



How to Take KUVAN® Powder



A simple solution

- Dissolved in 4 to 8 ounces (½ to 1 cup) of water or apple juice
- Taken once a day—as directed by your doctor
- Taken at the same time each day
—With food, preferably your largest meal of the day

It's easy!

- 1 Open the powder packet** by tearing along the top from the notch in the upper right-hand corner. You may also cut the packet open with scissors or the packet opener provided.
- 2 Dissolve the powder** by emptying the contents of the packet(s) in 4 to 8 ounces (½ to 1 cup) of water or apple juice. The powder should dissolve completely within 15 seconds. Be sure to open and dissolve all the packets needed for your dose of KUVAN® (sapropterin dihydrochloride).
- 3 Drink the mixture within 30 minutes** of preparation and make sure you drink all of the medicine in the glass. If any medicine remains in the glass, add 1 to 2 ounces (¼ cup or less) of liquid and drink immediately.

Don't be concerned if the powder changes the color of the liquid you mix it with. This is normal and expected.

Keep in mind...

Follow your doctor's directions for taking KUVAN Powder, including the right number of packets to take per day.

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If you forget to take your dose of KUVAN, take it as soon as you remember that day. If you miss a day, do not double your dose the next day—just skip the missed dose. If you take too much KUVAN, call your doctor for advice.

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KUVAN should be taken every day in conjunction with a low-Phe diet.

Don't change your diet without talking to your doctor or dietitian.

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.

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KUVAN®
(sapropterin dihydrochloride)
Powder for Oral Solution