

KUVAN[®] AND YOU

(sapropterin dihydrochloride) Tablets



How to Take KUVAN[®] (sapropterin dihydrochloride) Tablets for Oral Use

- 1 Once a day—as directed by your doctor
- 2 Same time each day
- 3 With food, preferably your largest meal of the day

Mix it up!

- **Either take the Tablets whole or crush and dissolve them** in 4 to 8 ounces (1/2 to 1 cup) of water or apple juice, or a small amount of soft food, such as apple sauce or pudding. You can crush the tablets before mixing and stir them up to make them dissolve faster, or put the mixture in a sealed container and shake it up.
- **Don't be concerned** if you see small, undissolved pieces—this is normal and safe for you to swallow.
- **Drink or eat the mixture within 15 minutes of preparation.** If you dissolve your KUVAN into liquid, make sure you drink all of the medicine in the glass.

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.

Please see other side for Important Safety Information.

Keep in mind...

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

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KUVAN study shows you may be able to add protein to the diet of children ages 0-4

Talk to your clinic team about the possibility of adding more natural protein to the diet of children ages 0-4 years who are treated with KUVAN under the guidance of a healthcare professional.

A recent study compared children with PKU taking KUVAN along with a low-Phe diet with those who only followed the diet. The results show that those who responded to KUVAN not only reduced their blood-Phe levels, but were also able to increase dietary Phe.

KUVAN may allow children 0-4 to add more natural protein to their diet to support critical growth and development while keeping blood Phe levels within the recommended range.

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.

Children younger than 7 years old treated with KUVAN doses of 20 mg/kg per day are at an increased risk for low levels of blood Phe compared with children 7 years and older. Frequent blood monitoring is recommended in this population to ensure that blood Phe levels do not fall too low.

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 the 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 or 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 experience:**
 - Severe upper stomach-area discomfort or pain
 - Blood in your vomit or stool
 - Nausea and vomiting
 - Black, tarry stools
- **Too much or constant activity (hyperactivity) can happen with KUVAN.** Tell your doctor if you experience hyperactivity, including fidgeting, moving around or talking too much.

For more information, call BioMarin RareConnections™ at 1.866.906.6100.

Please read the attached Full Patient Information.

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KUVAN®
(sapropterin dihydrochloride)
Powder for Oral Solution