

Cystagon(R)

Cysteamine (as bitartrate)

Consumer Medicine Information

What is this leaflet?

This leaflet answers some common questions about Cystagon capsules. It does not contain all of the available information. Reading this leaflet 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 your taking Cystagon capsules against the benefits they expect it will have for you or your child.

If you have any concerns about taking Cystagon capsules, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may want to read it again.

What Cystagon capsules are used for

Cystagon capsules contain a medicine called cysteamine that 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.

Cysteamine works by reacting with cystine so that the cystine level in cells is decreased.

Your doctor may have prescribed Cystagon capsules for another reason. Ask your doctor if you or your child have any questions about why Cystagon capsules have been prescribed for you.

Cystagon capsules are only available on a doctor's prescription.

Before you or your child takes Cystagon capsules

When you or your child must not take it

Do not take Cystagon capsules if:

- * You or your child is allergic to cysteamine, penicillamine or any of the other ingredients listed at the end of this leaflet.
- * The expiry date (EXP) printed on the bottle has passed. If you or your child take Cystagon capsules after the expiry date has passed, it may not work as well.
- * The packaging is torn or shows signs of tampering.

Before you or your child starts to take it

Tell your doctor if you or your child:

- * Have allergies to any other medicines, foods, preservatives or dyes.

- * Have a skin rash or any bone problems.
- * Have a history of seizures, exhaustion, depression or other nervous system problems.
- * Have or have had stomach or intestinal problems including ulcers or bleeding.
- * Have liver or blood problems.
- * Is pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

If you or your child have not told your doctor about any of the above, tell him/her before you or your child starts taking Cystagon capsules.

Taking other medicines

Replacement of electrolytes (like potassium) is still required during therapy with Cystagon capsules. Tell your doctor or pharmacist if you or your child is taking electrolyte replacement supplement.

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

How to take Cystagon capsules

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.

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

How much to take

The dose of Cystagon capsules prescribed for you or your child will be based on your or your child's weight.

The initial dose for both children and adults is 200mg to 300mg/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 which, for children up to 12 years is 1.3g/m²/day. For patients over 12 years and 50kg body weight the maintenance dose is 2g/day.

Do not give Cystagon capsules to children under six years of age because they may not be able to swallow them and they may choke. For children under six years of age, the capsule may be opened and the contents sprinkled on food or mixed in formula. Consult the doctor for complete directions.

When to take it

Take Cystagon capsules the same time each day.

This will help you or your child remember when to take the capsules.

How long to take it

Continue taking Cystagon capsules for as long as your doctor tells you or your child to.

If you or your child feels unwell during the course of treatment, tell your doctor.

If you or your child forgets to take Cystagon capsules

If you or your child misses a dose of Cystagon capsules, it should be taken as soon as possible. If it is within two hours of the next dose, skip the missed dose and go back to the regular dosing schedule.

Do not take a double dose to make up for the dose that you or your child has missed.

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

If you or your child has trouble remembering to take Cystagon capsules, ask your pharmacist for some hints.

If you or your child takes too much Cystagon capsules

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or your child or anyone else may have taken too many Cystagon capsules.

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 and a heart attack.

While you or your child is taking Cystagon capsules

Things you or your child must do

Make sure that all of your doctors and pharmacists know about your or your child's use of Cystagon capsules.

Remind them if any new medicines are about to be started.

Your or your child's medical treatment will include, in addition to Cystagon capsules, 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 or give extra doses to make up for the missed dose. If several doses of the

supplements are missed or weakness or drowsiness develops, call the doctor for instructions.

Regular blood tests to measure the amount of cystine inside white blood cells are necessary to help determine the correct dose of Cystagon capsules. Your doctor will arrange for the blood tests to be done.

Regular blood and urine tests to measure the levels of the body's important electrolytes are also necessary to help your doctor correctly adjust the doses of these supplements.

Follow your doctor's advice about tests needed to find out if unwanted serious side effects are occurring. The tests are very important because serious side effects can occur. Ask your or your child's doctor to explain the warning signs of the serious side effects.

Things you or your child must not do

Do not take Cystagon capsules to treat any complaint other than that directed by your doctor.

It may not be safe to take Cystagon capsules for another complaint.

Do not give your or your child's medicine to anyone else, even if they have the same condition as you or your child.

It may not be safe for another person to take Cystagon capsules.

Do not stop taking Cystagon capsules or change the dosage without checking with your doctor.

Things to be careful of

This medicine may cause some people to become drowsy or less alert than they are normally.

You should not drive, operate machinery or do any other activities that could be dangerous until you know how Cystagon capsules affect you.

Children should be careful when riding bicycles or climbing trees.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, drowsiness and being less alert may be worse.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you or your child does not feel well while taking Cystagon capsules.

Like all medicines, Cystagon capsules may have some side effects. Sometimes they are serious, most of the time, they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of possible side effects. You may not experience any of them.

The most common side effects of Cystagon capsules include:

- * Nausea
- * Vomiting
- * Loss of appetite
- * Diarrhoea
- * Drowsiness
- * Rash
- * Unpleasant breath odour
- * Fever

Tell your doctor as soon as possible if you or your child notices any of the following:

- * Stomach pain, loss of appetite, or throw up blood. Ulcers and bleeding in the digestive tract have occurred while taking this medicine.
- * 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 totally stop this medicine.

- * Central nervous system symptoms, such as seizures, depression, and excessive sleepiness.
- * Low white blood cell count and abnormal liver function on blood test. Your doctor will monitor you or your child for this.
- * Symptoms such as headache, buzzing or "whooshing" sound in the ear, dizziness, nausea, double vision, blurry vision, loss of vision, pain behind the eye or pain with eye movement. Patients may get benign intracranial hypertension, also called pseudotumour cerebri. This is a condition where there is high pressure in the fluid around the brain.
- * 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.

Other side effects not listed above may also occur in some patients. Tell your doctor if you or your child notices anything else that is making you or your child feels unwell.

After using Cystagon capsules

Storage

Keep Cystagon capsules in their bottle until it is time to take your or your child's dose.

If you or your child takes them out of their bottle, they may not keep well.

Keep Cystagon capsules in a cool dry place away from light where the temperature stays below 25 degrees C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it on a window sill or in the car on hot or cold days.

Heat, cold and dampness can destroy some medicines.

Keep Cystagon capsules where children cannot reach it.

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

Disposal

Ask your pharmacist what to do with any unused medicine.

Product description

What Cystagon capsules look like

Cystagon 50 mg capsules are white, opaque capsules printed with CYSTA 50 on the body and MYLAN on the cap.

Cystagon 150 mg capsules are white, opaque capsules printed with CYSTAGON 150 on the body and MYLAN on the cap.

Ingredients

Each Cystagon capsule contains cysteamine free base as cysteamine bitartrate.

Cystagon capsules contain the following inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, gelatin, magnesium stearate, microcrystalline cellulose, pregelatinised starch, silicon dioxide, sodium lauryl sulfate, iron oxide black, titanium dioxide, shellac, ethanol, isopropyl alcohol, ammonium hydroxide, n-butyl alcohol and propylene glycol.

Cystagon 50 mg or 150 mg capsules are available in bottles containing 500 capsules.

Manufacturer/Supplier

Cystagon capsules are made in the USA by Mylan Pharmaceuticals Inc., and are supplied in Australia by:

Orphan Australia Pty. Ltd.

48 Kangan Drive

Berwick

Victoria 3806

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Australian Registration Number:

50mg Capsules: AUST R 60451

150mg Capsules: AUST R 60452

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