

GETTING STARTED ON YOUR REVUFORJ

JOURNEY

A guide for patients and caregivers

Revuforj.com

 **Revuforj**[®]
(revumenib) tablets
25 mg • 110 mg • 160 mg

What is Revuforj?

Revuforj[®] (revumenib) 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

Important Safety Information

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.

Please see additional Important Safety Information throughout and Full Prescribing Information, including **BOXED WARNINGS, and Medication Guide and Instructions for Use.**

GETTING STARTED WITH REVUFORJ

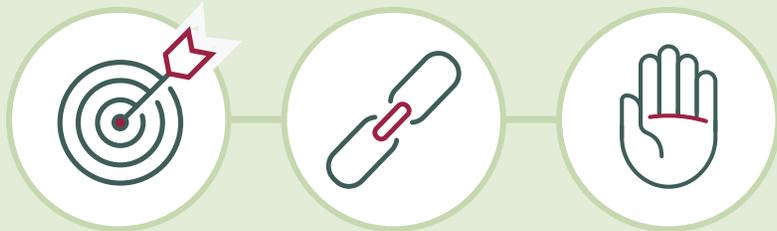


Actor portrayal.

Revuforj is a first-of-its-kind FDA-approved, targeted treatment called a menin inhibitor

Revuforj is an oral, targeted medication that works differently than chemotherapy. Revuforj works by targeting a protein called **menin** to disrupt interactions with other proteins—specifically wild-type KMT2A and KMT2A fusion proteins. These protein interactions are responsible for driving the growth of leukemia cells in people who have acute leukemia with a KMT2A translocation or AML with an *NPM1* mutation.

Targets, binds, and blocks



Revuforj targets and directly binds to menin to help block the source of what can drive your specific type of acute leukemia

Individual results may vary.

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Important Safety Information (cont'd)

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 while taking 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.

Download the **Differentiation Syndrome Wallet Card** and keep it with you at all times



Share this card with any doctor who is not part of your regular healthcare team, including in the hospital or emergency room, so they are aware that you are taking a medicine that can cause differentiation syndrome.

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REVEALING A POTENTIAL WAY TO REMISSION

If you have AML with an *NPM1* mutation, review these clinical trial results:

Revuforj was studied in the AUGMENT-101 clinical trial, which included both adult and pediatric patients with acute myeloid leukemia with an *NPM1* mutation whose disease had come back or had not improved after previous treatment(s).

The study was designed to measure the safety and effectiveness of Revuforj

- A total of 64 adults and 1 child from the study met the criteria to be evaluated for effectiveness
- The youngest person was 11 years old and the oldest was 84 years old

In patients with AML with an *NPM1* mutation:



~1 in 4 people achieved CR + CRh with Revuforj

In the clinical trial, about **1 in 4** people (15 out of 65, or 23%) achieved complete remission (CR) or complete remission with a partial hematological recovery (CRh).

- **CR**=signs of acute leukemia are gone, and blood cell counts are back to normal
- **CRh**=signs of acute leukemia are gone but some blood cell counts did not fully return to normal

About **1 in 6** people who needed transfusions at the start of the clinical trial became transfusion-free with Revuforj.

In the clinical trial, **7 people, or 11%,** underwent a stem cell transplant following treatment with Revuforj

Learn more at Revuforj.com



Actor portrayal.

Important Safety Information (cont'd)

Revuforj may cause serious side effects, including:

- **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.

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REVEALING A POTENTIAL WAY TO REMISSION

If you have **acute leukemia with a *KMT2A* translocation**, review these clinical trial results:

Revuforj was studied in the AUGMENT-101 clinical trial, which included both adult and pediatric patients with acute leukemia with a *KMT2A* translocation whose disease had come back or had not improved after previous treatment(s).

The study was designed to measure the safety and effectiveness of Revuforj

- A total of 104 people from the study met the criteria to be evaluated for effectiveness
- The youngest person was 1 year old and the oldest was 79 years old

In patients with **acute leukemia with a *KMT2A* translocation**:



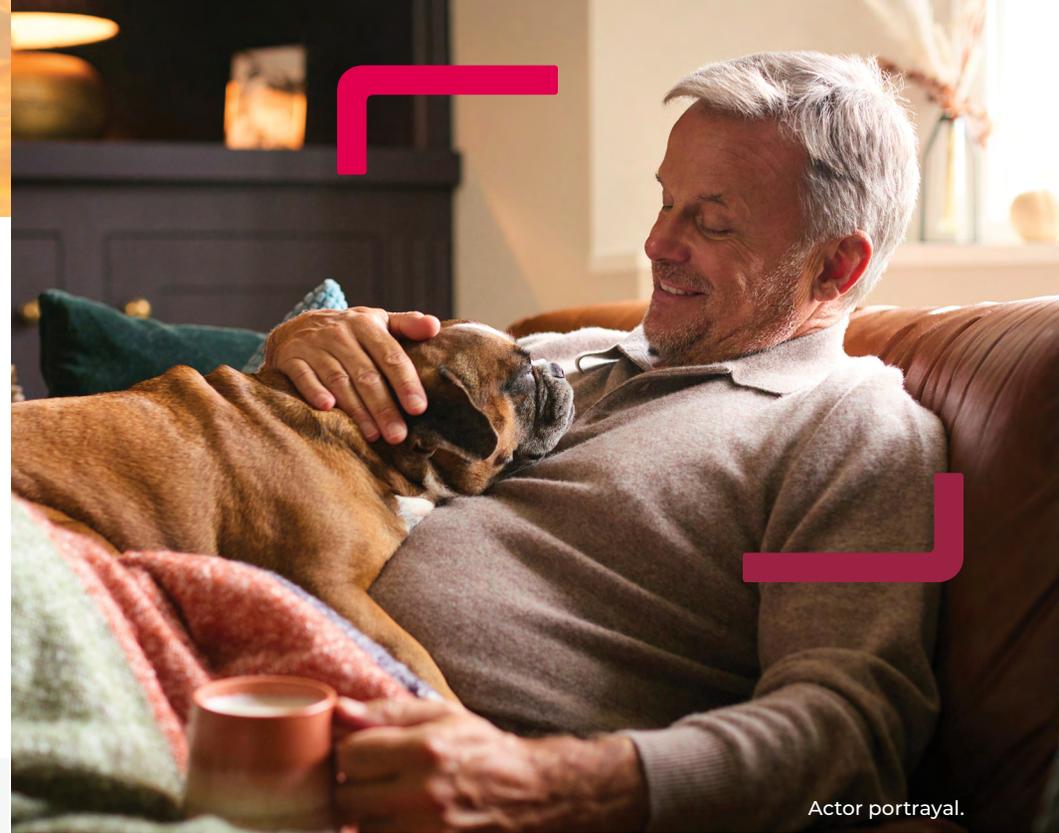
~1 in 5 people achieved CR + CRh with Revuforj

In the clinical trial, about **1 in 5** people (22 out of 104, or 21%) achieved complete remission (CR) or complete remission with a partial hematological recovery (CRh).

- **CR**=signs of acute leukemia are gone, and blood cell counts are back to normal
- **CRh**=signs of acute leukemia are gone but some blood cell counts did not fully return to normal

In the clinical trial, 24 people, or 23%, underwent a stem cell transplant following treatment with Revuforj

Learn more at [Revuforj.com](https://www.revuforj.com)



Actor portrayal.

Important Safety Information (cont'd)

Revuforj may cause serious side effects, including:

- **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.

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WHAT TO KNOW BEFORE TAKING REVUFORJ



Actor portrayal.

Revuforj tablets come in different strengths. Each strength is a different color:



Bottles and tablets shown are not actual size.

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 exactly as your healthcare provider tells you to. Do not change your dose or stop taking Revuforj unless your healthcare provider tells you to.

How to 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

Before taking Revuforj, tell your healthcare provider about all 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
- 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

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CONVENIENCE OF AN ORAL MEDICINE YOU CAN TAKE AT HOME

How to take Revuforj



2 times a day by mouth

Take at about the same time each day (about 12 hours apart)



On an empty stomach

In the clinical trial, this was defined as at least 2 hours after a meal and 1 hour before the next meal

OR



With a low-fat meal

Low-fat meals should be about 400 calories and contain 25% or less fat

- Swallow Revuforj tablets whole with a cup of water
- **Do not** cut or chew tablets
- If you are unable to swallow tablets, Revuforj can be crushed and dispersed in water as directed in the **Instructions for Use**.
 - See the **Instructions for Use** for detailed information on how to prepare and give Revuforj



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.

Tell your healthcare provider about all the 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.

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Actor portrayal.



Find helpful tools and resources that are designed to help you stay informed and feel supported as you or your loved one begins treatment with Revuforj.

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POSSIBLE SIDE EFFECTS OF REVUFORJ



Actor portrayal.

Revuforj may cause serious side effects, including: Differentiation syndrome, which may be life-threatening or lead to death if not treated

For more information about differentiation syndrome and a list of symptoms, please see page 3 of this brochure.



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



Revuforj can harm your unborn baby

Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with Revuforj.

Females who are able to become pregnant, your healthcare provider will perform a pregnancy test within 7 days before you start 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. 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.

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.

The most common side effects of Revuforj include:

- infections, including bacterial and viral
- 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.

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

You are encouraged to report side effects of prescription drugs to FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088

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HERE TO LISTEN,
HERE TO SUPPORT

SyndAccess[®]

Learn more about how the SyndAccess support team
may be able to help you or your loved one.



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us at 1-888-567-SYND (7963)
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The information provided here is not a substitute for talking with your healthcare
provider. Your healthcare provider is the best source of information about
your disease.

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