Skip to main content

Cystadane (Betaine Anhydrous)

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Adverse Reactions in Clinical Studies

The most serious adverse reaction reported with Cystadane (betaine anhydrous) treatment is the development of hypermethioninemia and cerebral edema in patients with CBS Deficiency [see **WARNINGS AND PRECAUTIONS**].

The assessment of clinical adverse reactions is based on a survey study of 41 physicians, who treated a total of 111 homocystinuria patients with Cystadane (betaine anhydrous) . Adverse reactions were retrospectively recalled and were not collected systematically in this open-label, uncontrolled, physician survey. Thus, this list may not encompass all types of potential adverse reactions, reliably estimate their frequency, or establish a causal relationship to drug exposure. The following adverse reactions were reported (Table 1):

Table 1: Number of Patients with Adverse Reactions to Cystadane (betaine anhydrous) by Physician Survey

Number of Patients	Adverse Reactions
2	Nausea
2	Gastrointestinal distress
1	Diarrhea
1	“Bad taste”
1	“Caused odor”
1	Questionable psychological changes
1	“Aspirated the powder”

Postmarketing Experience

The following adverse reactions have been identified during post approval use of Cystadane (betaine anhydrous) . Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

In postmarketing experience with Cystadane (betaine anhydrous) , severe cerebral edema and hypermethioninemia have been reported within 2 weeks to 6 months of starting betaine therapy, with complete recovery after discontinuation of Cystadane (betaine anhydrous) . All patients who developed cerebral edema had homocystinuria due to CBS deficiency and had severe elevation in plasma methionine levels (range 1,000 to 3,000 ?M). As cerebral edema has also been reported in patients with hypermethioninemia, secondary hypermethioninemia due to betaine therapy has been postulated as a possible mechanism of action.

The following adverse reactions have been reported in patients during postmarketing use of Cystadane (betaine anhydrous) : anorexia, agitation, depression, irritability, personality disorder, sleep disturbed, dental disorders, diarrhea, glossitis, nausea, stomach discomfort, vomiting, hair loss, hives, skin odor abnormalities, and urinary incontinence.