

Cystadane

Powder for preparing an oral solution

Active ingredient and quantity:

Betaine anhydrous 1 g /g.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have further questions, refer to your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

Treatment of homocystinuria.

Homocystinuria is an inherited (genetic) disease where the amino acid methionine cannot be broken down completely in the body.

Methionine is present in regular food protein (such as meat, fish, milk, cheese, eggs). It is converted into homocysteine, which is then converted into cysteine during digestion. Homocystinuria is a disease caused by accumulation of homocysteine which is not converted into cysteine, and is characterized by formation of venous blood clots, bone weakness, skeleton defects, and crystals on the eye lens.

The purpose of using Cystadane, together with other treatments, such as vitamin B6, vitamin B12, folic acid and a specific diet, is to reduce the elevated homocysteine levels in the body.

Therapeutic group: Amino acid derivatives.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to betaine.

Special warnings about using this medicine

- If you notice side effects like headaches, vomiting, or a change in your vision and you have a type of homocystinuria called CBS (cystathionine beta-synthase deficiency), contact the doctor immediately. This may be a sign of swelling in the brain (cerebral edema). In that case, your doctor will monitor the methionine level in your body and review your diet. Your treatment with Cystadane may need to be discontinued.
- If you are being treated with Cystadane and a mixture of amino-acids, and you need to take additional medicines concomitantly, wait 30 minutes after taking one medicine before taking the other.

If you are taking or have recently taken other medicines, including nonprescription medications and nutritional supplements, tell your doctor or pharmacist. In particular tell the doctor or pharmacist if you are taking a mixture of amino-acids or medicines such as vigabatrin or GABA analogues (medicines used to treat epilepsy). Tell your doctor because these medicines might interact with Cystadane.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to get pregnant, consult your doctor before taking this medicine. Your doctor will decide whether you can use this medicine during pregnancy or breast-feeding.

Driving and using machines

There is no known effect on ability to drive and use machines while using the medicine.

3. How to use this medicine?

Always use according to the doctor's instructions.

- Always take the medicine as instructed by the doctor or the pharmacist.
- You should check with the doctor or the pharmacist if you are not sure.
- The dosage and treatment regimen will be determined by the doctor treating the homocystinuria.
- The commonly accepted dosage in adults is 6 grams per day divided into 2 doses of 3 grams.

Use in children and adolescents

In children under 10 years old – daily dosage of 100 mg/kg/day given in 2 doses.

In children over 10 years old – daily dosage of 6 grams per day divided into 2 doses of 3 grams.

Regular blood tests should be performed to determine the correct daily dosage.

Cystadane must be taken orally (by mouth).

To measure the dose:

- Shake the bottle gently before opening.
- Measure using the measuring spoon supplied with the bottle.
- Each teaspoon (1.7 ml) is equivalent to 1 gram of betaine powder.
- Count the number of teaspoons prescribed by the doctor.
- Mix the measured dose of powder with water, juice, milk, formula, or food until completely dissolved, and swallow immediately after mixing.

If you have taken an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room and bring the medicine package with you.

If you forgot to take this medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult your doctor.

Persist with the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop taking this medicine without consulting your doctor or pharmacist.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

4. Side effects

Like all medicines, taking Cystadane may cause side effects in some of the patients. Do not be alarmed by this list of side effects. You may not experience any of them.

Very common side effects (occur in 1 of every 10 people)

- Elevated levels of methionine in the blood.

Uncommon side effects (occur in 1 of every 100 people)

- High methionine level which may be related to cerebral edema.
- If you experience morning headaches with vomiting and/or visual changes, contact your doctor immediately. (They could be signs of cerebral edema).
- Gastrointestinal disorders like diarrhea, nausea, vomiting, abdominal discomfort, inflammation of the tongue, and dental disorders.

- Decreased appetite, agitation, depression, irritability, personality disorder, sleep disorders, hair loss, urticaria, abnormal skin odor, urinary incontinence (urine leakage).

If any of the side effects gets worse, or if you experience a side effect not mentioned in this leaflet, you should consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by the online form for reporting side effects on the Ministry of Health home page (www.health.gov.il) or by using the following link: <https://sideeffects.health.gov.il/>

5. How to store the medicine?

- Prevent poisoning! This medicine and any other medicine should be kept in a closed place out of the reach of children and/or infants in order to prevent poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Storage conditions: store at a temperature at or below 25°C. Keep tightly closed and prevent penetration of air and moisture. After first opening of the bottle, use the product within 3 months.
- Do not discard the medicine via wastewater or household waste. Ask the pharmacist about how to dispose of the medicine. These measures will help protect the environment.

6. Additional information

Cystadane is a white crystalline powder.

Cystadane is supplied in a bottle containing 180 grams of betaine powder.

The package contains three measuring spoons to help you measure the dosage prescribed by your doctor.

In sizes: 1 g (pink), 150 mg (blue), 100 mg (green)

- Manufacturer name and address:
Recordati Rare Diseases
Immeuble "Le Wilson"
70 Avenue du General De Gaulle, F-92 800 Puteaux, France
- Registration holder's name and address: Medison Pharma Ltd., 10 Hashiloach St., P.O.Box 7090, Petach Tikva.
- This leaflet was reviewed and approved by the Ministry of Health in: Oct. 2016.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 1118729443