

KUVAN[®] (sapropterin dihydrochloride) Co-Pay Assistance Program

Eligible commercially insured patients may pay as little as \$0
for KUVAN prescriptions*



**BioMarin is committed to helping reduce the financial barriers
that can come between patients and their treatment.**

Call 1-877-MY-KUVAN (1-877-695-8826)

and speak with a BioMarin RareConnections[™] Case Manager

Please see Important Safety Information throughout and full [Prescribing Information](#).

*The KUVAN Co-Pay Assistance Program will cover up to \$18,200 in assistance per calendar year for eligible patients. Some restrictions apply. Valid only for those with commercial insurance. Offer not valid for prescriptions eligible to be reimbursed, in whole or in part, by Medicare, Medicaid, or any other federal or state program (including any state prescription drug assistance programs) (eg, VA, DoD, TriCare), for cash-paying patients, where product is not covered by patient's commercial insurance, or where plan reimburses you for entire cost of your prescription drug. No claim for reimbursement of the out-of-pocket expense amount covered by the program shall be submitted to any third party payer, whether public or private. Offer is not valid where prohibited by law. Valid only in the United States and Puerto Rico. This program is not health insurance. Offer may not be combined with any other rebate, coupon, or offer. Co-payment assistance under the program is not transferable. BioMarin Pharmaceutical Inc. reserves the right to rescind, revoke, or amend the program without notice. Patient certifies responsibility for complying with applicable limitations, if any, of any commercial insurance and reporting receipt of program rewards, if necessary, to any commercial insurer. This program is subject to termination or modification at any time. Offer is not valid where prohibited by law. Residents of CA and MA are not eligible.

KUVAN[®]
(sapropterin dihydrochloride)
Tablets or Powder for Oral Solution

\$0 co-pay for KUVAN® (sapropterin dihydrochloride) prescriptions*

Co-pay assistance for patients with commercial insurance taking KUVAN

The KUVAN Co-Pay Assistance Program covers all co-pay costs related to your KUVAN prescription, up to the annual maximum, for as long as the patient remains on therapy and eligible for the program. This program is subject to termination or modification at any time.

Pre-registration has begun

Patients currently taking KUVAN are being made aware that they may be eligible to participate. To determine eligibility, patients should **call 1-877-MY-KUVAN (1-877-695-8826)** and speak with a BioMarin RareConnections™ Case Manager.



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About the KUVAN[®] (sapropterin dihydrochloride) Co-Pay Assistance Program

The program covers:

- Drug co-pays for KUVAN prescriptions for eligible commercially insured patients
- Up to a maximum of \$18,200 in assistance per year for KUVAN prescription drug co-pay costs

The patient is responsible for:

- Any additional co-pay costs that exceed the annual program assistance limit

The program will not cover:

- Any out-of-pocket expenses for KUVAN beyond the \$18,200 annual maximum benefit
- Products that are not offered by BioMarin
- Insurance premiums
- Transportation costs for clinic visits
- Co-pays related to clinic visits or lab tests

To be eligible, patients must:

- Have a KUVAN prescription for an FDA-approved indication
- Have commercial insurance and not be eligible for reimbursement under a federal or state program
- Live in the United States or Puerto Rico

Additional eligibility may apply. Please see below for details.*

To determine eligibility and enroll:

- Visit [BioMarin RareConnections](#) or call 1-877-MY-KUVAN (1-877-695-8826)

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What is KUVAN?

KUVAN® (sapropterin dihydrochloride) Tablets for Oral Use and Powder for Oral Solution are prescription medicines used to lower blood Phe levels in adults and children over one month of age with a certain type of Phenylketonuria (PKU). KUVAN is to be used along with a Phe-restricted diet.

What is the most important information I should know about KUVAN? KUVAN can cause serious side effects, including:

- **Severe allergic reactions including anaphylaxis.** Stop taking KUVAN and get medical help right away if you develop any of these signs or symptoms of a severe allergic reaction:
 - Wheezing, coughing, or trouble breathing
 - Feeling flushed, nauseous, lightheaded or you faint
 - Rash
- **Inflammation of the lining of the esophagus or stomach (esophagitis and gastritis).** Your doctor will monitor you for symptoms of inflammation in your upper gastrointestinal tract, including your stomach and esophagus. If untreated that inflammation can lead to serious side effects including narrowing of the esophagus, ulcers, and bleeding. Call your doctor right away if you have any of these signs or symptoms:
 - Pain in the upper abdomen (stomach area), esophagus, or throat
 - Nausea, trouble swallowing, loss of appetite, or vomiting
 - Blood in your vomit or stool
 - Black, tarry stools
- **The levels that are too low.** Patients have experienced low blood Phe during treatment with KUVAN. Low blood Phe is more common in children under the age of 7 who take high doses of KUVAN each day.
- **Too much or constant activity (hyperactivity) can happen with KUVAN.** Tell your doctor if you have any signs of hyperactivity, including:
 - Fidgeting or moving around too much
 - Talking too much

What should I tell my doctor before I take KUVAN? Before you take KUVAN, tell your doctor about all your medical conditions, including if you:

- Are allergic to sapropterin dihydrochloride or any of the ingredients in KUVAN
- Have poor nutrition or have a loss of appetite
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed. It is not known if KUVAN passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take KUVAN

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal and dietary supplements. KUVAN and other medicines may interact with each other. Especially tell your doctor if you take:

- A medicine that contains levodopa
- An antifolate medicine such as methotrexate, valproic acid, phenobarbital, trimethoprim

- Sildenafil (Revatio, Viagra), tadalafil (Adcirca, Cialis), vardenafil (Staxyn, Levitra)

Tell your doctor if you are not sure if your medicine is one that is listed above. Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I take KUVAN?

See the detailed "Instructions for Use" that comes with KUVAN for information about the correct way to dissolve and take a dose of KUVAN tablets or KUVAN powder for oral solution.

- KUVAN does not work for everyone. It is not possible to know if KUVAN will work for you until you start taking KUVAN. Your doctor will check your blood Phe levels when you start taking KUVAN to see if the medicine is working.
- Take KUVAN exactly as your doctor tells you
- You can swallow KUVAN tablets whole or dissolve the tablets in water or apple juice
- KUVAN powder for oral solution should be dissolved in water or apple juice
- KUVAN should be taken with a PKU-specific diet. Any change you make to your diet 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 KUVAN, if your blood Phe levels are not well controlled, you can develop severe neurologic problems.
- Your doctor should continue to monitor your blood Phe levels often during your treatment with KUVAN **to make sure that your blood Phe levels are not too high or too low and frequent monitoring for pediatric patients is recommended. Both high and low Phe can result in serious problems. Active management of dietary Phe intake while taking KUVAN is required.**
- If you have a fever, or if you are sick, your blood Phe level may go up. Tell your doctor as soon as possible so he or she can change your dose of KUVAN to help keep your blood Phe levels in the desired range.
- If you forget to take your dose of KUVAN, take it as soon as you remember that day. Do not take 2 doses in a day.
- If you take too much KUVAN, call your doctor for advice

The most common side effects of KUVAN are: headache, runny nose and nasal congestion, sore throat, diarrhea, vomiting, and cough.

These are not all the possible side effects of KUVAN. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects.

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to BioMarin Pharmaceutical Inc. at 1-866-906-6100.

Please read the full Prescribing Information by clicking [here](#).