KUVAN Powder
Option Offers Added Convenience

KUVAN Powder is a convenient option to help manage your child’s PKU, even while on-the-go:

- Easy-to-carry packets fit into a purse or diaper bag
- Quick and easy preparation—just open, pour, mix, and consume

Established safety profile in infants and children

- Research confirms the safety profile of KUVAN in children as young as 1 month of age
- Side effects are similar to those seen in older patients treated with KUVAN
- KUVAN may cause low blood Phe levels in children younger than 7 years
- Always consult your doctor or dietitian before making changes to your child’s diet

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.

Talk with your clinic team to learn more!

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.

Please see other side for Important Safety Information.

*According to the American College of Medical Genetics and Genomics (ACMG) guidelines, “every PAH-deficient patient should be offered a trial of sapropterin therapy to assess responsiveness except those with two null mutations in trans.”
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 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
  - Flushing
  - Coughing
  - Nausea
  - Lightheadedness or fainting
  - 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
  - Nausea and vomiting
  - Black, tarry stools

• **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 RareConnections™ at 1-877-MYKUVAN (1-877-695-8826).

Please read the attached full Patient Information.