1. NAME OF THE MEDICINAL PRODUCT

FLUDITEC CHILDREN 2% syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Carbocisteine.....2.00 g
For 100 ml of syrup.

Excipients with known effect: sucrose, sodium, methyl parahydroxybenzoate (E218), sunset yellow FCF (E110).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of bronchial secretion disorders in children from 2 years of age, particularly during acute bronchiopathy: acute bronchitis and acute episode of chronic bronchopneumopathy.

4.2 Posology and method of administration

FOR CHILDREN (FROM 2 YEARS OF AGE) ONLY.

Posology

A measuring cup filled up to the 5 ml graduation contains 100 mg of carbocisteine.

Children from 2 to 5 years of age: 200 mg per day, 2 times a day, i.e. 1 measuring cup filled up to the 5 ml graduation twice a day.
Children over 5 years of age: 300 mg per day, 3 times a day, i.e. 1 measuring cup filled up to the 5 ml graduation 3 times a day.

Treatment duration should not exceed 8 to 10 days without medical advice.

Method of administration

Oral route.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 (especially methyl parahydroxybenzoate and other parahydroxybenzoate salts).
- Infants (less than 2 years of age) (see section 4.4).

4.4 Special warnings and precautions for use

Special warnings

In case of productive cough with purulent sputum, in case of fever or chronic disease of the bronchial tree or lungs, the clinical situation should be reassessed.

Productive cough, which is an essential part of the bronchopulmonary defence mechanism, should not be suppressed.
It is irrational to combine bronchial mucous modifiers with anti-cough medicines and/or substances that dry out secretions (atropines).

Mucolytics can induce bronchial congestion in infants. The capacity for draining bronchial mucus is limited in infants due to the physiological characteristics of their respiratory tree. They should not be used in infants (see sections 4.3 and 4.8).

Treatment should be reassessed in case of persistence or worsening of the symptoms or disease.

This medicinal product contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Precautions for use

If gastrointestinal disorders (gastric pain, nausea, vomiting, diarrhoea) occur, the dose should be reduced.

Caution is recommended in patients with a history of gastroduodenal ulcers, or those taking concomitant medications known to cause gastrointestinal bleeding. If gastrointestinal bleeding occurs, patients should discontinue the treatment.

This medicinal product contains 3.5 g of sucrose per 5 ml dose. This should be taken into account in patients with diabetes mellitus.

This medicine contains less than 1 mmol sodium (23 mg) per 5 ml dose, that is to say essentially ‘sodium-free’.

This medicinal product contains methyl parahydroxybenzoate (E218) which may cause allergic reactions (possibly delayed).

This medicinal product contains an azo agent (E110) which may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable.

4.6 Fertility, pregnancy and lactation

Pregnancy

Animal studies have not shown any teratogenic effects. In the absence of teratogenic effects in animals, malformations are not expected in humans. To date, substances responsible for malformations in humans were found to be teratogenic in animals during properly carried out studies in two different species.
From a clinical point of view, no malformations or foetotoxicity have occurred. However, the follow-up of pregnancies in which there is exposition to carbocisteine is not sufficient to exclude all risks.
Consequently, carbocisteine should not be used during pregnancy unless necessary.

Breastfeeding

There is no data on the passage of carbocisteine into breast milk.
However, given its low toxicity, the potential risks for children seem negligible in case of treatment with this medicine. Consequently, breastfeeding is possible.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

- Risk of bronchial congestion in infants (see sections 4.3 and 4.4).
- Allergic skin reactions such as pruritus, erythematous rash, urticaria and angioedema.
- A few cases of fixed drug eruption have been reported.
- Gastrointestinal disorders (stomach pain, nausea, vomiting, diarrhoea) (see section 4.4).
- Gastrointestinal bleeding (see section 4.4).
- Isolated cases of bullous dermatitis such as Steven-Johnson syndrome and erythema multiforme have been reported.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system: *Agence nationale de sécurité du médicament et des produits de santé* (ANSM - French Health Products Safety Agency) and Regional Pharmacovigilance Centers - Website: www.signalement-sante.gouv.fr.

4.9 Overdose

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: MUCOLYTIC, ATC Code: R05CB03 (R: RESPIRATORY SYSTEM).

Carbocisteine is a mucolytic agent that modifies mucous secretions. It acts during the mucous gel phase, most likely by breaking up the disulfide bonds in glycoproteins, thereby favouring expectoration.

5.2 Pharmacokinetic properties

After oral administration, carbocisteine is rapidly absorbed; peak plasma concentrations are reached in two hours.
Its bioavailability is low, less than 10% of the administered dose, most likely due to intraluminal metabolism with a significant hepatic first pass effect.

Elimination

Its elimination half-life is about 2 hours.
Carbocisteine and its metabolites are excreted primarily through the kidneys.

5.3 Preclinical safety data

Non-clinical data are quite limited. Unconventional studies of reproductive and developmental toxicity in rats have not revealed any particular risk to humans.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose, glycerol, banana flavour, methyl parahydroxybenzoate (E218), sunset yellow FCF (E110), sodium hydroxide, purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

125 ml bottle (clear type III glass) with a white Vistop cap (polyethylene) and a 20 ml measuring cup (polypropylene).

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

LABORATOIRE INNOTECH INTERNATIONAL
22 AVENUE ARISTIDE BRIAND
94110 ARCUEIL

8. MARKETING AUTHORISATION NUMBER(S)

- 34009 338 346 7 8: 125 ml bottle (clear type III glass) + 20 ml measuring cup.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21 December 1994
Date of latest renewal: 21 December 2009

10. DATE OF REVISION OF THE TEXT

29 August 2019

11. DOSIMETRY

Not applicable.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product not subject to medical prescription.