

PACKAGE LEAFLET: INFORMATION FOR THE USER

Xtex 250 mg/5 ml Oral Solution

carbocisteine

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

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1. What Xtex is and what it is used for

Xtex 250 mg/5 ml Oral Solution (called Xtex in this leaflet) contains a medicine called carbocisteine. This belongs to a group of medicines called 'mucolytics'. It works by making mucus (phlegm) less sticky. This makes the mucus easier to cough up.

Xtex is used for problems with the breathing passages (respiratory tract). These problems happen when too much mucus is made or the mucus is too sticky.

2. What you need to know before you take Xtex

Do not take this medicine and tell your doctor if:

- You are allergic to carbocisteine or any of the other ingredients of this medicine (listed in Section 6)
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue
- You have an ulcer in your stomach or gut (small intestine).

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Xtex.

Warnings and Precautions

Talk to your doctor or pharmacist or nurse before taking Xtex if:

- You have a history of stomach ulcers (peptic ulceration)
- Your doctor has told you that you cannot tolerate some sugars.

Children and adolescents

Xtex should not be given to children under two years of age.

Other medicines and Xtex

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

Pregnancy, breast-feeding and fertility

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.

This medicine should not be taken during pregnancy or if you are breast-feeding or planning to breast-feed, unless your doctor has recommended the use.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

However, as in all cases you should not drive if you feel unwell or if your doctor has advised you not to drive.

Xtex contains:

- Maltitol: If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- Sunset yellow: May cause allergic reactions.
- Sodium: This medicine contains 44.5 mg of sodium per 5 ml. The maximum recommended adult daily dose of this medicine contains 400.5 mg sodium (found in table salt). This is equivalent to 20.23% of the adult recommended maximum daily dietary intake for sodium.
Talk to your pharmacist or doctor if you need Xtex on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.
- Methyl- and propyl parahydroxybenzoate: May cause allergic reactions (these may not happen straight away). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.
- Propylene glycol: This medicine contains 30 mg propylene glycol in each 5 ml.

3. How to take Xtex

Always take Xtex exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you. You should check with your doctor or pharmacist or nurse if you are not sure.

Taking this medicine

- Take this medicine by mouth
- If you feel that this medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

How much to take

Adults (including the elderly) and children 12 years and older:

- The recommended dose is 15ml three times each day (every eight hours)
- If your symptoms improve, your dose may be lowered to 10ml, three times, each day.

Children 2 years and older:

The usual daily dose is 20mg/kg in divided doses.

Children 6-12 years: Usual dose is one 5ml teaspoon (250mg) two to three times daily

Children 2-6 years: Usual dose is half a 5ml teaspoon (125mg) two to three times daily.

Always rinse the measuring cup with water after use.

Talk to a doctor if you do not feel better or if you feel worse after 5 days.

If you take more Xtex than you should

If you take more Xtex than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. If you take too much Xtex, it is likely that you will get an upset stomach (gastrointestinal disturbance).

If you forget to take Xtex

If you forget a dose, do not worry. Just wait until the next dose is due. Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

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

Stop taking Xtex and see a doctor or go to a hospital straight away if:

- You have an allergic reaction. The signs may include a rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.
- Itchy skin rash affecting the whole body.
- Blood in your vomit or black tarry stools.

Side effects are:

Gastrointestinal disorders:

Common: (may affect up to 1 in 10 people) dyspepsia, nausea, vomiting, diarrhoea.

They can occur especially at high doses. In these cases it may be useful to reduce the dose.

Rare: (may affect up to 1 in 1,000 people) gastrointestinal haemorrhage.

Nervous system disorders:

Rare: (may affect up to 1 in 1,000 people) headache, dizziness.

Skin and subcutaneous tissue disorders:

Rare: (may affect up to 1 in 1,000 people) rash, pruritus.

Very rare: (may affect up to 1 in 10,000 people) fixed erythema.

Immune system disorders:

Rare: (may affect up to 1 in 1,000 people) hypersensitivity reactions.

Very rare: (may affect up to 1 in 10,000 people) bronchospasm.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Xtex

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

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

Once opened, use within 30 days.

Do not store above 30°C.

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 to protect the environment.

6. Contents of the pack and other information

What Xtex contains

The active substance is carbocisteine. Each 5 ml contains 250 mg of carbocisteine.

The other ingredients are: liquid maltitol (E-965), sodium hydroxide (E-524), sodium citrate (E-331), propylene glycol (E-1520), hydroxyethylcellulose, citric acid monohydrate, sodium methyl parahydroxybenzoate (E-219), sodium saccharine, orange flavour, sodium propyl parahydroxybenzoate (E-217), sunset yellow FCF (E-110), purified water.

What Xtex looks like and contents of the pack

Xtex is an orange-coloured transparent solution.

Xtex is available in a 200 ml bottle and comes with a measuring cup.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Rowa Pharmaceuticals Ltd., Newtown, Bantry, Co Cork, Ireland.

Manufacturers:

Rowa Pharmaceuticals Ltd., Newtown, Bantry, Co Cork, Ireland.

Laboratorios Cinfa, S.A. Olaz-Chipi, 10. Polígono Industrial Areta. 31620 Huarte, (Navarra) Spain.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

This leaflet was prepared in April 2022