

**PART III: CONSUMER INFORMATION**

Pr Cystadane®

**Betaine anhydrous powder for oral solution**

**This leaflet is part III of a three-part "Product Monograph" designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CYSTADANE. Contact your doctor or pharmacist if you have any questions about the drug.**

**ABOUT THIS MEDICATION****What the medication is used for:**

CYSTADANE is used in the treatment of homocystinuria. Homocystinuria is a rare disease in which abnormal levels of a naturally occurring amino acid, homocysteine, is found in blood and urine. Homocystinuria is caused by a lack of enzymes, cystathionine beta-synthase (CBS) or methylenetetrahydrofolate reductase (MTHFR), or a defect in the cobalamin cofactor metabolism (cbl).

**What it does:**

CYSTADANE reduces the extra homocysteine from the body by aiding in the conversion of homocysteine to methionine.

**When it should not be used:**

Do not use if you (or your child) are allergic to betaine (bay-ta-een).

**What the medicinal ingredient is:**

CYSTADANE contains the medicinal ingredient betaine (bay-ta-een).

**What the important nonmedicinal ingredients are:**

There are no nonmedicinal ingredients in CYSTADANE.

**What dosage forms it comes in:**

CYSTADANE is available in a powder form for oral solution.

CYSTADANE is available in plastic bottles of 180 g. Each bottle contains a measuring scoop. One level scoop (1.7 cc) equals 1 gram of betaine anhydrous powder.

**WARNINGS AND PRECAUTIONS**

BEFORE you use CYSTADANE talk to your doctor or pharmacist:

- About your past and present health problems and medical condition.
- If you are pregnant, plan to become pregnant, or are breast-feeding.

CYSTADANE may cause hypermethioninemia resulting in cerebral edema. Methionine blood levels should be monitored while taking CYSTADANE.

**INTERACTIONS WITH THIS MEDICATION**

Before you (your child) use CYSTADANE tell your (your child's) doctor or pharmacist if you (your child) take or plan to take any other medication including prescription and non-prescription medication, vitamin supplements, and natural health products. CYSTADANE has been used with vitamin B<sub>6</sub> (pyridoxine), B<sub>12</sub> (cobalamin), and folate.

**PROPER USE OF THIS MEDICATION**

The prescribed dose of CYSTADANE should be measured with the measuring scoop provided. One level 1.7 cc scoop is equal to 1 gram of betaine anhydrous powder. Mix the measured dose with 120 to 180 mL (4 to 6 ounces) of water, juice, milk, or infant formula until completely dissolved, or mix with food. Take immediately after preparing dose.

**Adult dose:**

Take as prescribed by your doctor. The usual dose is 6 grams per day taken orally in divided doses of 3 grams two times per day. Your doctor may adjust your dose as needed.

**Children dose:**

In children, the dose is based on body weight. Your doctor may prescribe an initial dose of 100 mg/kg body weight per day and then may increase the dose by 50 mg/kg body weight after 4 to 6 weeks to a maximum of 150 mg/kg/day. The maximum dose must not exceed 6 grams per day.

**Overdose:**

If you think you or someone else has taken an overdose of CYSTADANE, tell your doctor or go to the emergency room at the nearest hospital.

**Missed Dose:**

Take the missed dose of CYSTADANE as soon as you remember. If it is almost time for your next dose, skip the one you missed and go back to your regular dosing schedule.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Side effects may include: nausea, diarrhea, body odour, stomach and intestinal problems. Consult your doctor or pharmacist if any side effects continue or are bothersome.

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

| Symptom / effect  | Talk with your doctor or pharmacist |              | Stop taking drug and call your doctor or pharmacist |
|---|-------------------------------------|--------------|---|
|   | Only if severe                      | In all cases |   |
| Cerebral edema (abnormal pooling of fluid in the brain with associated symptoms of severe headache, nausea, vomiting, loss of eyesight, confusion and coma) |                                     |              | √   |
| Allergic reaction (rash, swelling of the lips, face or neck, difficulty breathing or speaking)  |                                     |              | √   |

*This is not a complete list of side effects. For any unexpected effects while taking CYSTADANE, contact your doctor or pharmacist.*

**HOW TO STORE IT**

Store CYSTADANE at room temperature (15°-30°C). Replace cap tightly after using. Protect from moisture.

Keep all medicines away from children.

**REPORTING SUSPECTED SIDE EFFECTS**

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance by:

toll-free telephone: 866-234-2345  
 toll-free fax: 866-678-6789  
 Online: [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)  
 By email: [CanadaVigilance@hc-sc.gc.ca](mailto:CanadaVigilance@hc-sc.gc.ca)

**By regular mail:**  
**Canada Vigilance National Office**  
**Marketed Health Products Safety and Effectiveness Information Bureau**  
**Marketed Health Products Directorate Health Products and Food Branch Health Canada**  
**Tunney's Pasture, AL 0701C Ottawa ON K1A 0K9**

**NOTE:** Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.

**MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be obtained by contacting the Canadian distributor, Recordati Rare Diseases Canada Inc., at: 905-827-1300

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