

PACKAGE LEAFLET: INFORMATION FOR THE USER

FLUDITEC CHILDREN 2%, syrup

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 indicated by your doctor or pharmacist.

- 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 8 to 10 days.

Do not leave this medicine within the reach of children.

What is in this leaflet

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

1. WHAT FLUDITEC CHILDREN 2%, syrup IS AND WHAT IT IS USED FOR

Pharmacotherapeutic class : MUCOLYTIC - ATC code: R05CB03

This medicine is indicated in children over 2 years.

This medicine thins bronchial secretions which makes it easier to cough them up.

This medicine is recommended in case of bronchial obstruction, particularly during acute episodes of bronchitis.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FLUDITEC CHILDREN 2%, syrup

Do not take FLUDITEC CHILDREN 2 %, syrup:

- if you are allergic (hypersensitive) to carbocisteine or any of the other ingredients of this medicine listed in section 6;
- in infants (under 2 years) because of the risk of worsening of bronchial obstruction.

If you have any doubts, ask your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking FLUDITEC CHILDREN 2%, syrup.

Special warnings

You should seek medical advice:

- if you have a productive cough with purulent sputum or fever;
- if you have a chronic (long-term) disease of the bronchi and lungs.

Treatment should not be continued in the event of worsening of the symptoms. In such cases, consult your doctor for reassessment of your treatment.

Precautions for use

This medicine should be used with caution in case of a stomach or duodenal ulcer.

If you have any doubts, ask your doctor or pharmacist.

Children and adolescents

FOR CHILDREN ONLY(over 2 years).

Never use FLUDITEC CHILDREN 2%, syrup in infants (under 2 years) because of the risk of worsening of bronchial obstruction (see Never take FLUDITEC CHILDREN 2%, syrup).

Other medicines and FLUDITEC CHILDREN 2%, syrup

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

It is recommended not to take antitussive medication (to stop coughing) or medicines for drying bronchial secretions while you are taking this medicine.

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.

This medicine should only be used during pregnancy on the advice of your doctor.

It is possible to breastfeed while taking this medicine.

Ask your doctor or pharmacist before taking any medicine.

FLUDITEC CHILDREN 2%, syrup contains sucrose, methyl parahydroxybenzoate (E 218), sodium and sunset yellow (E110).

This medicine contains 3.5 g of sucrose (sugar) per 5 ml dose of syrup to be taken into account in the daily ration in case of a low sugar diet or diabetes. If your doctor has told you are intolerant to some sugars, contact him/her before taking this medicine.

Use of this medicine is not recommended in patients with fructose intolerance, glucose-galactose malabsorption syndrome or sucrase/isomaltase insufficiency (rare hereditary diseases).

Treatment should not be continued in case of worsening of symptoms. In such cases, contact your doctor for the reassessment of your treatment.

This medicine contains methyl parahydroxybenzoate (E218) and an azo colouring agent (E110); they may cause allergic reactions.

This medicine contains sodium. This medicine contains 0.57 mmol (or 13 mg) of sodium per 5 ml dose of syrup. This should be taken into account in patients on a controlled sodium diet.

3. HOW TO TAKE FLUDITEC CHILDREN 2%, syrup

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

Dosage

1 measuring cup filled to the 5 ml mark contains 100 mg of carbocisteine.

Children from 2 to 5 years: 200 mg per day divided into 2 doses, or a measuring cup filled to the 5 ml mark 2 times daily.

Children over 5 years: 300 mg per day divided into 3 doses, or a measuring cup filled to the 5 ml mark 3 times daily.

Rinse the measuring cup after use. Recap the bottle after use.

The duration of treatment should be brief. Never take the treatment for more than 8 to 10 days without medical advice.

Oral route.

If you take more FLUDITEC CHILDREN 2%, syrup than you should

Immediately contact your doctor or pharmacist.

If you forget to take FLUDITEC CHILDREN 2%, syrup

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.

4. POSSIBLE SIDE EFFECTS

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

Risk of worsening of bronchial obstruction in infants.

Allergic skin reactions such as itching, rash, hives and facial swelling.

A few cases of fixed drug eruption (brown patches on the skin) have been reported.

Possibility of gastrointestinal disorders: nausea, diarrhoea, vomiting, stomach pain.

In such cases, it is advised to reduce the dose.

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 Competent Authority for pharmacovigilance in your country.

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

5. HOW TO STORE FLUDITEC CHILDREN 2%, syrup

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 box and bottle. The expiry date refers to the last day of that month.

Do not store above 25°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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What FLUDITEC CHILDREN 2%, syrup contains

- The active substance is:
Carbocisteine 2.00 g
For 100 ml syrup.
- The other ingredients are:
Glycerol, methyl parahydroxybenzoate (E218), sucrose, sunset yellow (E110), sodium hydroxide, banana flavour, purified water.

What FLUDITEC CHILDREN 2%, syrup looks like and contents of the pack

This medicine is available as a syrup in a 125 ml bottle with a measuring cup.

Marketing authorisation holder

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22 AVENUE ARISTIDE BRIAND
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Manufacturer

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