

CYSTAGON<sup>®</sup> Capsules, 150 mg are white, opaque capsules printed with **CYSTAGON 150** on the body and **MYLAN** on the cap. They are available as follows:

NDC 0378-9045-05  
bottles of 500 capsules

**Store at 20° to 25°C (68° to 77°F). [See USP for Controlled Room Temperature.]**

**Protect from light and moisture.**

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.

**PHARMACIST:** Detach Patient Information Leaflet at each perforation and give leaflet to patient.



Mylan Pharmaceuticals Inc.  
Morgantown, WV 26505

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CYST:RX2P

The following information is available for patients and/or guardians in the patient leaflet.

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**Patient and Parent Information About  
CYSTAGON<sup>®</sup> (SIS-ta-gon)  
(cysteamine bitartrate)  
Capsules**

**Read the Patient Information that come with CYSTAGON<sup>®</sup> before you or your child starts taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your or your child's medical condition or treatment.**

**What is CYSTAGON<sup>®</sup>?**

CYSTAGON<sup>®</sup> is a medicine used to manage a medical condition called nephropathic cystinosis, in children and adults.

Nephropathic cystinosis is a rare inherited condition which causes the build up of a protein building block called cystine in the kidneys. The build up of cystine causes kidney problems. These kidney problems cause the body to lose too much sugar (glucose), proteins, and electrolytes. Cystinosis may lead to slow body growth, weak bones and worsening kidney failure.

### **Who should not take CYSTAGON®?**

Do not take CYSTAGON® if you or your child is allergic to any of the ingredients in it, other products containing cysteamine, or penicillamine. See the end of this leaflet for a complete list of ingredients in CYSTAGON®.

### **What should I tell my or my child's doctor before taking CYSTAGON®?**

Tell your doctor about all of your medical conditions, including if you or your child:

- have had an allergic reaction to a medicine containing cysteamine in the past.
- 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.
- are pregnant or plan to become pregnant. It is not known whether CYSTAGON® may harm your unborn baby. Do not take CYSTAGON® during pregnancy unless you and your doctor decide that the possible benefit of taking CYSTAGON® is more important than the risk to an unborn baby.
- It is not known if CYSTAGON® will pass into breast milk. You and your doctor should decide whether to stop nursing or to stop taking the medicine.

**Tell your doctor about all of the medicines that you or your child takes**, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Know the medicines you or your child takes. Keep a list of your or your child's medicines and show it to your or your child's doctor and pharmacist when you get a new medicine.

### **How should CYSTAGON® be taken ?**

- **Take CYSTAGON® exactly as prescribed.** Do not increase or decrease the amount of medicine without your doctor's approval.
- If you or your child misses a dose of medicine, 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 double dose.
- If you or your child takes too much CYSTAGON®, call your doctor or Poison Control Center, or go to the nearest hospital emergency room right away.
- Do not give CYSTAGON® capsules to children under six years of age. They may not be able to swallow them and may choke. For children under six years of age, the capsule may be opened and the contents sprinkled on food. Talk to your doctor for complete directions.
- Your doctor will arrange for regular blood tests to be done to measure the amount of cystine inside white blood cells. This will help to determine the correct dose of CYSTAGON®. Regular blood and urine tests will also be done to measure the levels of the body's important electrolytes. This will help your doctor to correctly adjust the doses of these supplements.
- Your doctor may also want to do certain tests to find out if unwanted effects are occurring. The tests are very important because serious side effects, including ulcers or bleeding in the stomach and intestines (digestive tract), can occur.

### **What should I or my child avoid while taking CYSTAGON®?**

CYSTAGON® may cause some people to become sleepy or less alert than they are normally. You or your child should not drive, operate machinery, or do other dangerous activities until you know how CYSTAGON® affects you.

### **What are the possible side effects of CYSTAGON®?**

CYSTAGON® can cause serious side effects, including:

1. **Skin rash.** Tell your doctor right away if you or your child gets a skin rash.

CYSTAGON® may need to be temporarily stopped until the rash goes away. If the rash is severe, your doctor may totally stop the CYSTAGON®.

2. **Central nervous system symptoms:** Some patients taking cysteamine have developed seizures, depression, and become too sleepy (excessive sleepiness). Tell your doctor if you or your child has these symptoms.

3. **Stomach and intestinal (gastrointestinal) problems:** Patients taking cysteamine have developed ulcers and bleeding. Tell your doctor right away if you or your child get stomach pain, nausea, vomiting, loss of appetite, or throw up blood.

4. **Low white blood cell count and abnormal liver function on blood tests.** Your doctor will monitor you or your child for this.

5. **Benign intracranial hypertension, also called pseudotumor cerebri,** has been reported. This is a condition where there is high pressure in the fluid around the brain. Tell your doctor right away if you or your child develop any of the following symptoms while taking CYSTAGON®: 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. Your doctor will monitor you or your child with eye examinations to find and treat this problem early. This will help lessen the chance of loss of eyesight.

6. **Skin lesions, bone lesions, and joint problems.** Children treated with high doses of cysteamine may develop skin lesions. These include skin striae (which are like stretch marks), bone injuries (such as fractures), bone deformities, and joint problems. Examine your or your child’s skin while taking CYSTAGON®. Report any changes to your doctor. Your doctor will monitor you or your child for these problems.

The most common side effects of CYSTAGON® include:

- Vomiting
- Loss of Appetite
- Fever
- Diarrhea
- Drowsiness
- Rash

### **How should I store CYSTAGON®?**

- Store CYSTAGON® in a dry place away from light.
- Store CYSTAGON® **between 68° to 77°F (20° to 25°C)**

**Keep CYSTAGON® and all medicines out of the reach of children.**

### **General Information about CYSTAGON®**

Medicines are sometimes prescribed for conditions that are not mentioned in the patient leaflet. Do not use CYSTAGON® for a condition for which it was not prescribed. Do not give

CYSTAGON® to other people, even if they have the same symptoms that you or you child have. It may harm them.

This patient information summarizes the most important information about CYSTAGON®. If you would like more information about CYSTAGON®, talk with your doctor. You can ask your doctor or pharmacist for information about CYSTAGON® that is written for health professionals. For more information call 1-877-446-3678.

**What are the ingredients in CYSTAGON®?**

**Active ingredients:** cysteamine free base as cysteamine bitartrate.

**Inactive ingredients:** colloidal silicon dioxide, croscarmellose sodium, D&C Yellow No. 10 aluminum lake, FD&C Blue No. 1 aluminum lake, FD&C Blue No. 2 aluminum lake, FD&C Red No. 40 aluminum lake, gelatin, magnesium stearate, microcrystalline cellulose, pharmaceutical glaze, pregelatinized starch, silicon dioxide, sodium lauryl sulfate, synthetic black iron oxide and titanium dioxide.



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