ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

FLUDITEC 5% ADULTS EXPECTORANT, syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Carbocisteine..... 5.00 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

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

4.2. Posology and method of administration

Posology

A measuring cup filled to the 15 ml mark contains 750 mg of carbocisteine.

Take 1 dose of 15 ml, 3 times a day, preferably between meals.

Method of administration

Oral route.

Duration of treatment

Treatment duration should be brief and should not exceed 5 days.

4.3. Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4. Special warnings and precautions for use

Special warnings

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).

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 5.25 g of sucrose per 15 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 4.4 mmol (or 100 mg) of sodium per 15 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

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

Possibility of allergic skin reactions such as urticaria, angioedema, pruritus, erythematous skin eruptions.

A few cases of fixed drug eruption 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 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, methyl parahydroxybenzoate (E218), Patent Blue V, sunset yellow (E110), caramel flavour, sodium hydroxide, purified water.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

2 years.

6.4. Special precautions for storage

Not applicable.

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).
300ml bottle (clear Type III glass) with a white Vistop cap (polyethylene) and a 20ml dosing cup (polypropylene).

Not all pack sizes may be marketed.

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 NUMBERS

- 34009 353 813 1 6: 125 ml in a bottle (clear Type III glass) + a 20-ml dosing cup.
- 34009 353 814 8 4: 300 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: 22 December 1994

Date of last renewal of the authorisation: 21 December 2009

10. DATE OF REVISION OF THE TEXT

10 January 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.