

The Importance of Blood Phe Control for *You*

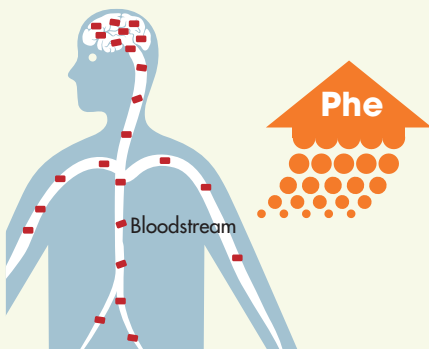


Why is Blood Phe Control Important?

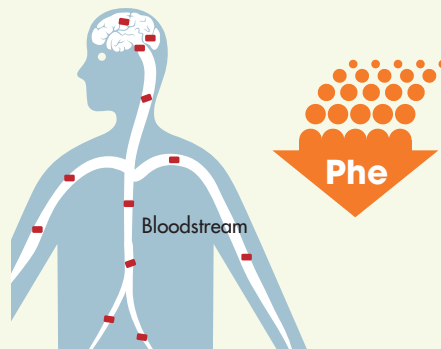
For people with Phenylketonuria (PKU), the amino acid phenylalanine (Phe) cannot be converted as effectively or at all by the phenylalanine hydroxylase (PAH) enzyme into tyrosine.

Tyrosine is an important building block for the brain chemicals (neurotransmitters) that affect thinking, mood and behavior.

For individuals with PKU, high and unstable Phe can cause toxic levels to build up in the blood and brain causing changes in the way you feel, think and act.



In a person with PKU, the PAH enzyme cannot convert Phe into tyrosine as effectively or at all. Without treatment, this can cause toxic levels of Phe to build up in the blood and brain.



In people who respond to treatment with KUVAN (sapropterin dihydrochloride) Tablets, it works with the residual PAH enzyme activity in your body to help convert Phe to tyrosine lowering Phe levels in the blood and brain.

Options for Controlling Phe

It is important to know there are options available for treating your PKU. By partnering with your doctor and dietitian an individual treatment plan can be created for you.

A low-Phe diet is the foundation of life-long treatment for PKU. For many individuals with PKU, KUVAN (sapropterin dihydrochloride) Tablets along with a low-Phe diet can work together for better Phe control!

Could KUVAN® (sapropterin dihydrochloride) Tablets be right for you?

Talk with your doctor and together, *You* can decide!

Typical Symptoms of High or Unstable Blood Phe Levels

To see if high or unstable Phe levels are affecting you, ask yourself the following questions:

- Is it frustrating to try to solve problems?
- Is it hard to plan and organize your menus?
- Do others say you are moody or irritable?
- Do you often forget to take your medical food?
- Do you feel foggy?
- Does it take you a long time to complete tasks?
- Do you have problems concentrating at work or in school?
- Do you feel depressed or anxious?

If you can answer "YES" to several of these questions, it may be a sign that your Phe levels are too high.

KUVAN (sapropterin dihydrochloride) Tablets are approved to reduce blood Phe levels in patients with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4-) responsive Phenylketonuria (PKU). KUVAN is to be used with a Phe-restricted diet.

Important Safety Information

High blood Phe levels are toxic to the brain and can lead to lower intelligence and decrease in the ability to focus, remember and organize information. Any change you make to your diet may impact your blood Phe level. Follow your doctor's instructions carefully. Your doctor and dietitian will continue to monitor and may adjust your diet throughout your treatment with KUVAN (sapropterin dihydrochloride) Tablets.

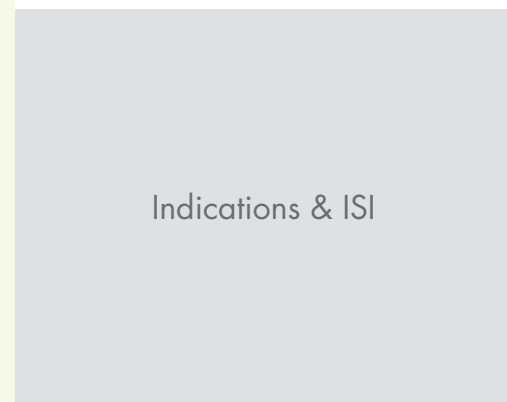
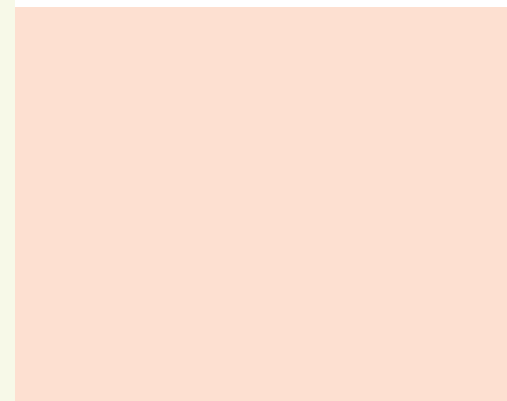
If you have a fever, or if you are sick, your Phe level may go up. Tell your doctor or dietitian as soon as possible so they can see if they have to adjust your treatment to help keep your blood Phe levels in the desired range.

KUVAN is a prescription medicine and should not be taken by people who are allergic to any of its ingredients. Tell your doctor if you have ever had liver problems, are nursing or pregnant or may become pregnant, have poor nutrition or are anorexic. Your doctor will decide if KUVAN is right for you. Tell your doctor about all the medicines you take.

The most common side effects reported when using KUVAN are headache, diarrhea, abdominal pain, upper respiratory tract infection (like cold), throat pain, vomiting, and nausea.

To report SUSPECTED ADVERSE REACTIONS, contact BioMarin Pharmaceutical Inc. at 1-866-906-6100, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see attached prescribing information.



Indications & ISI



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KUVAN[®]
(sapropterin dihydrochloride) Tablets