SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients: sodium methyl parahydroxybenzoate (E 219), sorbitol liquid (non cristallising), 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 medicinal product is indicated in adults and children 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

FOR ADULTS AND CHILDREN OVER 15 YEARS

Oral route.

1 single dose sachet of 10 ml contains 750 mg of carbocisteine.

The usual posology is 750 mg per dose, in 3 doses per day, i.e. 1 sachet 3 times daily.

This medicine can be used by patients following an hypoglucidic or low-calorie diet.

Duration of treatment:

It has to be short and should not exceed 5 days.

4.3. Contraindications

Hypersensitivity to the active substance or to any of the excipients.

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).

This medicine contains methyl parahydroxybenzoate (E219) and it may cause allergic reactions (possibly delayed).

This medicine contains maltitol and sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

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

Precautions for use

Caution is recommended in patients with gastroduodenal ulcers.

This medicine contains sodium. This medicine contains 97,5 mg (4.24 mmol) per dose. This has to be taken into account for the patients following a strict low sodium diet.

4.5. Interactions with other medicinal products and other forms of interaction

Not applicable.

4.6. 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

Possible digestive intolerance (gastralgia, nausea, diarrhoea). If this occurs, it is recommended to reduce the dose.

Possible cutaneous allergic reactions such as pruritus, urticarial, erythematous rash, face oedema.

4.9. Overdose

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic class: MUCOLYTIC, ATC code: R05CB03

(R: respiratory system)

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

Saccharine sodium, sodium methyl parahydroxybenzoate (E 219), hydroxyethyl cellulose, caramel/vanilla flavour*, sorbitol liquid (non cristallising), maltitol liquid, sodium hydroxyde, purified water.

* Composition of the caramel/vanilla flavour : acetyl methyl carbinol, benzaldehyde, caramel flavour natural, cocoa distillate, coffee extract, diacetyl, ethanol, ethyl vanillin, foenugreek extract, glucose syrup, glycerol, maltol, meadow-sweet extract, mint lactone, 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 et contenu de l'emballage extérieur

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

6.6. Special precautions for disposal and handling

No special requirements.

7. MARKETING AUTORISATION HOLDER

LABORATOIRE INNOTECH INTERNATIONAL
22 AVENUE ARISTIDE BRIAND
94110 ARCUEIL
FRANCE

8. MARKETING AUTORISATION NUMBERS

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

9. DATE OF FIRST AUTORISATION/RENEWAL OF AUTHORISATION

Date of first autorisation: January 08, 2024.

10. DATE OF REVISION OF THE TEXT

January 08, 2024.

11. DOSIMETRY

Not applicable.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

CONDITIONS OF PRESCRIPTION AND DELIVERY

Medicinal product not subject to medical prescription.