

PACKAGE LEAFLET: INFORMATION FOR THE USER

FLUDITEC 5 % ADULTS EXPECTORANT, 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 5 days.

Do not leave this medicine within the reach of children.

What is in this leaflet

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

1. WHAT FLUDITEC 5% ADULTS EXPECTORANT, syrup IS AND WHAT IT IS USED FOR

Pharmacotherapeutic class : MUCOLYTIC - ATC code: R05CB03.

This medicine is indicated in adults (over 15 years) in case of recent respiratory tract disorders with difficulty expectorating (difficulty spitting up bronchial secretions).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FLUDITEC 5% ADULTS EXPECTORANT, syrup

Do not take FLUDITEC 5% ADULTS EXPECTORANT, SYRUP:

- if you are allergic (hypersensitive) to carbocisteine or any of the other ingredients of this medicine listed in section 6.

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

Warnings and precautions

Talk to your doctor or pharmacist before taking FLUDITEC 5% ADULTS EXPECTORANT, 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 for advice.

Children and adolescents

For adults and adolescents over 15 years of age.

Other medicines and FLUDITEC 5% ADULTS EXPECTORANT, syrup

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

This medicine should always be accompanied by voluntary efforts to cough up sputum.

Do not take cough medicine (to stop coughing) or medicine to dry out the bronchial secretions during treatment with carbocisteine.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, 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 5% ADULTS EXPECTORANT, syrup contains sucrose, methyl parahydroxybenzoate (E 218), sodium and sunset yellow (E110).

This medicine contains 5.25 g of sucrose (sugar) per 15 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 4.35 mmol (or 100 mg) of sodium per 15 ml dose of syrup. This should be taken into account in patients on a controlled sodium diet.

3. HOW TO TAKE FLUDITEC 5% ADULTS EXPECTORANT, syrup

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.

Dose

The recommended dose is 1 measuring cup morning, noon and night, outside meal times, without exceeding 3 measuring cups per day.

1 measuring cup = 15 ml = 750 mg of carbocisteine.

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 5 days without medical advice.

Oral route.

If you take more FLUDITEC ADULTS EXPECTORANT 5%, syrup than you should

Immediately contact your doctor or pharmacist.

If you forget to take FLUDITEC ADULTS EXPECTORANT 5%, 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 everybody gets them.

Possibility of gastrointestinal disorders: stomach pain, nausea, diarrhoea. In such cases, it is advised to reduce the dose.

Possibility of allergic skin reactions such as hives, itching, rash, and facial swelling (angioedema).

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

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 5% ADULTS EXPECTORANT, 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 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 5 % ADULTES EXPECTORANT, syrup contains

- The active substance is:

Carbocisteine 5.00 g

For 100 ml syrup.

- The other ingredients are: glycerol, methyl parahydroxybenzoate (E218), sucrose, patent blue V, sunset yellow (E110), sodium hydroxide, caramel flavour, purified water.

What FLUDITEC 5% ADULTS EXPECTORANT, SYRUP looks like and contents of the pack

This medicine is available as a syrup in a 125 ml or 300 ml bottle with a measuring cup.

Marketing authorisation holder

LABORATOIRE INNOTECH INTERNATIONAL
22 AVENUE ARISTIDE BRIAND
94110 ARCUEIL - FRANCE

Manufacturer

INNOTHERA CHOUZY
RUE RENE CHANTEREAU – CHOUZY-SUR-CISSE
41150- VALLOIRE-SUR-CISSE - FRANCE

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