



Frequently Asked Questions About KUVAN®



Q: What is the difference between KUVAN® (sapropterin dihydrochloride) Powder for Oral Solution and KUVAN® (sapropterin dihydrochloride) Tablets?

A: The main difference between the two formulations is the way in which they are prepared and taken. One is a powder that you dissolve in water or apple juice and then drink. The other may be swallowed whole (in its original tablet form) or crushed and dissolved into water or apple juice before drinking. Otherwise, both KUVAN Tablets and KUVAN Powder work in the same way.

Q: Can I receive both Tablets and Powder?

A: Possibly. One packet of KUVAN Powder is equal to one KUVAN Tablet. KUVAN Powder can be more convenient in certain situations, so your doctor can write a prescription for both KUVAN Powder and KUVAN Tablets. Please note, however, that each medication may require a separate co-pay.

Q: Can I try a sample of KUVAN Powder?

A: BioMarin does not offer samples of KUVAN.

Q: If my insurance plan covers KUVAN Tablets, will it cover KUVAN Powder?

A: Not necessarily. BioMarin Patient and Physician Support (BPPS) will need to verify your coverage for Powder, and obtain prior authorization requirements, if any.

Q: If I am currently taking KUVAN Tablets, can I switch the prescription to Powder?

A: Yes, but a new prescription will need to be submitted to BPPS. Based on information from previous benefit investigations, BPPS will determine if a new benefit investigation is needed.

Q: Can I get part of the prescription in Tablets and part in Powder?

A: Possibly, but the prescription will need to be submitted to BPPS. The case manager will then check to confirm that your insurance plan will cover a combination of KUVAN types. Also, please remember that you may need to pay 2 separate co-pays for the medications.

Please see other side for Important Safety Information.

Additional Questions?

If you have additional questions, needs, or concerns, talk to your doctor or contact us:

Phone

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

Fax

1-888-863-3361

Email

bpps@BMRN.com

Hours of Operation

M-F, 6 AM-5 PM (PT)

Indication

KUVAN® (sapropterin dihydrochloride) Tablets for Oral Use and Powder for Oral Solution are approved to reduce blood Phe levels in people with a certain type of Phenylketonuria (PKU). KUVAN is to be used with a Phe-restricted diet.

Important Safety Information

It is not possible to know if KUVAN will work for you without a trial of the medicine.

Your doctor will check your blood Phe levels when you start taking KUVAN to see if the medicine is working.

Starting KUVAN does not eliminate the need for ongoing dietary management. Any change to your diet may impact your blood Phe level. Follow your doctor's instructions carefully. Your doctor and dietitian will continue to monitor your diet and blood Phe levels throughout your treatment with KUVAN **to make sure your blood Phe levels are not too high or too low**. If you have a fever, or if you are sick, your Phe level may go up. Tell your doctor and dietitian as soon as possible so they can make any necessary changes to your treatment.

Tell your doctor if you have ever had liver or kidney problems, have poor nutrition or have a loss of appetite, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed.

KUVAN is a prescription medicine and should not be taken by people who are allergic to any of its ingredients. KUVAN and other medicines may interact with each other. Tell your doctor about **all the medicines you take**, including prescription and over-the-counter medicines, vitamins, herbal and dietary supplements.

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 reported when using KUVAN are headache, runny nose and nasal congestion, sore throat, diarrhea, vomiting, and cough. Additional adverse reactions reported in connection with worldwide marketing include sore throat, heartburn or pain in the esophagus, inflammation of the lining of the stomach, indigestion, stomach pain, and nausea. These are not all the possible side effects seen with KUVAN. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

KUVAN can cause serious side effects, including:

- **Severe allergic reactions.** Stop taking KUVAN and **get medical help right away** if you develop any of these symptoms of a severe allergic reaction:
 - Wheezing or trouble breathing
 - Nausea
 - Flushing
 - Lightheadedness or fainting
 - Coughing
 - Rash
- **Inflammation of the lining of the stomach (gastritis).** Gastritis can happen with KUVAN and may be severe. **Call your doctor right away if you have any:**
 - Severe upper stomach-area discomfort or pain
 - Blood in your vomit or stool
 - Black, tarry stools
 - Nausea and vomiting
- **Too much or constant activity (hyperactivity) can happen with KUVAN.** Tell your doctor if you have any signs of hyperactivity, including fidgeting, moving around or talking too much.

For more information, call BioMarin Patient and Physician Support (BPPS) at 1-866-906-6100.

Please read the attached full Patient Information.

B:OMARIN

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