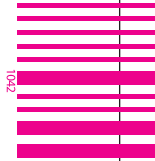


## Package leaflet: Information for the user

# Trebon 600 mg powder for oral solution

## acetylcysteine



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

#### 1. What Trebon is and what it is used for

Trebon contains the active substance acetylcysteine and dissolves thick mucus in the airways.

Trebon is used to loosen mucus and to ease coughing up in cases of lung diseases such as chronic bronchitis in adults.

#### 2. What you need to know before you take Trebon

##### Do not take Trebon

- If you are allergic to acetylcysteine or any of the ingredients of this medicine (listed in section 6).
- Children under 2 years of age must not take Trebon.

##### Warnings and precautions

Talk to your doctor or pharmacist before taking Trebon if you have

- asthma
- If you have asthma then you should not take this medicine.
- skin and lining of the mouth and groin changes
- The occurrence of severe skin reactions, has very rarely been reported in connection with the use of acetylcysteine. If you experience any skin and lining of the mouth and groin changes, you should immediately stop taking this product and inform your doctor.
- a history of stomach or bowel ulcers or currently have them.
  - if you are allergic to histamine
- Long-term therapy should be avoided in these patients, since taking Trebon may lead to symptoms of intolerance (e.g. headache, running nose, itching).
- an inability to cough up mucus
  - kidney or liver disorders

##### Children and adolescents

Children under 2 years of age may have a difficulty in coughing. Therefore, children under 2 years of age must not take Trebon.

Trebon 600 mg powder for oral solution has not been used in children aged 2 years and older and adolescents. Therefore, in children aged 2 years and older and in adolescents it is not recommended to take Trebon. Other medicinal products with lower amount of acetylcysteine are more suitable for them.

##### Other medicines and Trebon

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

medicines. This particularly applies to:

- cough suppressants: Combined use of Trebon with cough suppressants may cause a dangerous build-up of mucus due to the reduced need to cough.
- antibiotics: Studies have shown evidence of a weakening effect of antibiotics, such as tetracyclines (e.g. doxycycline, minocycline), aminoglycosides (e.g. neomycin, streptomycin, kanamycin, gentamicin, tobramycin), penicillins (e.g. amoxicillin, cloxacillin), carbapenem, fluoroquinolones (e.g. ciprofloxacin, levofloxacin) and cephalosporins (e.g. cefatrizine, cefoxitin, loracarbef, cefepime) due to acetylcysteine. For safety reasons, antibiotics should be taken separately and at an interval of at least 2 hours.
- activated charcoal - used to help treat a drug overdose or a poisoning.
- glycerol trinitrate: a medicine known also as nitroglycerin, used to widen the blood vessels. This could lead to severely reduced blood pressure, which could be serious.

##### Laboratory tests

Tell your doctor that you are taking Trebon if you are going to take a test for the following, because the results may be affected:

- salicylates: medicines to treat pain, inflammation or rheumatic disease
- ketone bodies in the urine

##### 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 or pharmacist for advice before taking this medicine.

##### • Pregnancy

Not enough experience is available about the use of acetylcysteine in pregnant women. Trebon is not recommended during pregnancy.

##### • Breast-feeding

No information is available about the transfer of acetylcysteine into breast milk. You should therefore use Trebon during breast-feeding only if your doctor deems it absolutely necessary.

##### Driving and using machines

Trebon is not known to influence the ability to drive or operate machines.

##### Trebon contains sorbitol

This medicine contains 2,167.9 mg sorbitol in each sachet. Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take or receive this medicine.

##### Trebon contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per sachet, that is to say essentially 'sodium-free'.

##### Trebon contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. May be harmful to the teeth.

### 3. How to take Trebon

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, if not otherwise prescribed by the doctor, is:

#### Adults

Take 1 sachet once daily.

#### Patients with kidney and liver deficiency

Consult your doctor because your dose may have to be adjusted.

#### Method of administration

Dissolve Trebon in half a glass of water. This produces a solution that should be consumed immediately.

#### Duration of use

The duration of therapy depends on your condition and should be decided by your doctor.

#### If you take more Trebon than you should

If you take too much Trebon, please inform your doctor or pharmacist immediately.

In the event of an overdose, you might experience symptoms from the stomach and bowel, such as abdominal pain, nausea, vomiting and diarrhoea.

Therapeutic measures in case of an overdose are according to the symptoms.

#### If you forget to take Trebon

Do not use a double dose to make up for a forgotten dose. Just use your next dose at the usual time.

#### If you stop taking Trebon

Do not stop taking Trebon prescribed by your doctor without asking your doctor as this could reduce the success of therapy.

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

### 4. Possible side effects

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

Stop taking Trebon and contact your doctor if signs of an allergic or serious skin reaction occur.

#### Uncommon side effects (may affect up to 1 in 100 people):

- allergic reactions, showing difficulty in breathing or wheezing and breathlessness, faster heart beat, itching, hives and serious allergic reaction which causes swelling of the face or throat.
- headache
- ringing in the ears
- faster heart beat
- low blood pressure
- vomiting, diarrhoea, mouth inflammation, abdominal pain, feeling sick
- hives, swelling of the face or throat, itching
- fever

#### Rare side effects (may affect up to 1 in 1,000 people):

- difficulty in breathing or wheezing, breathlessness
- indigestion

#### Very rare side effects (may affect up to 1 in 10,000 people):

- severe allergic reactions, including anaphylactic reaction (serious allergic reaction which causes difficulty in breathing or dizziness)
  - bleeding
- Not known** (frequency cannot be estimated from the available data):
- swelling

### 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:

IE: HPRA Pharmacovigilance Website: [www.hpra.ie](http://www.hpra.ie).

UK: Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

### 5. How to store Trebon

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 sachet and the carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.

Store in the original package in order to protect from moisture. After preparation, the solution should be used immediately.

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 Trebon contains

The active substance is acetylcysteine.

Each sachet contains 600 mg of acetylcysteine.

The other ingredients are citric acid (E330), lemon juice flavour in powder (natural flavouring substances, maltodextrin (maize), modified starch (E1450) (waxy maize), sucrose), saccharin sodium (E954), macrogol (E1521), sorbitol (E420).

#### What Trebon looks like and contents of the pack

Trebon is presented as white powder with lemon flavour, packed in sachets.

Pack sizes:

10 sachets

20 sachets

30 sachets

Not all pack sizes may be marketed.

#### Marketing Authorisation Holder and Manufacturer

Uni-pharma Kleon Tsetis Pharmaceutical Laboratories S.A.

14<sup>th</sup> km National Road 1

GR-145 64 Kifissia

Greece

#### This medicine is authorised in the Member States of the EEA under the following names:

UK: Trebon 600 mg Powder for Oral Solution

Ireland: Trebon 600 mg Powder for Oral Solution

This leaflet was last revised in 03/2020.



Pharmaceutical Laboratories S.A.