CYSTAGON®

Mercaptamine (cysteamine) (as bitartrate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CYSTAGON. It does not contain all 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 CYSTAGON against the benefits they expect it will have for you.

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

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

What CYSTAGON is used for

CYSTAGON contains a medicine called mercaptamine (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 while blood cells and other body cells. The results of cystinosis are slow body growth, weak bones and progressive kidney failure.

Mercaptamine 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.

CYSTAGON is only available with a doctor's prescription.

Before you take CYSTAGON

When you must not take it

Do not take CYSTAGON if you have an allergy to:

- any medicine containing mercaptamine, penicillamine
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.
If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have ever had any of the following medical conditions:

- a skin rash or any bone problems
- a history of seizures, exhaustion, depression or other nervous system problems
- stomach or intestinal problems including ulcers or bleeding
- or blood problems

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.
Your doctor can discuss with you the risks and benefits involved.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get 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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to 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.

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

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: 1.3g/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 it

Take your medicine 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 it

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

If you forget to take it

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 that you.

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 (overdose)

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 anyone else may have taken too much CYSTAGON. Do this even if there are no signs of discomfort or poisoning.
You may need urgent medical attention.

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

While you are taking CYSTAGON

Things you or your child must 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.

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 doses 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 must not do

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.

Things to be careful of

Be careful driving or operating machinery 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking CYSTAGON.

This medicine helps most people with nephropathic cystinosis but it may have unwanted side effects in a few people. All medicines can have 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 lists 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 or pharmacist if you notice any of the following and they worry you:

- 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 throwing up blood. Ulcers and bleeding in the digestive tract have occurred whilst 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 completely stop this medicine.
- central nervous system symptoms, such as seizures, depression and excessive sleepiness
- low white blood cell count and abnormal liver function tests on blood tests. Your doctor will monitor you for this.
- 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 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.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using CYSTAGON

Storage

Keep your capsules in the bottle until it is time to take them.
If you take the capsules out of the bottle they may not keep well.

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

Do not store CYSTAGON or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.
Heat, cold and dampness can destroy some medicines.

Keep it 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

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What Cystagon capsules looks 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.

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

Ingredients

Each capsule contains mercaptamine free base as mercaptamine bitartrate.

The capsules contain the following inactive ingredients:

- microcystralline cellulose
- pregelatinised maize starch
- magnesium stearate
- sodium lauryl sulfate
- silicon dioxide
- croscarmellose sodium
- titanium dioxide
- gelatin

The printing ink on the capsules contains the following inactive ingredients:

- shellac
- ethanol
- iron oxide black CI77499
- n-butyl alcohol

- propylene glycol
- isopropyl alcohol
- ammonium hydroxide

Manufacturer

Alphapharm Pty Limited
(ABN 93 002 359 739)
Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
Phone: (02) 9298 3999
www.mylan.com.au

Australian Registration Numbers:

50 mg Capsules: AUST R 60451

150 mg Capsules: AUST R 60452

This leaflet was prepared in March 2018.