ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

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 (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, especially during acute disorders of the bronchial tree: acute bronchitis and acute episodes of chronic bronchopneumopathy.

4.2. Posology and method of administration

Posology

A 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, i.e. 1 measuring cup filled to the 5 ml mark 2 times a day.

Children over 5 years: 300 mg per day divided into 3 doses, i.e. 1 measuring cup filled to the 5 ml mark 3 times a day.

Method of administration

Oral route.

Duration of treatment

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

4.3. Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Infants (less than 2 years) (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 a basic part of the bronchopulmonary defence mechanism, should not be suppressed.

It is irrational to combine bronchial fluidifying agents with antitussives and/or medications for drying respiratory secretions (atropine).

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.

Special precautions for use

Caution is recommended in patients with gastroduodenal ulcers.

This medicinal product contains sucrose. Its use is not recommended in patients with fructose intolerance, or glucose-galactose malabsorption syndrome or sucrase/isomaltase insufficiency.

This medicinal product contains 3.5 g of sucrose per 5 ml dose which should be taken into account in the daily ration in patients on a low-sugar diet or with diabetes.

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

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. Interactions with other medicinal products and other forms of interaction

Not applicable.

4.6. Fertility, pregnancy and lactation

Pregnancy

Animal studies have not revealed any teratogenic effects. In the absence of teratogenic effects in animals, a malformative effect in humans is not expected. To date, the substances responsible for malformations in humans have all proved to be teratogenic in animals during well-conducted studies in two species.

No particular malformative or foetotoxic effects have been observed to date with clinical use. However, the monitoring of pregnancies exposed to carbocisteine is insufficient to exclude any risk.

Consequently, the use of carbocisteine should only be considered during pregnancy if absolutely necessary.

Breast-feeding

There is no data on the passage of carbocisteine into breast milk. However, given its low toxicity, the potential risks to the child appear negligible in case of treatment with this medicinal product. Therefore, 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 skin eruptions, urticaria and angioedema.

A few cases of fixed drug eruption have been reported.

Possibility of gastrointestinal intolerance (gastric pain, nausea, diarrhoea). In such cases, it is advised to reduce the dose.

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 ratio of the medicinal product. Healthcare professionals are asked to report any suspected adverse effects via the national reporting system of your country.

4.9. Overdose

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: MUCOLYTIC, ATC Code: R05CB03.

Carbocisteine is a mucolytic mucus fluidifying agent. It exerts its action on the mucus gel phase, presumably by disrupting the disulphide bonds of glycoproteins, thereby promoting expectoration.

5.2. Pharmacokinetic properties

After oral administration, carbocisteine is rapidly absorbed; its peak plasma concentration is reached in two hours.

Its bioavailability is low, less than 10% of the administered dose, probably due to intraluminal metabolism and significant first-pass metabolism.

Its elimination half-life is approximately two hours.

It and its metabolites are eliminated essentially through the kidneys.

5.3. Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sucrose, glycerol, banana flavour, methyl parahydroxybenzoate (E218), sunset yellow (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

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

6.6. Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

LABORATOIRE INNOTECH INTERNATIONAL
22 AVENUE ARISTIDE BRIAND
94110 ARCUEIL
FRANCE

8. MARKETING AUTORISATION NUMBER(S)

- 34009 338 346 7 8: 125 ml in a bottle (clear Type III glass) + a 20-ml dosing cup.

9. DATE OF FIRST AUTORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: December 21, 1994

Date of last renewal of the authorisation: December 21, 2009

10. DATE OF REVISION OF THE TEXT

January 10, 2018

11. DOSIMETRY

Not applicable.

12. INSTRUCTIONS FOR THE PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

CONDITIONS OF PRESCRIPTION AND DELIVERY

Medicinal product not subject to medical prescription.