

FIRST TIME GENERIC APPROVAL

Brand Name	Cystadane®
Generic Name	betaine
Drug Manufacturer	Novitium Pharma LLC

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

November 23, 2021

LAUNCH DATE

February 3, 2022

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 214864

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Betaine Anhydrous for Oral Solution is indicated for the treatment of homocystinuria to decrease elevated homocysteine blood concentrations in pediatric and adult patients. Included within the category of homocystinuria are:

- Cystathionine beta-synthase (CBS) deficiency
- 5,10-methylenetetrahydrofolate reductase (MTHFR) deficiency
- Cobalamin cofactor metabolism (cbl) defect

MECHANISMS OF ACTION

Betaine Anhydrous for Oral Solution acts as a methyl group donor in the remethylation of homocysteine to methionine in patients with homocystinuria. Betaine occurs naturally in the body. It is a metabolite of choline and is present in small amounts in foods such as beets, spinach, cereals, and seafood.

DOSE FORM AND STRENGTH

Betaine Anhydrous for Oral Solution is a white to off-white, crystalline, hygroscopic powder for oral solution available in bottles containing 180 grams of betaine anhydrous.

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DOSE & ADMINISTRATION

Therapy with Betaine Anhydrous for Oral Solution should be directed by physicians knowledgeable in the management of patients with homocystinuria.

Adults and Pediatric Patients 3 Years of Age and Older

The recommended dosage is 6 grams per day, administered orally in divided doses of 3 grams twice daily.

Pediatric Patients Less than 3 Years of Age

The recommended starting dosage is 100 mg/kg/day divided in twice daily doses, and then increased weekly by 50 mg/kg increments.

Monitoring

Monitor patient response to Betaine Anhydrous for Oral Solution by homocysteine plasma concentration. Increase the dosage in all patients gradually until the plasma total homocysteine concentration is undetectable or present only in small amounts. An initial response in homocysteine plasma concentrations usually occurs within several days and steady state plasma concentrations occur within a month.

Monitor plasma methionine concentrations in patients with CBS deficiency.