

Package leaflet: Information for the user

Expudyne 250mg/5ml oral solution

Carbocisteine

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have 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.
- 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.

What is in this leaflet

1. What Expudyne oral solution is and what it is used for
2. What you need to know before you take Expudyne oral solution
3. How to take Expudyne oral solution
4. Possible side effects
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1. What Expudyne oral solution is and what it is used for

Expudyne 250mg/5ml oral solution, (called Expudyne oral solution in this leaflet) contains the active substance carbocisteine. This belongs to a group of medicines called “mucolytics”. Mucolytics work by making mucus less sticky and easier to cough up. Expudyne oral solution is used to treat problems of the breathing passages (respiratory tract) in adults and children 2 years and above. These problems happen when too much mucus is made or the mucus is too sticky. You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

2. What you need to know before you take Expudyne oral solution

Do not take Expudyne oral solution:

- If you are allergic to carbocisteine or any of the other ingredients of this medicine (listed in Section 6).
- If you have an ulcer in your stomach or gut (small intestine).

Warnings and precautions

Talk to your doctor or pharmacist before you start taking this medicine if:

- You have an ulcer in your stomach or gut.
- You are taking other medicines known to cause bleeding in the stomach.
- You are elderly.

Children and adolescents

Do not give Expudyne oral solution to children younger than 2 years of age.

Other medicines and Expudyne oral solution

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

this includes other cough medicines.

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 before taking this medicine.

Pregnancy

Expudyne oral solution is not recommended during pregnancy.

Breastfeeding

It is unknown whether carbocisteine/metabolites are excreted in human milk. Expudyne oral solution should not be used during breast-feeding.

Fertility

There is no known data available on the effects of carbocisteine on fertility.

Driving and using machines

No effects were seen on the ability to drive and use machines.

Important information about some of the ingredients of Expudyne oral solution.

This medicine contains:

- **Sodium:** 95.6mg (4.2mmol) per 15ml. This is equivalent to 4.8% of the recommended maximum daily dietary intake of sodium for an adult.
- **Sodium methyl parahydroxybenzoate:** it may cause allergic reactions (possible delayed).
- **Propylene glycol:** this medicine contains 4mg propylene glycol per 5ml, which is equivalent to 0.8mg/ml.
- **Glucose:** this medicine contains 0.9mg glucose per 5ml. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product

3. How to take Expudyne oral solution

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure. Talk to a doctor if you do not feel better or if you feel worse after 5 days.

- For oral use only. Take this medicine by mouth.
- To give the correct dose, use the 5ml measuring cup with graduations 1.25 – 2.5 – 3.75 – 5ml
- Shake the bottle before use.
- Wash the cup after use.

Adults including the elderly and adolescents >12 years:

The initial dose is 15ml three times a day; if symptoms improve, your dose may be lowered to 10ml, three times a day. The maximum daily dose is 45ml

Children:

Children 6 – 12 years: The usual dose is 5 ml two to three times daily

Children 2 – 5 years: The usual dose is 2.5 ml two to three times daily

Children under 2 years:

Not recommended.

If you take more Expudyne oral solution than you should

- If you take more Expudyne oral solution than the label states or if you think a child has accidentally swallowed any, epigastralgia, nausea and vomiting may occur. You should stop taking Expudyne and contact the nearest hospital casualty department or a doctor for advice **immediately**.

- Take this leaflet with you.

If you forget to take Expudyne oral solution

If you forget a dose, take the next dose as soon as you remember.

Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

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

Stop taking Expudyne oral solution immediately and see a doctor or go to hospital straightaway if:

- You have an allergic reaction. Signs of an allergic reaction include: a rash, problems swallowing or breathing, swelling of the lips, face, throat or tongue.
- You have blistering or bleeding of the skin, including around your lips, eyes, mouth, nose and genitals. You may have flu-like symptoms and fever. This may be something called “Stevens-Johnson syndrome”.
- You have blood in your vomit or black tarry stools.

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

- Feeling sick (nausea) or being sick (vomiting)
- Diarrhoea
- Stomach pain
- Headache
- 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, Website: www.hpra.ie.

5. How to store Expudyne oral solution

Do not store above 25°C.

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 carton after “EXP”. The expiry date refers to the last day of that month.

Once the bottle is opened use within one month.

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

Wash and dry the measuring cup after use.

6. Contents of the pack and other information

What Expudyne oral solution contains

- each 5ml of oral solution contains 250mg of the active substance is carbocisteine.
- The other ingredients are: Glycerol, Sodium Saccharin, Hydroxyethylcellulose, Xanthan gum, Caramel powder, Raspberry flavour (contains propylene glycol E1520), Sodium Methyl Parahydroxybenzate (E219), Sodium hydroxide and Purified water.

What Expudyne oral solution looks like and contents of the pack

Expudyne oral solution, is clear, amber-coloured liquid, with raspberry odour.
Expudyne oral solution, is packed in 300ml amber type III glass bottle with child resistant screw cap, which seal is made of HDPE and internal seal is made of PE. It comes with a measuring cup with graduations 1.25 – 2.5 – 3.75 – 5ml.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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