

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Cystadane?

Cystadane contains the active ingredient betaine anhydrous. Cystadane is used to decrease high levels of homocysteine in the blood, referred to as homocystinuria. For more information, see Section [1. Why am I using Cystadane?](#) in the full CMI.

2. What should I know before I use Cystadane?

Do not use if you have ever had an allergic reaction to Cystadane or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Cystadane?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Cystadane and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Cystadane?

- The normal initial dose given to children under 3 years of age is 100mg per kilogram of body weight per day. The dose in all patients can be gradually increased until plasma homocysteine is undetectable or present only in small amounts.
- In paediatric and adult patients, the usual dose of Cystadane is 6 grams per day administered orally, in divided doses of 3 grams two times per day.
- Cystadane powder should be measured using the measuring scoops provided and then dissolved in 120 – 180 mL of water and then consumed immediately after.

More instructions can be found in Section [4. How do I use Cystadane?](#) in the full CMI.

5. What should I know while using Cystadane?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Cystadane.• If you become pregnant while you are taking Cystadane, contact your doctor immediately.• Your blood homocysteine levels should be checked regularly while you are taking this medicine.
Things you should not do	<ul style="list-style-type: none">• 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.
Driving or using machines	<ul style="list-style-type: none">• There is no information regarding any warnings to consider before driving or operating machinery.
Drinking alcohol	<ul style="list-style-type: none">• There is no information regarding drinking alcohol while using this medicine.
Looking after your medicine	<ul style="list-style-type: none">• Keep the powder in the bottle until it is time for administration. Keep the bottle tightly closed in order to protect from moisture. 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.

For more information, see Section [5. What should I know while using Cystadane?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them. Sometimes they are serious, most of the time they are not. Possible effects include nausea, gastrointestinal distress and diarrhoea. You may need medical treatment if you get some of the side effects. Ask your doctor or pharmacist to answer any questions you may have.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Cystadane®

Active ingredient: *betaine anhydrous for oral administration*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Cystadane. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Cystadane.**

Where to find information in this leaflet:

- [1. Why am I using Cystadane?](#)
- [2. What should I know before I use Cystadane?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Cystadane?](#)
- [5. What should I know while using Cystadane?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Cystadane?

Cystadane contains the active ingredient betaine anhydrous.

Cystadane is used to decrease high levels of homocysteine in the blood, referred to as homocystinuria. The high levels of homocysteine in the blood may be caused by 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 using Cystadane.

2. What should I know before I use Cystadane?

Warnings

Check with your doctor if you:

- You are allergic to betaine anhydrous, or any of the ingredients listed at the end of this leaflet.
- 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

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

Always check the ingredients to make sure you can use this medicine.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Cystadane and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Cystadane.

4. How do I use 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 can 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.

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

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

How to take Cystadane

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

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

- Vitamin B6 (pyridoxine)
- Vitamin B12 (cobalamin)
- Folic acid
- Methionine restriction
- Cysteine supplements

If you forget to use Cystadane

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose 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 use too much Cystadane

If you think that you have used too much Cystadane, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia calling 13 11 26), or (New Zealand 0800 764 766)
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Cystadane?

Things you should do

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

Call your doctor straight away if you:

- 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.

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

Remind any doctor, dentist or pharmacist you visit that you are using Cystadane.

Things you should 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Cystadane affects you.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Looking after your medicine

- **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.

Keep the bottle somewhere that children cannot reach it.

When to discard your medicine (as relevant)

When stored at below 25°C, an unopened bottle has a lifespan of 4 years, and an open bottle has a lifespan of 3 months.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal disorders: <ul style="list-style-type: none">• Vomiting• Gastrointestinal discomfort• Diarrhoea	Speak to your doctor if you have any of these less serious side effects and they worry you.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What Cystadane contains

Active ingredient (main ingredient)	Betaine anhydrous
Other ingredients (inactive ingredients)	None.

This medicine does not contain lactose or gluten.

Do not take this medicine if you are allergic to any of these ingredients.

What Cystadane 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.

AUST R: 57379

® Cystadane is a registered trademark of Recordati Orphan Drugs.

Who distributes Cystadane

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