

FIRST TIME GENERIC APPROVAL

Brand Name	Kuvan®
Generic Name	sapropterin dihydrochloride
Drug Manufacturer	PAR Pharm Inc.

New Drug Approval

FDA Approval Date:

- Tablets: May 10, 2019
- Powder for Oral Solution: August 20, 2019

Generic Manufacturer(s): PAR Pharm Inc.

Therapeutic Equivalent Code: AB

Dosage Form(s):

- Tablets: 100 mg
- Powder for Oral Solution: 100 mg, 500 mg

Indications for Use

Sapropterin dihydrochloride is a synthetic form of the cofactor BH4 (tetrahydrobiopterin) for the enzyme phenylalanine hydroxylase (PAH). PAH hydroxylates phenylalanine to form tyrosine. BH4 activates residual PAH enzyme to improve normal phenylalanine metabolism and decrease phenylalanine levels.

It is indicated for the reduction of blood phenylalanine (Phe) levels in patients with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4-) responsive Phenylketonuria (PKU).