

TWICE DAILY DOSING FOR ALL-DAY LIVING

PROCYSBI (cysteamine bitartrate) delayed-release capsules and delayed-release oral granules are the first and only cystine-depleting therapy (CDT) with 12-hour dosing approved for the management of nephropathic cystinosis in adults and children at least one year old.

PROCYSBI Microbeads Make 12-Hour Dosing Possible

Each microbead granule has a protective coating that surrounds the medicine inside (cysteamine bitartrate). This allows it to pass through the acidic stomach into the less acidic small intestine, where it can begin dissolving slowly to release cysteamine over 12 hours.

Create an Acidic Environment in the Stomach

If your stomach is not as acidic as it should be, the medicine contained inside the microbeads could be released too soon. That could make you feel nauseated. It's important to take PROCYSBI exactly as directed.

Take Charge

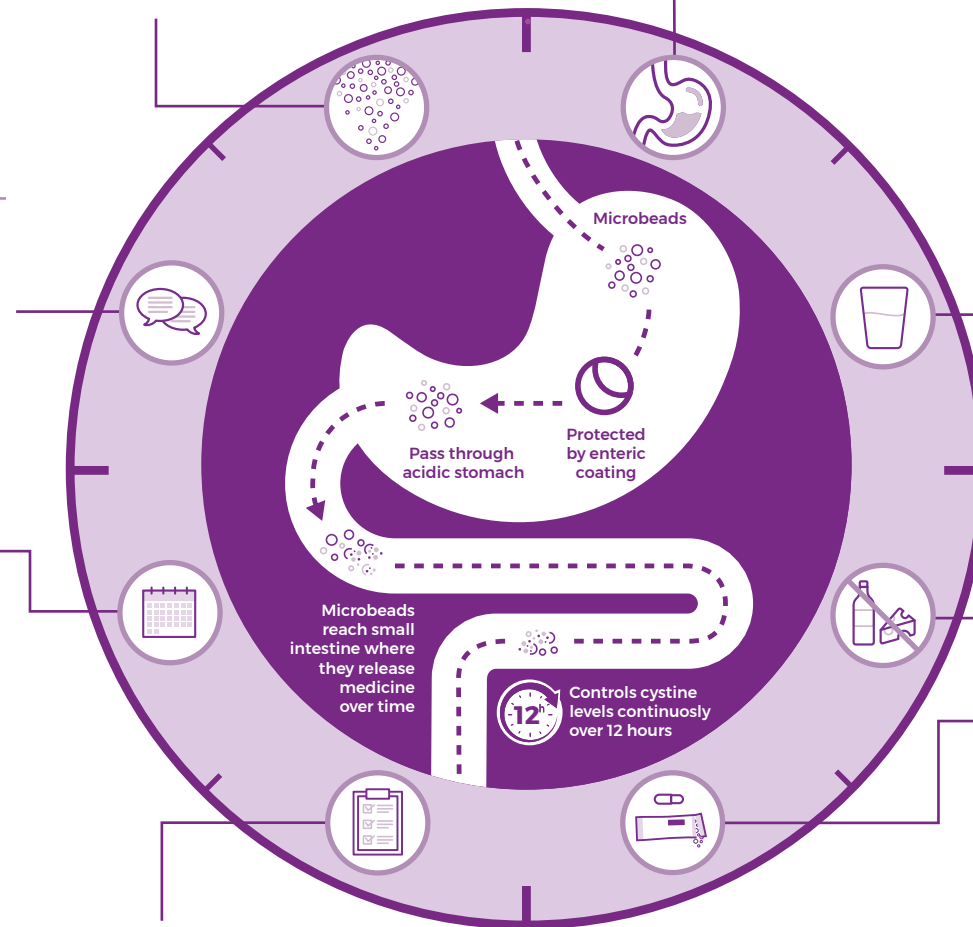
Consistent, continuous control of cystine levels can help limit the damage the disease causes to your body. Talk to your doctor about all your treatment options.

Establish a Consistent Routine

PROCYSBI is 2 doses in 24 hours, taken every 12 hours at the same time every day. Consistency is key to putting you in charge of your day, and night.

"With PROCYSBI's 12-hour dosing schedule I can get more sleep, and I'm able to do more with my time."

Adult with Cystinosis



YES

- Take capsules with water or fruit juice (except grapefruit juice)
- Mix granules with foods like applesauce or berry jelly, which are acidic

NO

- Alcohol
- High-fat foods too close to the time you take a dose
- Antacids containing bicarbonate or carbonate, 1 hour before or after you take a dose

Choose one of two formulations

- Capsules - for swallowing whole or mixing with select foods and liquids
- Packets - for use with g-tube or mixing with select foods and liquids

Know What to Expect

Your doctor may start you on a low dose of PROCYSBI and slowly increase it to manage possible side effects. Take your starting dose as prescribed, every 12 hours. Regular cystine level testing helps your doctor find the right dose for you.

Please see Important Safety Information on the reverse side.

**PROCYSBI**[®]
(cysteamine bitartrate)
delayed-release capsules
delayed-release oral granules

APPROVED USE AND IMPORTANT SAFETY INFORMATION FOR PROCYSBI

What is PROCYSBI?

PROCYSBI (cysteamine bitartrate) delayed-release capsules is a prescription medicine used to treat a medical condition called nephropathic cystinosis in adults and children 1 year of age and older. It is not known if PROCYSBI is safe and effective in children under 1 year of age.

IMPORTANT SAFETY INFORMATION

What is the most important safety information I should know about PROCYSBI?

PROCYSBI can cause serious side effects, including:

- **Skin, bone, and joint problems.** People treated with high doses of cysteamine bitartrate may develop abnormal changes of their skin and bones, such as stretch marks, bone injuries (such as fractures), bone deformities, and joint problems. Check your skin while taking.
- **Skin rash.** Skin rash is common with cysteamine bitartrate and may sometimes be severe. Your dose of PROCYSBI may need to be decreased until the rash goes away. If the rash is severe, your doctor may tell you to stop taking PROCYSBI. Tell your doctor right away if you get a skin rash.
- **Stomach and bowel (intestinal) problems.** Some people who take other medicines that contain cysteamine bitartrate develop ulcers and bleeding in their stomach or bowel. Tell your doctor right away if you get stomach-area pain, nausea, vomiting, loss of appetite, or vomit blood.
- **Central nervous system symptoms.** Some people who take other medicines that contain cysteamine bitartrate develop seizures, depression, and become very sleepy. The medicine may affect how your brain is working (encephalopathy). Tell your doctor right away if you develop any of these symptoms.
- **Low white blood cell count and certain abnormal liver function blood tests.** Your doctor should check you for these problems.
- **Benign intracranial hypertension** (pseudotumor cerebri) has happened in some people who take immediate-release cysteamine bitartrate. This is a condition where there is high pressure in the fluid around the brain. Your doctor should do eye examinations to find and treat this problem early. **Tell your doctor right away if you develop any of the following symptoms while taking PROCYSBI:** 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.

Who should not take PROCYSBI?

Do not take PROCYSBI if you are allergic to penicillamine or cysteamine.

What should I tell my doctor before taking PROCYSBI?

Tell your doctor if you have any other medical conditions, including if you:

- drink alcohol.
- have a skin rash or bone problems.
- have or have had stomach or bowel (intestinal) problems including ulcers or bleeding.
- have a history of seizures, lack of energy, unusual sleepiness, depression, or changes in your ability to think clearly.
- have liver or blood problems.
- are pregnant or plan to become pregnant. It is not known if PROCYSBI will harm your unborn baby. Tell your doctor right away if you think that you are pregnant. Talk with your doctor about the benefits and risks of taking PROCYSBI during pregnancy.
- are breastfeeding or plan to breastfeed. You should not breastfeed during treatment with PROCYSBI. Talk with your doctor about the best way to feed your baby if you take PROCYSBI.

What should I avoid while taking PROCYSBI?

- Do not drive or operate machinery until you know how PROCYSBI affects you. PROCYSBI can make you sleepy or less alert than normal.
- Do not drink alcohol if you take PROCYSBI. Drinking alcohol while taking PROCYSBI may change how PROCYSBI works and may cause an increase in the amount of PROCYSBI in your blood that may cause serious side effects.

What are the possible side effects of PROCYSBI?

- See “What is the most important safety information I should know about PROCYSBI?”

The most common side effects of PROCYSBI include: vomiting, nausea, stomach (abdominal) pain, breath odor, diarrhea, skin odor, tiredness, skin rash, headache, problems with body salts or electrolytes.

These are not all of the possible side effects of PROCYSBI. Call your doctor for medical information about side effects.

You are encouraged to report all the possible side effects of prescription drugs to the FDA. Visit <http://www.fda.gov/medwatch> or call 1-800-FDA-1088.

For additional important safety information, see the Patient Package Insert available at PROCYSBI.com and discuss with your doctor.



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