



PATIENT INFORMATION LEAFLET

EXPUTEX^{*} 250mg/5ml Oral Solution
(Carbocisteine)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What Exputex Oral Solution is and what it is used for
2. Before you take Exputex Oral Solution
3. How to take Exputex Oral Solution
4. Possible side effects
5. How to store Exputex Oral Solution
6. Further information

1. WHAT EXPUTEX ORAL SOLUTION IS AND WHAT IT IS USED FOR

Exputex Oral Solution contains the active ingredient carbocisteine, which liquefies viscous mucus and assists in the clearance of phlegm.

2. BEFORE YOU TAKE EXPUTEX ORAL SOLUTION

Do NOT take the solution if you:

- are allergic (hypersensitive) to carbocisteine or any of the other ingredients in the solution (see Section 6 and end of Section 2)
- suffer from peptic ulcers (stomach ulcers)

Take special care

Talk to your doctor before taking the solution if you have:

- a history of peptic ulcers (stomach ulcers)

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Exputex Oral Solution with food and drink.

You can take the solution with or without food.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, think you may be pregnant or are planning to become pregnant, or if you are breast-feeding.

Exputex Oral Solution should not be taken by pregnant or breast-feeding women unless advised to by a doctor.

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

Driving and using machinery

Exputex Oral Solution should not have any effect on your ability to drive or operate machinery; however if you do feel unwell, do not drive or use machinery and ask your doctor for advice.

Important information about some of the ingredients of this medicine

Exputex Oral Solution contains:

- **sodium** - 100mg sodium per 15ml dose. To be taken into consideration by patients on a controlled sodium diet
- **parahydroxybenzoates (E215, E217 and E219)** which may cause allergic reactions (possibly delayed)
- **ethanol** - contains small amounts of ethanol, less than 100mg per dose
- **sunset yellow FCF (E110)** - which may cause allergic reactions

3. HOW TO TAKE EXPUTEX ORAL SOLUTION

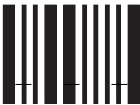
Always take the solution exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure about the dose you should take.

To be taken by mouth only.

The dose should be measured using the spoon enclosed with this pack. The spoon has a measure at each end, and lets you choose either the 2.5ml or 5ml quantity. Do not take/give more Exputex than the quantities shown below:

If symptoms persist for more than a week consult your doctor.

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Adults and children over the age of 12

Initially 15ml (three 5ml spoonfuls) three times a day, reducing to 10ml (two 5ml spoonfuls) three times daily when the mucus starts to go.

Children 6 to 12 years

Give 5ml (one 5ml spoonful) two to three times a day.

Children 2 to 5 years

Give 2.5ml (one 2.5ml spoonful) two to three times a day.

Children under 2 years

Do not give this medicine to children under 2 years except on the instruction of your doctor.

If you take more solution than you should

If you have taken/given more solution than you should, contact your doctor immediately or go to your nearest hospital accident and emergency department. Take this leaflet and/or the bottle with you.

If you forget to take a dose

If it is more than half-way to your next dose, leave out the missed dose completely and continue with the next dose at the normal time it is due. Do not take a double dose to make up for a missed dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Exputex Oral Solution can cause side effects, although not everybody gets them.

STOP taking Exputex Oral Solution and **seek medical help immediately** if you have any of the following which may be signs of an **allergic reaction**:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps.

The following side effects may occur:

- nausea, headache, stomach upset and skin rash

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE EXPUTEX ORAL SOLUTION

Keep out of the reach and sight of children.

Do not store above 25°C.

Once opened use within one month.

Store bottle in original carton in order to protect from light

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

Do not use Exputex if you notice that the colour or smell is different from normal.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

Exputex Oral Solution contains:

- the **active ingredient**: carbocisteine. Each 5ml spoonful of Exputex contains 250mg of carbocisteine
- **other ingredients**: levomenthol, ethanol (alcohol), saccharin sodium, sunset yellow FCF (E110), sodium ethyl parahydroxybenzoate (E215), sodium propyl parahydroxybenzoate (E217), sodium methyl parahydroxybenzoate (E219), citric acid monohydrate, sodium hydroxide, carmellose sodium, glycerol, orange flavour, condensed milk flavour and purified water (*see also end of Section 2 for further information on some of the ingredients*).

What Exputex Oral Solution looks like and contents of the pack

Exputex Oral Solution is a viscous, orange coloured liquid with an odour of condensed milk and orange.

The solution is provided in amber glass bottles of 100ml, 200ml, 300ml.

A spoon with a 2.5ml and 5ml measure is supplied with all packs of this product.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Phoenix Labs, Suite 12, Bunkilla Plaza, Bracetown Business Park, Clonee, Co. Meath, Ireland.

Manufacturer responsible for batch release

Laboratórios Basi - Indústria Farmacêutica, S.A., Parque Industrial Manuel Lourenço Ferreira, Lotes 15 e 16, 3450-232 Mortágua - Portugal

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