Javygtor™

(sapropterin dihydrochloride)

Tablets or Powder for Oral Solution

This guide will support you in taking JAVYGTOR yourself or giving the medication to a loved one. Following these steps carefully may help you better manage the condition.

This guide also contains useful information about Cycle Vita™, our dedicated hub support platform, which delivers individualized support for patients.*

NOT AN ACTUAL PATIENT

This brochure is intended for patients and caregivers in the US who have been prescribed JAVYGTOR. It is provided for information purposes only. It is not intended to be, and should not be used as, a substitute for medical advice.

Important Safety Information[1]

Javygtor™
(sapropterin dihydrochloride)
Tablets or Powder for Oral Solution

JAVYGTOR Tablets for Oral Use and JAVYGTOR Powder for Oral Solution

What Important Information Should I Know About JAVYGTOR Tablets for Oral Use and Powder for Oral Solution?

- **Sapropterin Dihydrochloride can cause serious side effects including:**

Severe allergic reactions, including anaphylaxis – JAVYGTOR is not recommended in patients with a history of anaphylaxis to Sapropterin Dihydrochloride. Stop taking JAVYGTOR and get medical help right away if you develop any of these symptoms of severe allergic reaction:
- Wheezing or trouble breathing
- Coughing
- Flushing
- Nausea
- Feeling lightheaded or you faint
- Rash

Inflammation of the lining of the stomach (gastritis) or esophagus (esophagitis) - Gastritis or esophagitis can happen with Sapropterin Dihydrochloride and may be severe. Patients should be monitored by their doctor for signs and symptoms of upper gastrointestinal mucosal inflammation.

Call your doctor right away if you have any of these signs or symptoms:
- Severe upper stomach area (abdominal) discomfort or pain, nausea and vomiting
- Blood in your vomit or stool
- Black, tarry stool
- Difficulty swallowing
- Loss of appetite
- Pain in the throat

Phenylalanine (Phe) levels that are too low - Some PKU patients have experienced low blood Phe during treatment. Some children under the age of 7 years who take high doses of Sapropterin Dihydrochloride each day may experience low Phe levels.

Too much or constant activity (hyperactivity) can happen with Sapropterin Dihydrochloride - Tell your doctor if you have any signs of hyperactivity, including:
- Fidgeting or moving around too much
- Talking too much

It is not possible to know if Sapropterin Dihydrochloride will work for you until you start treatment. Your doctor will check your blood Phe levels when you start taking JAVYGTOR to see if the medicine is working

- All patients with PKU who are being treated with JAVYGTOR should also be treated with a Phe restricted diet, including dietary protein and Phe restriction

- Your doctor should continue to monitor your blood Phe levels often during your treatment with JAVYGTOR to make sure that your blood Phe levels are not too high or too low. Frequent blood monitoring is recommended in the pediatric population

- Avoid any dietary changes which may affect your blood Phe level. Follow your doctor's instructions carefully and do not make any changes to your dietary Phe intake without first talking with your doctor. Even if you take JAVYGTOR and your Phe blood levels are not well controlled, you can develop severe neurologic problems

- Tell your doctor as soon as possible if you are sick or have fever as this may increase your blood Phe level

- Take JAVYGTOR exactly as your doctor tells you to

- Do not take 2 doses in a day. If you take too much JAVYGTOR, call your doctor for advice or seek medical attention

Important Safety Information[1] (Continued)

Who Should Not Use JAVYGTOR Tablets for Oral Use and Powder for Oral Solution?

- JAVYGTOR Tablets for Oral Use and Powder for Oral Solution are not recommended in patients with a history of anaphylaxis to Sapropterin Dihydrochloride or any of the ingredients in Sapropterin Dihydrochloride

What Should I Tell My Doctor Before Taking JAVYGTOR Tablets for Oral Use and Powder for Oral Solution?

Before taking JAVYGTOR Tablets for Oral Use or Powder for Oral Solution, tell your doctor if you:

- Are allergic to Sapropterin Dihydrochloride or any of the ingredients in Sapropterin Dihydrochloride
- Have poor nutrition or have loss of appetite
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed

Provide your doctor with a complete list of medications you take, including prescription and over-the-counter medications, vitamins, and dietary or herbal supplements. JAVYGTOR can interact with other medications that you are taking.

What Should I Tell My Doctor Before Taking JAVYGTOR Tablets for Oral Use and Powder for Oral Solution? (cont.)

Especially tell your doctor if you take:

- A medication that contains levodopa
- An antifolate medication, such as methotrexate, phenobarbital, trimethoprim, valproic acid
- Sildenafil (Revatio, Viagra), tadalafil (Adcirca, Cialis), vardenafil (Staxyn, Levitra)

Tell your doctor if you are unsure if your medication is one of the above listed. Always share your complete list of medications with your doctor and pharmacist.

What Are the Most Common Side Effects of JAVYGTOR Tablets for Oral Use and Powder for Oral Solution?

- Headache
- Runny nose and nasal congestion
- Sore throat
- Diarrhea
- Vomiting
- Cough

What Are the Most Common Side Effects of JAVYGTOR Tablets for Oral Use and Powder for Oral Solution? (cont.)

These are not all of the possible side effects of JAVYGTOR. Call your doctor for medical advice about side effects.

To report SUSPECTED Side Effects, contact Dr. Reddy's Laboratories, Inc. at 1-888-375-3784 or by email: medinfo@drreddys.com, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Please see accompanying full Prescribing Information at www.JAVYGTOR.com/PI for further information.

Welcome from Cycle Vita!

At Cycle Vita, we understand that as a patient with a rare disease, or their caregiver, it can be challenging to access your medication, while keeping on top of everything else, like formula and diet.

Our specialist team are here for you. We provide continuous support* tailored to your needs, whether it be help accessing JAVYGTOR from your insurance provider, guidance on how to take the medication, or assistance adhering to your clinic's diet plan.

This guide provides further information on taking JAVYGTOR and the support available with the medication, which could help you better manage your condition.

We recognize JAVYGTOR is only a small part of your life with PKU, but we hope this guide will be a useful resource to you when taking the medication or giving it to a loved one.

Best Wishes,

Cycle Vita

CYCLE VITA™
SUPPORT FOR LIFE

Indication[1]

JAVYGTOR (sapropterin dihydrochloride) Tablets for Oral Use and Powder for Oral Solution are indicated to reduce blood phenylalanine (Phe) levels in adult and pediatric patients one month of age and older with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin-(BH4-) responsive Phenylketonuria (PKU). JAVYGTOR is to be used in conjunction with a Phe-restricted diet.

Important Safety Information[1]

Sapropterin Dihydrochloride can cause serious side effects including: Severe allergic reactions, including anaphylaxis – JAVYGTOR is not recommended in patients with a history of anaphylaxis to sapropterin dihydrochloride.

Please see the complete Important Safety Information on pages 2-3 and accompanying full Prescribing Information at www.JAVYGTOR.com/PI

Living with PKU

PKU is an inherited disorder caused by a deficiency of an enzyme (phenylalanine hydroxylase, sometimes known as PAH). The PAH enzyme is needed to process phenylalanine (Phe), which is found in all foods containing protein. High levels of Phe can cause brain damage if left untreated.[2] The incidence of PKU is highest among Caucasians, occurring in approximately 1 in 10,000 births.[3]

The first line of therapy to treat PKU is a Phe-restricted diet. This involves medical foods which have been modified to be low in protein and medical formula which provides the nutrients a person without PKU would typically get from protein.[4]

Always talk to your dietitian before considering changes to your diet plan.

At the time of publication, Eli and Ruby were taking JAVYGTOR™

Important Safety Information[1]

Stop taking JAVYGTOR and get medical help right away if you develop any of these symptoms of severe allergic reaction:

- Wheezing or trouble breathing
- Coughing
- Flushing
- Nausea
- Feeling lightheaded or you faint
- Rash

Please see the complete Important Safety Information on pages 2-3 and accompanying full Prescribing Information at www.JAVYGTOR.com/PI

Taking JAVYGTOR

In addition to the Phe-restricted diet, some patients with PKU also take a medication called sapropterin dihydrochloride, the active ingredient in JAVYGTOR. This medication helps the PAH enzyme work more effectively to break down Phe in the body.[1]

JAVYGTOR is not a cure for PKU, but when combined with a Phe-restricted diet it can help keep Phe levels under control, and may help you better manage your condition.[1]

Not all patients with PKU respond to sapropterin dihydrochloride:

- You will be eligible for JAVYGTOR without a trial if you have responded to sapropterin therapy previously.
- For patients new to sapropterin therapy, the American College of Medical Genetics and Genomics (ACMG) recommends a trial to assess your responsiveness to the medication.[4]

Important Safety Information[1]

Inflammation of the lining of the stomach (gastritis) or esophagus (esophagitis) - Gastritis or esophagitis can happen with sapropterin dihydrochloride and may be severe. Patients should be monitored by their doctor for signs and symptoms of upper gastrointestinal mucosal inflammation. Call your doctor right away if you have any of these signs or symptoms: severe upper stomach area (abdominal) discomfort or pain, nausea and vomiting; blood in your vomit or stool; black, tarry stool; difficulty swallowing; loss of appetite; pain in the throat.

Please see the complete Important Safety Information on pages 2-3 and accompanying full Prescribing Information at www.JAVYGTOR.com/PI

Taking JAVYGTOR

JAVYGTOR is the same proven sapropterin dihydrochloride you may have taken previously and is available as Tablets for Oral Use or Powder for Oral Solution.[1] Always take JAVYGTOR as your doctor has prescribed it.

How to take JAVYGTOR Tablets for Oral Use[1]

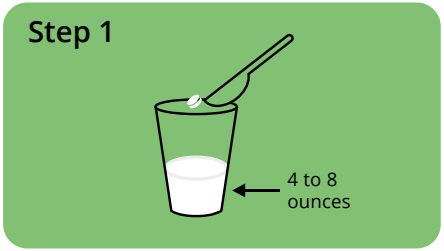
Swallow the tablets whole or create an oral solution:

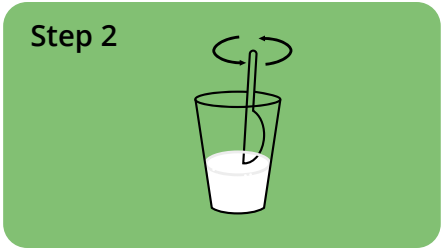
Step 1. Mix JAVYGTOR tablets in 4 ounces to 8 ounces (½ cup to 1 cup) of water or apple juice. It may take a few minutes for the tablets to dissolve. To make the tablets dissolve faster, you can stir or crush them. You may also mix in a small amount of food such as apple sauce or pudding.

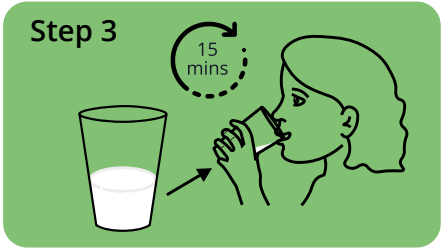
Step 2. Stir the mixture to dissolve the tablets. The tablets may not dissolve completely. You may see small pieces floating on top of the water or apple juice. This is normal and safe for you to swallow.

Step 3. Drink the mixture within 15 minutes.

Note: After drinking your medicine, if you still see small pieces of the tablet, add more water or apple juice and drink to make sure that you take all of your medicine.







Important Safety Information[1]

Phenylalanine (Phe) levels that are too low - Some PKU patients have experienced low blood Phe during treatment. Some children under the age of 7 years who take high doses of sapropterin dihydrochloride each day may experience low Phe levels.

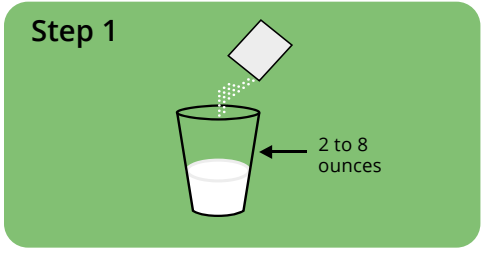
Too much or constant activity (hyperactivity) can happen with sapropterin dihydrochloride - Tell your doctor if you have any signs of hyperactivity, including: fidgeting or moving around too much; talking too much.

Please see the complete Important Safety Information on pages 2-3 and accompanying full Prescribing Information at www.JAVYGTOR.com/PI

Taking JAVYGTOR

How to take JAVYGTOR Powder for Oral Solution[1]

Patients weighing more than 22 pounds



Step 1.

Empty the packet(s) into 2 to 8 ounces (¼ cup to 1 cup) of water, apple juice, or a small amount of soft food such as apple sauce or pudding.

Step 2.

Mix thoroughly until the powder has completely dissolved.

Step 3.

Take the mixture orally within 30 minutes.

Important Safety Information[1]

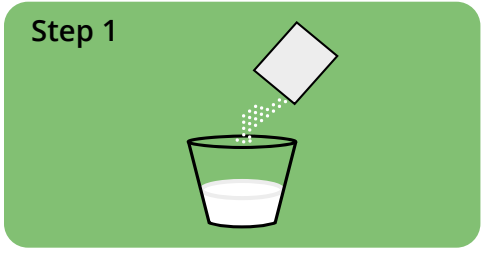
It is not possible to know if sapropterin dihydrochloride will work for you until you start treatment. Your doctor will check your blood Phe levels when you start taking JAVYGTOR to see if the medicine is working.
All patients with PKU who are being treated with JAVYGTOR should also be treated with a Phe restricted diet, including dietary protein and Phe restriction.

Please see the complete Important Safety Information on pages 2-3 and accompanying full Prescribing Information at www.JAVYGTOR.com/PI

Taking JAVYGTOR

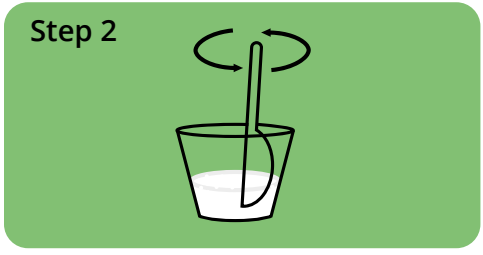
How to take JAVYGTOR Powder for Oral Solution[1]

Patients weighing less than 22 pounds



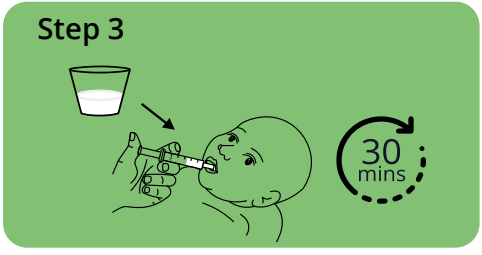
Step 1.

Empty the packet(s) into water or apple juice as prescribed by your physician. The amount needed will change as your baby grows.



Step 2.

Mix thoroughly until the powder has completely dissolved.



Step 3.

Administer the portion of the mixture your doctor has prescribed within 30 minutes of mixing. This can be administered using an oral syringe if necessary.

Note: If you are not able to give your baby's dose within 30 minutes after mixing, pour the unused medicine into the trash. You will need to mix a new dose.

Important Safety Information[1]

Your doctor should continue to monitor your blood Phe levels often during your treatment with JAVYGTOR to make sure that your blood Phe levels are not too high or too low. Frequent blood monitoring is recommended in the pediatric population. Avoid any dietary changes which may affect your blood Phe level. Follow your doctor's instructions carefully and do not make any changes to your dietary Phe intake without first talking with your doctor. Even if you take JAVYGTOR and your Phe blood levels are not well controlled, you can develop severe neurologic problems.

Please see the complete Important Safety Information on pages 2-3 and accompanying full Prescribing Information at www.JAVYGTOR.com/PI

Cycle Vita Patient Support

CYCLE VITA™ SUPPORT FOR LIFE

When you are prescribed JAVYGTOR, you may be eligible for the following support:*

New Patient Free Trial*
Cycle Vita will provide a 30-day supply of JAVYGTOR if you are new to sapropterin dihydrochloride therapy to assess your responsiveness to JAVYGTOR as measured by healthcare provider administered labs and appropriate lab results.

Bridge Program*
A free supply of JAVYGTOR is available to allow you to begin therapy immediately while Cycle Vita secures appropriate Benefit Verification and assists with Prior Authorization. The Bridge Program may also be requested if you're an existing patient who is temporarily experiencing disruption in therapy due to insurance coverage.

Co-Pay Assistance Program*
We will work with you and your insurance provider to understand what co-pay will be required as part of your JAVYGTOR treatment. With JAVYGTOR, commercially insured eligible patients may pay as little as $0.

Continuous Support*
You will have access to a Clinical Education Manager to provide medication administration and adherence support as well as nutrition support by reinforcing your clinic's nutrition plan.

Since 2022
100% of patients
enrolled in the JAVYGTOR Co-Pay Program
paid $0.[5]

Important Safety Information[1]

Tell your doctor as soon as possible if you are sick or have fever as this may increase your blood Phe level.
Take JAVYGTOR exactly as your doctor tells you to.
Do not take 2 doses in a day. If you take too much JAVYGTOR, call your doctor for advice or seek medical attention.

Please see the complete Important Safety Information on pages 2-3 and accompanying full Prescribing Information at www.JAVYGTOR.com/PI

Cycle Vita Patient Support

Our dedicated team of experts are here for you. Throughout your JAVYGTOR treatment you can expect to hear from two specialists at Cycle Vita:

Clinical Education Managers
Provide you with clinical education, product support and medication administration and adherence support.*

Access Specialists
Help you access JAVYGTOR through enrollment, financial and pharmacy support.*

If you have any questions during your JAVYGTOR treatment, the team at Cycle Vita are just a call away at 888-360-8482

CYCLE VITA™
SUPPORT FOR LIFE

Important Safety Information[1]

Who Should Not Use JAVYGTOR Tablets for Oral Use and Powder for Oral Solution?

JAVYGTOR Tablets for Oral Use and Powder for Oral Solution are not recommended in patients with a history of anaphylaxis to sapropterin dihydrochloride or any of the ingredients in sapropterin dihydrochloride.

Available Resources

- **National PKU Alliance**
  www.npkua.org
- **National Organization for Rare Disorders (NORD)**
  www.rarediseases.org
- **Cook For Love**
  www.cookforlove.org

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Tablets or Powder for Oral Solution

Please see the complete Important Safety Information on pages 2-3 and accompanying full Prescribing Information enclosed and available at www.JAVYGTOR.com/PI

References:

1. JAVYGTOR (sapropterin dihydrochloride). Prescribing Information. Dr Reddy's Laboratories Ltd.
2. National Institutes of Health. Phenylketonuria (PKU). Available at: https://www.nichd.nih.gov/health/topics/pku. Accessed March 25, 2026.
3. Williams, R. A. et al. 2008. Phenylketonuria: An Inborn Error of Phenylalanine Metabolism. The Clinical Biochemist Reviews. 29(1) 31-41.
4. Vockley J., et al; for the American College of Medical Genetics and Genomics Therapeutic Committee. Phenylalanine hydroxylase deficiency: diagnosis and management guideline. Genet Med. 2014;16(2):188-200. doi:10.1038/gim.2013.157.
5. REF-00102.

*Some areas of support may not be accessible to all patients. Eligibility criteria may apply to ensure compliance with all applicable federal and state requirements, and benefits may be limited to commercially insured patients only. For more detailed information about eligibility, terms and conditions, please contact the Cycle Vita team at 888-360-8482.

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