

CYSTADANE- betaine powder, for solution
Orphan Europe SARL

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

Package leaflet: Information for the patient

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cystadane is and what it is used for
2. What do you need to know before you take Cystadane
3. How to take Cystadane
4. Possible side effects
5. How to store Cystadane
6. Contents of the pack and other information

1. What Cystadane is and what it is used for

Cystadane contains betaine anhydrous which is intended to be an adjunctive treatment of homocystinuria, an inherited (genetic) disease where the amino acid methionine cannot be broken down completely by the body.

Methionine is present in regular food protein (e.g. meat, fish, milk, cheese, eggs). It is converted into homocysteine which is then normally converted into cysteine during digestion. Homocystinuria is a disease caused by the accumulation of homocysteine which is not converted to cysteine and is characterised by formation of clots in the veins, bone weakness, and skeletal and crystalline lens abnormalities. The use of Cystadane together with other treatments such as vitamin B6, vitamin B12, folate and a specific diet aims to reduce the elevated homocysteine levels in your body.

2. What you need to know before you take Cystadane

Do not take Cystadane

If you are allergic to betaine anhydrous.

Warnings and precautions

Talk to your doctor or pharmacist before taking Cystadane.

If you notice side effects like headaches, vomiting or a change in your vision and you are of the homocystinuria subtype called CBS (cystathionine beta-synthase deficiency), please contact your doctor immediately, they could be signs of a swelling in the brain (cerebral oedema). In that case your doctor will monitor your methionine level in your body and may review your diet. Your treatment with Cystadane may need to be interrupted.

If you are treated with Cystadane and with an amino-acid mixture and if you need to take other medicines at the same time, leave 30 minutes between the intake (see “section “Other medicines and Cystadane”).

Other medicines and Cystadane

Tell your doctor if you are taking, have recently taken or might take any other medicines.

If you are taking amino-acid mixture or medicines such as vigabatrin or Gaba analogues (medicine used to treat epilepsy), please tell your doctor as they might interact with your treatment with Cystadane.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will decide if you can use this medicine during pregnancy and breast-feeding.

Driving and using machines

Cystadane has no or negligible influence on the ability to drive and use machines.

3. How to take Cystadane

The use of this medicine will be supervised by a doctor experienced in the treatment of patients with homocystinuria.

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose in children and adults is 100mg/kg/day divided in 2 doses per day. In some patients doses above 200 mg/kg/day were needed to reach therapeutic goals. Your doctor may adapt the dose depending on your laboratory values.

You will therefore need regular blood tests to determine the correct daily dose.

You should take Cystadane orally (by mouth).

To measure the dose:

- shake the bottle lightly before opening
- take the correct measuring spoon:
 - the small green spoon measures 100 mg of betaine anhydrous powder;
 - the middle size blue spoon measures 150 mg of betaine anhydrous powder;
 - the large pink spoon measures 1 g of betaine anhydrous powder.
 - take a heaped spoonful of powder out of the bottle
 - pass the flat back of a knife over the top of the spoon
 - the powder left in the spoon is one spoonful
 - take the correct number of spoonfuls of powder from the bottle

Mix the measured dose of powder with water, juice, milk, formula or food until completely dissolved and ingest immediately after mixing.

If you take more Cystadane than you should

If you accidentally take too much Cystadane, talk to a doctor or pharmacist immediately.

If you forget to take Cystadane

Do not take a double dose to make up for forgotten doses. If you forget to take a dose take it as soon as you remember it and continue the next dose as planned.

If you stop taking Cystadane

Do not stop the treatment without consulting your doctor. Contact your doctor or pharmacist before stopping.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most commonly side effect when taking Cystadane which may affect more than 1 in 10 people (frequency very common) is elevated levels of methionine in the blood.

Methionine level can be related to swelling in the brain (cerebral swelling), which may affect up to 1 in 100 people (frequency uncommon). If you experience morning headaches with vomiting and/or visual changes, contact immediately your doctor (they could be signs of a swelling in the brain).

Gastrointestinal disorders like diarrhoea, nausea, vomiting, stomach discomfort and inflammation of the tongue may occur uncommonly (may affect up to 1 in 100 people).

Other uncommon side effects (may affect up to 1 in 100 people) may include decreased appetite (anorexia), agitation, irritability, hair loss, hives, skin odour abnormal, lack of control over passing urine (urinary incontinence).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cystadane

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle label and the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Keep the bottle tightly closed in order to protect from moisture. After the first opening of the bottle, the medicine should be used within 3 months.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Cystadane contains

- The active substance is betaine anhydrous. 1 g of oral powder contains 1 g of betaine anhydrous.
- There is no other ingredient.

What Cystadane looks like and contents of the pack

Cystadane is a white crystalline free flowing powder. It is presented in bottles with child resistant closures. Each bottle contains 180 g of powder. Each carton contains one bottle and three measuring spoons.

Marketing Authorisation Holder

Orphan Europe SARL
Immeuble “Le Wilson”
70, avenue du General de Gaulle
F-92 800 Puteaux
France

Manufacturer

Orphan Europe SARL
Immeuble “Le Wilson”
70, avenue du Général de Gaulle
F-92800 Puteaux
France

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

This leaflet was last revised in 8/12/2016

Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu/>. There are also links to other websites about rare diseases and treatments.

Orphan Europe Ltd. Tel : + 44 (0)14 9141 4333

United Kingdom - Ireland

APPENDIX

UNITED KINGDOM

Reporting of side effects

Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Health Care Provider Letter

IMPORTANT PRESCRIBING INFORMATION

22 December 2017

Subject: Temporary importation of CYSTADANE® (betaine anhydrous for oral solution) to address impending shortage

Dear Health Care Provider,

There has been a manufacturing issue with the CYSTADANE® (betaine anhydrous for oral solution) approved for use and distribution in the United States (“U.S.-labeled CYSTADANE”), which has resulted in an interim shortage of this product in the U.S. market.

In order to alleviate the shortage of CYSTADANE in the U.S., Recordati Rare Diseases Inc. (Recordati) is coordinating with the U.S. Food and Drug Administration (FDA) to increase the availability of CYSTADANE. Recordati has initiated temporary importation of its CYSTADANE product approved for use in the United Kingdom into the U.S. market. This product is manufactured by Orphan Europe SARL in France. At this time, no other entity except Recordati, as the U.S. agent of Orphan Europe SARL, is authorized to import or distribute these products in the United States. FDA has not approved the product manufactured by Orphan Europe SARL’s manufacturing facility in France. The imported CYSTADANE is lot CYP1705. It will be dispensed by the U.S. specialty pharmacy, AnovoRx Group LLC.

There are some key differences between the FDA-approved CYSTADANE and the imported CYSTADANE.

- **Measuring scoops:** FDA-approved CYSTADANE is packaged with one scoop (white) that dispenses 1g of betaine anhydrous. Imported CYSTADANE is packaged with 3 measuring scoops (green, blue, and pink) that dispense 100mg, 150mg, or 1g of betaine anhydrous. The large 1g pink scoop in the imported CYSTADANE is equivalent to the white 1g scoop in the FDA-approved CYSTADANE. Patients should pay careful attention to use the appropriate scoop to take their prescribed dose. **Please pass this information along to the patients. If the incorrect scoop is utilized, improper dosing may result, and the CYSTADANE treatment can be ineffective. This may result in an increased risk for cognitive disability and/or stroke due to the progression of the underlying disease.**
- **Dosing:** The labeled dosing in the FDA-approved CYSTADANE is 6 grams/day in divided doses of 3 grams twice daily, and, for pediatric patients less than 3 years of age, dosage may be started at 100 mg/kg/day divided in twice daily doses and increased weekly by 50 mg/kg increments. The labeled dosing in the imported CYSTADANE is 100 mg/kg/day divided into 2 doses per day. **Practitioners should be aware of these differences when prescribing and monitoring CYSTADANE.**

A copy of the FDA-approved full prescribing information is being distributed with the imported CYSTADANE. Please refer to the FDA-approved package insert for full prescribing information. Storage conditions are the same as that of the FDA-approved product. Store at room temperature, 15° – 30°C (59° – 86°F). CYSTADANE is for oral use only. Protect from moisture. Keep this and all medications out of the reach of children.

U.S. FDA-approved Indication

CYSTADANE (betaine anhydrous for oral solution) is a methylating agent indicated for the treatment of homocystinuria to decrease elevated homocysteine blood levels. Included within the category of homocystinuria are:

- Cystathionine beta-synthase (CBS) deficiency
- 5,10-methylenetetrahydrofolate reductase (MTHFR) deficiency
- Cobalamin cofactor metabolism (cbl) defect

For reporting of adverse events and more information

Any adverse effects or medication issues resulting from the use of this drug or quality issues should be reported to Recordati Rare Diseases Inc. at 1-888-575-8344.

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax:

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Important Safety Information

- **Hypermethioninemia**: CYSTADANE may worsen elevated plasma methionine concentrations in patients with CBS deficiency. Cerebral edema has been reported in patients receiving CYSTADANE.
- **Monitoring**: Monitor plasma methionine concentrations in patients with CBS deficiency. Keep plasma methionine concentrations below 1,000 $\mu\text{mol/L}$ through dietary modification and, if necessary, a reduction of CYSTADANE dose.
- **Most common adverse reactions** (incidence > 2%) were nausea and gastrointestinal distress, based on physician survey.
- **Pregnancy**: Animal reproduction studies have not been conducted with CYSTADANE. Use only if clearly needed.
- **Nursing women**: It is not known whether CYSTADANE is excreted in human milk. Use only if clearly needed.
- **Pediatrics**: Pediatric patients ranging in age from 24 days to 17 years have been treated with CYSTADANE. Children younger than 3 years of age may benefit from dose titration.

We are committed to helping address patients' unmet needs through our corporate mission. If you have questions or concerns regarding this product, please call AnovoRx Group, the specialty pharmacy that dispenses CYSTADANE, at 1-888-487-4703 or Recordati Rare Diseases Medical Information at 1-888-575-8344.

Steven R. Peltier

Vice President, Regulatory & Quality Compliance

Chief Compliance Officer

Recordati Rare Diseases Inc.

Product Comparison

FDA Approved (U.S.) Dosing and How Supplied Section	Imported (UK) Dosing and How Supplied Section
<p>2 DOSAGE AND ADMINISTRATION</p> <p>2.1 Dosage</p> <p>The usual dosage in adult and pediatric patients is 6 grams per day administered orally in divided doses of 3 grams twice daily. In pediatric patients less than 3 years of age, dosage may be started at 100 mg/kg/day divided in twice daily doses, and then increased weekly by 50 mg/kg increments. Therapy with Cystadane should be directed by physicians knowledgeable in the management of patients with homocystinuria. Patient response to Cystadane can be monitored by homocysteine plasma levels. Dosage in all patients can be gradually increased until plasma total homocysteine is undetectable or present only in small amounts. Response (by homocysteine plasma levels) usually occurs within several days and steady state within a month. Plasma methionine concentrations should be monitored in patients with CBS deficiency [See <i>Warnings and Precautions (5.1)</i>].</p> <p>Dosages of up to 20 grams per day have been necessary to control homocysteine levels in some patients. However, one pharmacokinetic and pharmacodynamic <i>in vitro</i> simulation study indicated minimal benefit from exceeding a twice-daily dosing schedule and a 150 mg/kg/day dosage for Cystadane.</p> <p>2.2 Administration</p> <p>The prescribed amount of Cystadane should be measured with the measuring scoop provided (one level 1.7 mL scoop is equal to 1 gram of betaine anhydrous powder) and then dissolved in 4 to 6 ounces (120 to 180 mL) of water, juice, milk, or formula, or mixed with food for immediate ingestion.</p>	<p><u>3. How to take Cystadane</u></p> <p>The use of this medicine will be supervised by a doctor experienced in the treatment of patients with homocystinuria. Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The recommended dose in children and adults is 100mg/kg/day divided in 2 doses per day. In some patients doses above 200 mg/ kg/day were needed to reach therapeutic goals. Your doctor may adapt the dose depending on your laboratory values. You will therefore need regular blood tests to determine the correct daily dose. You should take Cystadane orally (by mouth). To measure the dose:</p> <ul style="list-style-type: none"> • shake the bottle lightly before opening • take the correct measuring spoon: <ul style="list-style-type: none"> – the small green spoon measures 100 mg of betaine anhydrous powder; – the middle size blue spoon measures 150 mg of betaine anhydrous powder; – the large pink spoon measures 1 g of betaine anhydrous powder. • take a heaped spoonful of powder out of the bottle • pass the flat back of a knife over the top of the spoon • the powder left in the spoon is one spoonful • take the correct number of spoonfuls of powder from the bottle <p>Mix the measured dose of powder with water, juice, milk, formula or food until completely dissolved and ingest immediately after mixing.</p>
<p>16 HOW SUPPLIED/STORAGE AND HANDLING</p> <p>Cystadane is available in plastic bottles containing 180 grams of betaine anhydrous. Each bottle is equipped with a plastic child-resistant cap and is supplied with a polystyrene measuring scoop. One level scoop (1.7 mL) is equal to 1 gram of betaine anhydrous powder. NDC 52276-400-01 180 g/bottle</p>	<p><u>6. Contents of the pack and other information</u></p> <p>What Cystadane contains</p> <ul style="list-style-type: none"> • The active substance is betaine anhydrous. 1 g of oral powder contains 1 g of betaine anhydrous. • There is no other ingredient. <p>What Cystadane looks like and contents of the pack</p> <p>Cystadane is a white crystalline free flowing powder. It is presented in bottles with child resistant closures. Each bottle contains 180 g of powder. Each carton contains one bottle and three measuring spoons.</p>

FDA-approved (U.S.) Bottle Label:

Supplied by:
Orphan Europe SARL
Puteaux, France

Licensed to and Distributed by:
Recordati Rare Diseases Inc.
Lebanon, NJ 08833 U.S.A.



NDC 52276-400-01

CYSTADANE[®]

betaine anhydrous for oral solution

1 gram of betaine anhydrous powder per scoopful

180 grams

Lot #:
EXP:

Rev Date: April 2017
OEP999

Made in Germany



N 3 52276-400-01 6

Dosage and Administration:
See package insert for dosage information.

Preparation:

1. Shake bottle lightly before removing cap.
2. Measure with the scoop provided.
3. One level scoop (1.7 cc) is equivalent to 1 gram of betaine anhydrous powder. Measure the number of scoops your physician has prescribed.
4. Mix with 4 to 6 ounces (120 to 180 mL) of water, juice, milk, or formula, until completely dissolved, or mix with food, then ingest immediately.



Keep this and all medication out of the reach of children.

Always replace the cap tightly after using. Store at room temperature, 15° – 30°C (59° – 86°F). Protect from moisture.

Imported (U.K.) Bottle Label:

Lot / Date / Serial / BE / CH / AR /
 Import / Import / No. Serial / C. Serial
 EXP / CAD / UH / ped / T / T / B / B /
 Exp. Date / Ave. Date / Serial /
 Keresztelő dátum / Közvetlen / Gyártási
 AHA / H / Termék azonosító

CYSTADANE[®]

1g

Cystadane 1 g nepopanex npax	Бетанн, безводен (BG)	Cystadane 1 g polvere orale	Betainna anidra (IT)
Cystadane 1 g peroralni prašek	Betainum anhydricum (CS)	Cystadane 1 g geriamleji miltelisi	Bevandenis betainas (LT)
Cystadane 1 g orali pulver	Betain, vandfri (DA)	Cystadane 1 g pulveris iekšīgai lietošanai	Betaine anhydrous (LV)
Cystadane 1 g Pulver zum Einnehmen	Wasserfreies Betain (DE)	Cystadane 1 g trab għall-baliq	Betaine anidru (MT)
Cystadane 1 g νόσσηρ κόβωρ	Ανεύρηρη βήταϊνη (EL)	Cystadane, 1 g poeder voor oraal gebruik	Watervrij betaine (NL)
Cystadane 1 g oral powder	Betaine anhydrous (EN)	Cystadane 1 g pulver	Betain, vannfritt (NO)
Cystadane 1 g polvo oral	Betaina anhidra (ES)	Cystadane 1 g proszek doustny	Betaina bezwodna (PL)
Cystadane 1 g suukaudne pulber	Veevaba betaiin (ET)	Cystadane 1 g pó oral	Betaina anidra (PT)
Cystadane 1 g jauhe	Betaini, vedetön (FI)	Cystadane 1 g pulbere orali	Betaini anhidra (RO)
Cystadane 1 g poudre orale	Betaine anhydre (FR)	Cystadane 1 g peroralneho prášku	Bezvodý betain (SK)
Cystadane 1 g oralni prašek	Bezvodni betain (HR)	Cystadane 1 g peroralni prašek	Bezvodni betain (SL)
Cystadane 1 g beśwódeśes por	Vízmentes betain (HU)	Cystadane 1 g orali pulver	Betain vattenfritt (SV)
Cystadane 1 g duft til inntöku	Vatnsfritt betain (IS)		

EU/1/06/379/001

Orphan Europe SARL - Immeuble "Le Wilson" - 70 avenue du Général de Gaulle F-92800 Puteaux - France

Imported (U.K.) Carton:



Package/Label Display Panel

CYSTADANE®

1 g

Orphan Europe SARL

Immeuble "Le Wilson"

70 avenue du Général de Gaulle

F-92800 Puteaux

Cystadane 1 g oral powder.

Betaine anhydrous

1 g of powder contains 1 g of betaine anhydrous. 180 g of oral powder and three measuring spoons. Three measuring spoons (green, blue, pink) dispense 100mg, 150mg or 1g of betaine anhydrous. Lightly shake the bottle before opening. Read the package leaflet before use. **ORAL USE.** Keep out of the sight and reach of children. Do not store above 25°C. Keep the bottle tightly closed in order to protect from moisture. Medicinal product subject to medical prescription.

Shelf life after the first opening: 3 months

Lot:

EXP:



EN - MT - ES - PT - LV - LT

FI - SV - DA - NO - ET - IS

<p>Cystadane 1 g oral powder. Betaine anhydrous 1 g of powder contains 1 g of betaine anhydrous. 180 g of oral powder and three measuring spoons. Three measuring spoons (green, blue, pink) dispense 100mg, 150mg or 1g of betaine anhydrous. Lightly shake the bottle before opening. Read the package leaflet before use. ORAL USE. Keep out of the sight and reach of children. Do not store above 25°C. Keep the bottle tightly closed in order to protect from moisture. Medicinal product subject to medical prescription.</p> <p>Cystadane 1 g trab għall-haq. Betaine anidru 1 g ta' trab fih 1 g ta' betaine anidru. 180 g ta' trab għall-haq u tliet imgharef tal-kejl. Tliet imgharef tal-kejl (ħadra, blu, roża) jagħtu, 100mg, 150 mg jew 1 g ta' betaine anidru. Hallat daqqoġ il-flaskun qabel ma tiftiha. Aqra l-fuġġiet ta' taġġir qabel l-użu. JITTIEHD MILL-ĦALQ. Żomm fejn ma jidherx u ma jindagħx mit-tfal. Taħżen f'temperatura oġġja minn 25°C. Żomm il-flaskun magħluq sew sabiex ttiproteġi mill-umidità. Prodott medikinali li jingħata bir-riċetta ta-t-talib.</p> <p>United Kingdom & Ireland POM</p>	<p>Cystadane 1 g polvo oral. Betaina anhídru 1 g de polvo contiene 1 g de betaina anhídru. 180 g de polvo oral e tres cucharas graduadas. Tres cucharas graduadas (verde, azul, rosa) dispensan 100 mg, 150 mg o 1 g de betaina anhídru. Antes de abrir, agitar ligeramente el frasco. Leer el prospecto antes de utilizar este medicamento. VÍA ORAL. Mantener fuera de la vista y del alcance de los niños. No conservar a temperatura superior a 25°C. Mantener el frasco perfectamente cerrado para protegerlo de la humedad. Medicamento sujeto a prescripción médica.</p> <p>Cystadane 1 g pó oral. Betaina anidru 1 g de pó contém 1 g de betaina anidru. 180 g de pó oral e três colheres-medida. As três colheres-medida (verde, azul, rosa) dispensam 100 mg, 150 mg ou 1 g de betaina anidru. Agite ligeiramente o frasco antes de o abrir. Consulte o folheto informativo. VIA ORAL. Manter fora da vista e do alcance das crianças. Não conservar acima de 25°C. Manter o frasco bem fechado para protegê-lo da humidade. Medicamento sujeito a receita médica.</p> <p>ESPAÑA C.N. 638697.6 HX Uso hospitalario 8 470006 586976</p> <p>Portugal Nº de código nacional : 5022728 Medicamento sujeito a receita medica 5022728</p>	<p>Cystadane 1 g pulveris iekšējīgai lietošanai. Betaine anhydrous 1 g pulvera satur 1 g bezūdeņaina betaīna. 180 g pulvera iekšējīgai lietošanai un trīs mērkarotes. Pievienotus trīs mērkarotes (zaļā, zilā, rozā krāsā) 100 mg, 150 mg vai 1 g bezūdeņaina betaīna dozēšanai. Pūdeli pirms atvēršanas viegli sakratiet. Pirms lietošanas izlasiet lietošanas instrukciju. IEKŠĒJĪGAI LIETOŠANAI. Uzglabāt bērniem nerezāma un nepieejamā vietā. Uzglabāt temperatūrā līdz 25°C. Pūdeli uzglabāt droši noslēgtu, lai pasargātu no mitruma. Receptu zāles.</p> <p>Cystadane 1 g geriamieji milteliai. Bēvandenis betainas 1 g milteliņa yra 1 g bevandenio betaīno. 180 g geriamųjų miltelių ir trys matavimo šaukšteliai. Įtrims matavimo šaukštėlis (žaliu, mėlynu, rausvu) atmatuojama 100 mg, 150 mg arba 1 g bevandenio betaīno. Prieš atidarydami buteliuką nesmarkiai pakratykite. Prieš vartojimą persikaityti pakuočius lapelį. VARTOTI PER BURNĄ. Laikyti vaikams nepasiekiamoje vietoje. Laikyti ne aukštesnėje kaip 25°C temperatūroje. Buteliuką laikyti sandariu, kad preparatas būtų apsaugotas nuo drėgmės. Receptinis vaistinis preparatas.</p> <p>Latvia Receptu zāles</p>	<p>Cystadane 1 g jauhe. Betaiini, vedetön 1 g jauhetta sisältää 1 g vedetöntä betaiinia. 180 g jauhetta ja kolme mittalusikkaa. Kolmella mittalusikalla (vihreä, sininen, vaaleanpunainen), annostellaan 100 mg, 150 mg tai 1 g vedetöntä betaiinia. Sekoitá pulloa kevyesti ennen avaamista. Lue pakkausohjeet ennen käyttöä. SUUN KAUTTA. Elästen ulottuville eikä näkyville. Säilytä alle 25°C. Pidä pullo tiiviisti suljettuna. Herkää kosteudelle. Reseptilääke.</p> <p>Cystadane 1 g oralt pulver. Betain vattenfritt 1 g pulver innehåller 1 g betain vattenfritt. 180 g oralt pulver och tre doseringskedar. Tre doseringskedar (grön, blå, rosa) mäter upp 100 mg, 150 mg eller 1 g av betain vattenfritt. Skaka burken lätt innan du öppnar den. Läs bipackesedeln före användning. ORALT BRUK. Förvaras utom syn- och räckhåll för barn. Förvaras vid högst 25°C. Tillstut burken väl. Fuktkänsligt. Receptbelagt läkemedel.</p> <p>Finland/Suomi, Sverige, Danmark, Norge, Island Vnr 10 86 97 7 046261 086974</p>	<p>Cystadane 1 g oralt pulver. Betain, vandfritt 1 g pulver inneholder 1 g betain, vandfritt. 180 g pulver og tre måleskeer. Tre måleskeer (grøn, blå, lys rød) dispenserer 100 mg, 150 mg eller 1 g betain, vandfritt. Flasken rystes let før åbning. Læs indlægssedlen inden brug. ORAL ANVENDELSE. Opbevares utilgængeligt for børn. Må ikke opbevares over 25°C. Hold flasken godt lukket for at beskytte imod fugt. Receptpligtigt lægemiddel.</p> <p>Cystadane 1 g pulver. Betain, vannfritt 1 g pulver inneholder 1 g betain, vannfritt. 180 g pulver og tre måleskjeer. Tre måleskjeer (grønn, blå, rosa) til måling av 100 mg, 150 mg eller 1 g betain, vannfritt. Rist flasken forsiktig før den åpnes. Les pakningsvedlegget før bruk. ORAL BRUK. Oppbevares utilgjengelig for barn. Oppbevares ved høyest 25°C. Hold flasken tett lukket for å beskytte mot fuktighet. Reseptpliktig legemiddel.</p> <p>Finland/Suomi, Sverige, Danmark, Norge, Island Vnr 10 86 97 7 046261 086974</p>	<p>Cystadane 1 g suukaudne pulber. Veevaba betaiini 1 g pulbrit sisaldab 1 g veevaba betaiini. 180 g suukaudset pulbrit ja kolm mõõtelusikat. Kolm mõõtelusikat (roheline, sinine, roosa) 100 mg, 150 mg, või 1 g veevaba betaiini mõõtmiseks. Enne avamist püüdlid veidi loikutada. Enne ravimi kasutamist lugege pakendi infolehte. SUUKAUDNE. Hoida laste eest varjatud ja kättesaamatus kohas. Hoida temperatuuril kuni 25 °C. Hoida püüdlid tihedalt suletuna. Hoida niiskuse eest kaitsvalt. Receptiravim.</p> <p>Cystadane 1 g duft til inntöku. Vattsnúfritt betaiini 1 g af duft til inntöku er 1 g af vatnsfrú betaiini. 180 g af duft til inntöku og þrjár mæliskeiðar. Þrjár mæliskeiðar (græn, blá, bleik) fyrir 100 mg, 150 mg eða 1 g af vatnsfrú betaiini. Hristið glasið lauslega áður en það er opnað. Lesið fylgiseðilinn fyrir notkun. TIL INNTÖKU. Geymið þar sem börn hvorki ná til né sjá. Geymið ekki við hærri hita en 25°C. Geymið glasið vel lokað til varnar gegn raka. Lyfið er lyfseðilskytt.</p> <p>Finland/Suomi, Sverige, Danmark, Norge, Island Vnr 10 86 97 7 046261 086974</p>
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Sheff life after the first opening: 3 months /
 Vikra li jnlekuh 1-erwel darbe: Jskoih fi 3mian
 3 xadur / Período de validade uma vez aberto: 3 meses /
 / Prazo de validade após a primeira abertura: 3 meses /
 / Uzglabāšanas laiks pēc pudeles pirmās atvēršanas: 3 mēneši
 / Tinkamumo laikas po pirmojo atidarymo: 3 mėnesiai / Keszoalka
 avamisan jllkeen: 3 kuukautta / Hållbarhet av öppnad burk: 3 månader
 / Holdbarhet efter første åbning: 3 måneder / Holdbarhetsid etter andrud: 3 måneder / Kõlblikusaeg pärast esmakõrset avamist: 3 kuud / Geymslupot
 etter að glasið hefur verið opnað: 3 mánuðir.

Lot / Lots / Séri / Serija /
 Sats / Eta / Batch /
 Partii nr.

EXP / CAD / Utilizatsiata /
 Der. Lõike / Tinka Mi /
 Käilyt.Vim / Ugu.dat.

OEP 1013

CYSTADANE

betaine powder, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:52276-401
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BETAINE (UNII: 3SCV180C9W) (BETAINE - UNII:3SCV180C9W)	BETAINE	1 g in 1 g

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52276-401-01	1 in 1 CARTON	01/08/2018	08/31/2020
1		180 g in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug for use in drug shortage		01/08/2018	

Labeler - Orphan Europe SARL (767598352)**Registrant** - Orphan Europe SARL (767598352)**Establishment**

Name	Address	ID/FEI	Business Operations
Ropack Pharmaceutical		209989631	manufacture(52276-401)

Revised: 3/2018

Orphan Europe SARL