

The FIRST AB-RATED GENERIC Version of CYSTADANE®  
(betaine anhydrous for oral solution) Powder

# Betaine Anhydrous for Oral Solution

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NDC NUMBER	STRENGTH	FORM	TE RATING	COMPARE TO
0713-0352-81	1 gm/scoopful	Powder	AB	CYSTADANE®

## INDICATIONS AND USAGE

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

## IMPORTANT SAFETY INFORMATION / WARNINGS AND PRECAUTIONS

**Before starting BETAINE**, tell your doctor about all of your medical conditions, including if you: have a known hypersensitivity or Hypermethioninemia in Patients with CBS Deficiency: Betaine Anhydrous for Oral Solution may worsen elevated plasma methionine concentrations and cerebral edema has been reported. Monitor plasma methionine concentrations in patients with CBS deficiency. Keep plasma methionine concentrations below 1,000 micromol/L through dietary modification and, if necessary, a reduction of Betaine dosage.

## ADVERSE REACTIONS

Most common adverse reactions (> 2%) are: nausea and gastrointestinal distress, based on physician survey.

To report SUSPECTED ADVERSE REACTIONS, contact Cosette Pharmaceuticals, Inc. at 1-800-922-1038 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Click [here](#) for full prescribing information.

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South Plainfield, NJ 07080

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