

Consumer Medicine Information (CMI) summary

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

1. Why am I taking CYSTAGON?

CYSTAGON contains the active ingredient mercaptamine (cysteamine) bitartrate. CYSTAGON is used to manage nephropathic cystinosis, in children and adults.

For more information, see Section [1. Why am I taking CYSTAGON?](#) in the full CMI.

2. What should I know before I take CYSTAGON?

Do not take if you have ever had an allergic reaction to mercaptamine, penicillamine, 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 take CYSTAGON?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CYSTAGON 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 take CYSTAGON?

- The dose of CYSTAGON is based on your weight.

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

5. What should I know while taking CYSTAGON?

Things you or your child should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking CYSTAGON.• Take adequate precautions when using this medicine in children, especially those at risk of the medicine entering their airways or lungs.• Keep all of your doctor's appointments so that your progress can be checked.• Follow your doctor's advice about tests that are needed to find out if any unwanted serious side effects are occurring. The tests are very important because serious side effects can occur.
Things you should not do	<ul style="list-style-type: none">• Do not take CYSTAGON to treat any other complaints unless your doctor tells you to.• Do not give your medicine to anyone else, even if they have the same condition as you.• Do not stop taking your medicine or change the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how CYSTAGON affects you.• This medicine may cause drowsiness or tiredness in some people.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C in a cool dry place away from moisture, heat or sunlight.• Keep your capsules in the bottle until it is time to take them.• Keep CYSTAGON where young children cannot reach it.

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

6. Are there any side effects?

Less serious side effects include nausea, vomiting, loss of appetite, diarrhoea, drowsiness, rash, unpleasant breath odour, fever or feel tired or fatigued.

Serious side effects include stomach pain, loss of appetite, throwing up blood, seizures, depression, excessive sleepiness, low white blood cell count, abnormal liver function headache, dizziness, double vision, blurry vision, loss of vision, pain behind the eye or pain with eye movement, skin lesions, bone lesions or joint problems.

Please note this is not a complete list of possible side effects.

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.

CYSTAGON®

Active ingredient: mercaptamine (cysteamine) bitartrate

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking CYSTAGON?

CYSTAGON contains the active ingredient mercaptamine (cysteamine).

CYSTAGON is used to manage nephropathic cystinosis, in children and adults.

Nephropathic cystinosis is a rare inherited disorder characterised by the build-up of cystine in organs such as kidneys. Cystine build up causes kidney damage and excretion of excess amounts of glucose, proteins and electrolytes.

Cystinosis can be detected by measuring the amount of cystine in white blood cells and other body cells. The results of cystinosis are slow body growth, weak bones and progressive kidney failure.

Mercaptamine (cysteamine) works by reacting with cystine so that the cystine level in cells is decreased.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

2. What should I know before I take CYSTAGON?

Warnings

Do not take CYSTAGON if:

- you are allergic to mercaptamine, penicillamine, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
 - o shortness of breath
 - o wheezing or difficulty breathing
 - o swelling of the face, lips, tongue or other parts of the body
 - o rash, itching or hives on the skin.

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

- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes
- take any medicines for any other condition
- have or have ever had any of the following medical conditions:
 - o a skin rash or any bone problems
 - o a history of seizures, exhaustion, depression or other nervous system problems
 - o stomach or intestinal problems including ulcers or bleeding
 - o blood problems.

If you have not told your doctor about any of the above, tell them before you start taking CYSTAGON.

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

Tell your doctor if you are pregnant or plan to become pregnant or if you are breastfeeding or plan to breastfeed.

Your doctor can discuss with you the risks or benefits involved.

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.

Tell your doctor or pharmacist if you are taking an electrolyte replacement supplement.

Replacement of electrolytes (like potassium) is still required during therapy with CYSTAGON capsules.

Your doctor or pharmacist will have more information on medicines to be careful with or avoid while taking this medicine.

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

4. How do I take CYSTAGON?

Follow all directions given to you or your child by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

How much to take

- The dose of CYSTAGON is based on your weight.
- The initial dose for both children and adults is 200 mg to 300 mg/m²/day given in four divided doses.
- This dose will increase over a period of 4 to 6 weeks as directed by your doctor to a maintenance dose:
 - for children up to 12 years: 1.3 g /m²/day.
 - for patients over 12 years and 50 kg body weight: 2 g/day.
- Do not give the whole CYSTAGON capsule to children under six years of age because they may not be able to swallow it and they may choke. For those who are unable to swallow the capsules whole, the capsule may be opened and the contents sprinkled on food or mixed in formula.
- Ask your doctor for full instructions.

When to take CYSTAGON

- Take CYSTAGON at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take CYSTAGON

- Continue taking your medicine for as long as your doctor tells you.

If you forget to take CYSTAGON

If it is less than 2 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much CYSTAGON

If you think that you or anyone else has taken too much CYSTAGON, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- 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.

Symptoms of an overdose may include vomiting, dehydration, feeling of tiredness, drowsiness, lack of energy or heart attack.

5. What should I know while taking CYSTAGON?

Things you or your child should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking CYSTAGON.
- Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.
- Take adequate precautions when using this medicine in children, especially those at risk of the medicine entering their airways or lungs.
- Your medical treatment will include, in addition to CYSTAGON, one or more supplements to replace important electrolytes lost through the kidneys. It is important to take or give these supplements exactly as instructed. If a dose of one of these supplements is missed, do not take extra doses to make up for the missed dose. If several doses of the supplements are missed or weakness or drowsiness develops, call your doctor for instructions.
- Keep all of your doctor's appointments so that your progress can be checked.
- Regular blood tests to measure the amount of cystine present inside white blood cells are necessary to help determine the correct dose of CYSTAGON.
- Regular blood and urine tests are also necessary to measure the levels of various important electrolytes to help your doctor correctly adjust the dose of these supplements.
- Follow your doctor's advice about tests that are needed to find out if any unwanted serious side effects are occurring. The tests are very important because serious side effects can occur. Ask your doctor to explain the warning signs of the serious side effects.

Things you or your child should not do

- Do not take CYSTAGON to treat any other complaints unless your doctor tells you to.
- Do not give CYSTAGON to anyone else, even if they have the same condition as you.
- Do not stop taking CYSTAGON or change the dose without checking with your doctor.

Driving or using machines

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

This medicine may cause drowsiness or tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Children should be careful when riding bicycles or climbing trees.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Looking after your medicine

- Keep your capsules in the bottle until it is time to take them.

If you take your capsules out of the bottle they may not keep well.

- Store below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat, cold and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

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

Do not take 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
<ul style="list-style-type: none">• diarrhoea• drowsiness• feeling tired or fatigued• fever• loss of appetite• nausea• rash• unpleasant breath odour• vomiting	Speak to your doctor if you or your child have any of these less serious side effects.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• central nervous system symptoms, such as seizures, depression or excessive sleepiness• low white blood cell count and abnormal liver function tests on blood tests. Your doctor will monitor you for this	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you or your child

Serious side effects	What to do
<ul style="list-style-type: none">• skin lesions, bone lesions and joint problems. These include skin striae (which are like stretch marks), bone injuries (such as fractures), bone deformities and joint problems• skin rash. Your doctor may ask you to temporarily stop taking this medicine until the rash goes away. If the rash is severe, your doctor may completely stop this medicine• stomach pain, loss of appetite or throwing up blood. Ulcers and bleeding in the digestive tract have occurred whilst taking this medicine• symptoms such as headache, dizziness, nausea, double vision, blurry vision, loss of vision, pain behind the eye or pain with eye movement. Patients may get benign intercranial hypertension, also called pseudotumour cerebri. This is a condition where there is high pressure in the fluid around the brain	notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you or your child 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 only available with a doctor's prescription.

What CYSTAGON contains

Active ingredient (main ingredient)	mercaptamine free base as mercaptamine bitartrate 50 mg or 150 mg per capsule
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• microcrystalline cellulose• pregelatinised maize starch• magnesium stearate• sodium lauryl sulfate• silicon dioxide• croscarmellose sodium

	<ul style="list-style-type: none">• titanium dioxide• gelatin <p>The printing ink on the capsules contains the following inactive ingredients:</p> <ul style="list-style-type: none">• shellac• ethanol• iron oxide black• butan-1-ol• propylene glycol• isopropyl alcohol• sulfuric acid• strong ammonia solution
--	--

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

What CYSTAGON looks like

CYSTAGON 50 mg capsules are white, opaque capsules printed with "CYSTA 50" on the body and "MYLAN" on the cap (AUST R 60451).

CYSTAGON 150 mg capsules are white, opaque capsules printed with "CYSTA 150" on the body and "MYLAN" on the cap (AUST R 60452).

CYSTAGON 50 mg and 150 mg capsules are available in bottles of 500 capsules.

Who distributes CYSTAGON

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in October 2024.

CYSTAGON® is a Viatris company trade mark

CYSTAGON_cmi\Oct24/00