

CYSTADANE®

Betaine anhydrous powder for oral administration

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the more common questions about Cystadane.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Cystadane against the benefits he/she expects it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read this again.

What CYSTADANE is used for

Cystadane is used to decrease high levels of homocysteine in the blood, referred to as homocystinuria. Homocysteine is a breakdown product of the amino acid methionine that forms part of proteins present in food. The high levels of homocysteine in the blood may be caused by the various deficiencies in enzymes that break down proteins, specifically called cystathionine beta synthase (CBS) or from 5, 10-methylenetetrahydrofolate reductase deficiency (MTHFR deficiency) or cobalamin cofactor metabolism defect (CBL defect).

High levels of homocysteine in the blood can be toxic and may cause problems in the skeleton and the eyes, as well as mental retardation and cardiovascular disease.

Some people are born with inherited diseases that cause some of the body's natural enzymes of metabolism to be missing or defective. CBS deficiency, MTHFR deficiency and CBL defects are all rare disorders that result in patients not being able to perform the conversion of methionine to cysteine. This disorder presents at early childhood and persists for life, so therefore this treatment is lifelong.

Cystadane together with other treatments such as vitamin B6, vitamin B12 and folate helps the body effectively process homocysteine by triggering the enzymes required to convert it to methionine. This results in a decrease of plasma homocysteine levels.

Ask your doctor if you have any questions about why Cystadane has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before your doctor gives you CYSTADANE

Tell your doctor if you:

- Have allergies to any medicines
- Are taking or using any other medicines. These include medicines bought from pharmacies, supermarkets and health food stores
- Have any other medical conditions
- Are pregnant or breast feeding.

Do not take this medicine after the expiry date printed on the bottle.

If you want further information, consult your doctor.

How to take CYSTADANE

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

Your doctor will evaluate your individual responsiveness to Cystadane before initiating any long term treatment.

The dose will be individually adjusted in order to maintain normal blood levels of homocysteine.

How much to take

The initial dose given to children under 3 years of age is 100mg per kilogram of body weight per day. Dosage in all patients can be gradually increased until plasma homocysteine is undetectable or present only in small amounts.

In pediatric and adults patients, the usual dose of Cystadane is 6 grams per day administered orally in divided doses of 3 grams two times per day.

Always consult your doctor with questions about your prescribed dose.

How to take it

Cystadane powder should be measured using the measuring scoops provided and then dissolved in 120 – 180 mL of water and then drunk immediately after.

Cystadane may be taken along with one or more of the following treatments:

- Vitamin B6 (Pyridoxine)
- Vitamin B12 (Cobalamin)
- Folic acid
- Methionine restriction
- Cysteine supplements

Your doctor will advise on the most appropriate treatment.

How long to take it

Take Cystadane for as long as your doctor tells you.

Cystadane helps to lower your levels of homocysteine in the blood, but it does not cure your condition.

If you forget to take it

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, talk to your doctor or pharmacist.

If you take too much of it (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Cystadane. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking CYSTADANE

Things you must do

Your blood homocysteine levels should be checked regularly while you are taking this medicine.

If you become pregnant while you are taking Cystadane, contact your doctor immediately.

If you are about to be started on any new medication, remind your doctor and pharmacist that you are taking Cystadane.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

Things you must not do

Do not give Cystadane to anyone else even if they have the same condition as you.

Do not take Cystadane to treat any other complaints unless your doctor tells you.

Side Effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Vomiting;
- Gastrointestinal discomfort;
- Diarrhoea.

After taking CYSTADANE

Storage

Keep the powder in the bottle until it is time for administration.

If you pour the powder out of the bottle it may not keep well.

Do not freeze the powder.

Once the container has been opened, the bottle can be stored in a cool dry place out of direct sunlight, at below 25 °C.

At this temperature, an unopened bottle has a lifespan of 4 years and an open bottle has a lifespan of 3 months.

Keep the bottle somewhere that children cannot reach it.

Disposal

If your doctor tells you to stop taking Cystadane, or it has passed its expiry date, ask your pharmacist what to do with the powder that is left over.

Product Description

What it looks like

Cystadane is a white, granular powder.

It is supplied in a bottle containing 180 grams of betaine anhydrous. The powder is stored in a re-sealable container. Three measuring scoops are provided to dispense either 100 mg (green scoop), 150 mg (blue

scoop) or 1 g (pink scoop) of betaine anhydrous.

Ingredients

The active ingredient of Cystadane is anhydrous betaine. There are no other ingredients present in the product.

This medicine does not contain lactose or gluten.

Supplier

Cystadane is supplied in Australia by:

Recordati Rare Diseases

Australia Pty. Ltd.

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