SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

FLUDITEC 750 mg/10 ml ADULTS SUGAR FREE oral solution in sachets sweetened with sodium saccharin, sorbitol and maltitol liquid

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Carbocisteine ..... 750 mg
For a sachet of 10 ml.

Excipients with known effect: sodium methyl parahydroxybenzoate (E219), sorbitol liquid (non-crystallising), maltitol liquid, sodium, ethanol.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution in sachet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

FOR ADULTS AND ADOLESCENTS OVER 15 YEARS OF AGE ONLY.

This medicine is appropriate for patients following a low sugar or low-calorie diet.

Posology

One sachet of 10 ml contains 750 mg of carbocisteine.
The recommended dose is 750 mg per dose 3 times a day, i.e. 1 sachet 3 times a day.
Treatment duration should be brief and should not exceed 5 days.

Method of administration

Oral route.

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 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).

This medicine contains small amounts of ethanol (alcohol), less than 100 mg per sachet.

Precautions for use

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

Caution is recommended in the elderly, 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 97.5 mg sodium per dose, equivalent to 4.9% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

This medicinal product contains methyl parahydroxybenzoate (E219) which may cause allergic reactions (possibly delayed).

This medicinal product contains maltitol liquid and 910 mg sorbitol per dose. Patients with hereditary fructose intolerance (HFI) must not be given this medicine unless strictly necessary.

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

- 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

Sodium saccharin, sodium methyl parahydroxybenzoate (E219), hydroxyethyl cellulose, caramel/vanilla flavour*, sorbitol liquid (non-crystallising), maltitol liquid, sodium hydroxide, purified water.

*Composition of the caramel/vanilla flavour: acetyl-methyl-carbinol, benzaldehyde, natural caramel flavour, cocoa distillate, coffee extract, diacetyl, ethanol, ethyl vanillin, fenugreek extract, glucose syrup, glycerol, maltol, meadowsweet extract, mintlactone, gamma-nonalactone, piperonal (heliotropin), propylene glycol, vanillin, 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

10 ml in sachet (PET/Aluminium/PE).
Box of 10, 12 or 15.

Not all pack sizes may be marketed.

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 219 296 6 9: 10 ml in sachet (PET/Aluminium/PE); box of 10
- 34009 219 297 2 0: 10 ml in sachet (PET/ Aluminium/PE); box of 12
- 34009 219 298 9 8: 10 ml in sachet (PET/ Aluminium/PE); box of 15

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20 January 2012
Date of latest renewal: 20 January 2017

10. DATE OF REVISION OF THE TEXT

07 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.