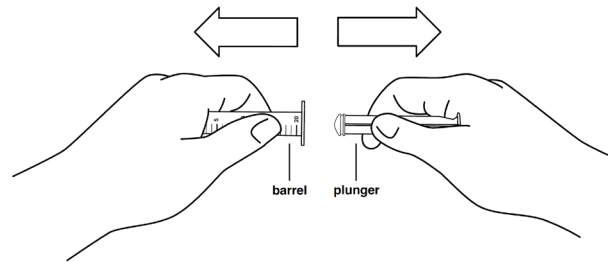
Step 8: Repeat **Step 5** and **Step 6** until no more medicine is left in the cup.

Cleaning the oral syringe after use

Follow the instructions below for cleaning and storing the oral syringe (**Step 9 through Step 15**). Throw away the oral syringe in your household trash if it is damaged (**See Step 15**), and use a new 20 mL oral syringe.

Step 9: Remove the plunger from the barrel of the oral syringe.

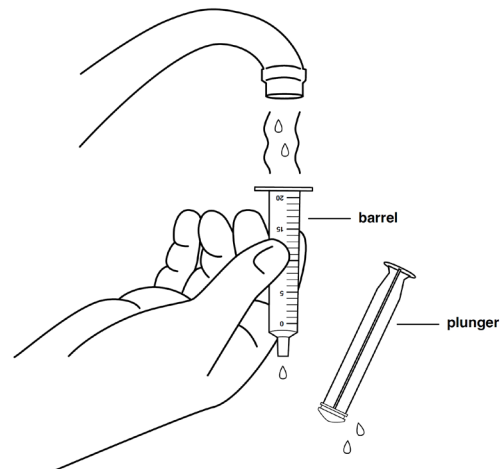
Figure J



Step 10: Rinse the barrel and plunger in warm running water to help make sure all of the medicine has been removed from the oral syringe.

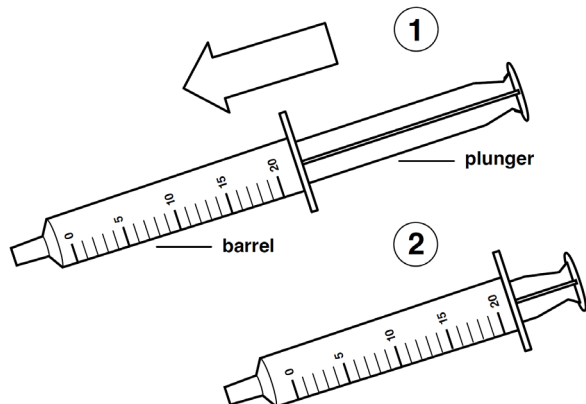
Do not boil the oral syringe.

Figure K



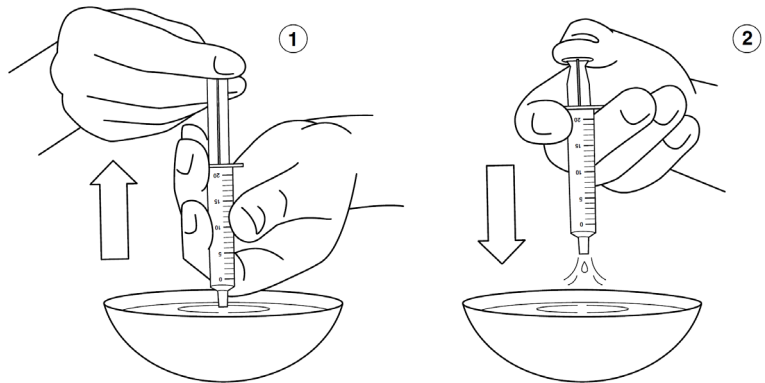
Step 11: Put the plunger into the barrel of the oral syringe.

Figure L



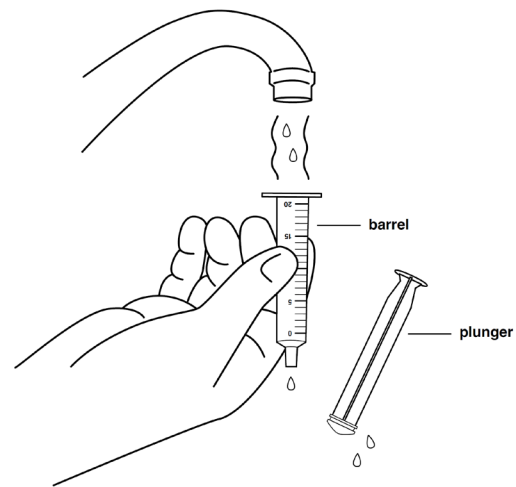
Step 12: Hold the oral syringe tip under water and draw warm water several times into the oral syringe and squirt out again until all of the medicine has been removed from the oral syringe. **Repeat this Step until the oral syringe is clean.**

Figure M



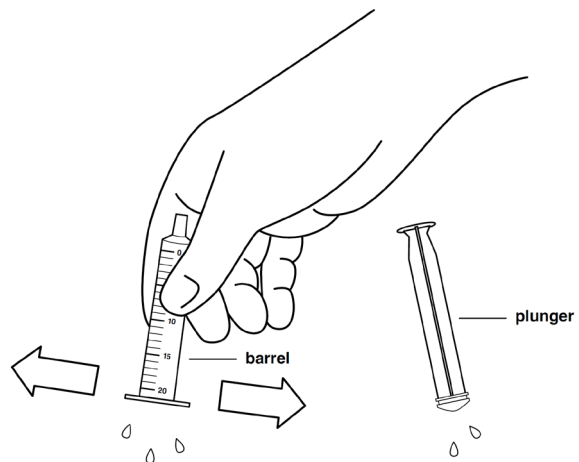
Step 13: Remove the plunger from the barrel of the oral syringe. Rinse the barrel and plunger again with warm water.

Figure N



Step 14: Shake off excess water or wipe off the outside of the plunger and barrel. Place the barrel and plunger on a clean, dry paper towel to dry.

Figure O



Step 15: Make sure the oral syringe parts are fully dry before putting the plunger back into the barrel of the oral syringe. Store the oral syringe in a clean place until the next use.

Replace the oral syringe if:

- there is any damage to the barrel, plunger, or tip.
- you cannot see the dosage markings or it becomes difficult to move the plunger.

Cleaning the pill crusher after use

Step 16: Rinse both parts of the pill crusher with water after use. Shake off excess water or wipe both parts of the pill crusher. Place both parts of the pill crusher on a clean, dry paper towel to dry.

Storing REVUFORJ

- Store REVUFORJ at room temperature between 68°F to 77°F (20°C to 25°C).
- Store the tablets in the bottle that it comes in until you are ready to take it.
- The REVUFORJ bottle has a drying agent (desiccant) and child resistant closure.

Keep REVUFORJ and all medicines out of reach of children.

Manufactured for: Syndax Pharmaceuticals, Inc., New York, NY 10017
REVUFORJ® is a registered trademark of Syndax Pharmaceuticals, Inc.
Copyright © 2025 Syndax Pharmaceuticals, Inc.
For more information, go to www.revuforj.com or call Syndax at 1-888-539-3REV.
218944-SYND-IFU-003

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Revised: 10/2025