SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

MUCOPLEXIL 5% ADULTS WITHOUT SUGAR, sodium saccharin sweetened syrup.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Carbocisteine.....5 g

For 100 mL of syrup.

One 15 mL measuring cup contains 750 mg carbocisteine and 90 mg sodium.

One 15 mL measuring cup = 0,020 kcal.

Excipients with known effect: sodium methyl p-hydroxybenzoate (E 219), sodium.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

This medicine is indicated in adults and adolescents over 15 years of age in the event of a recent respiratory disease with expectoration difficulties (difficulty in clearing bronchial secretions via sputum).

4.2. Posology and method of administration

Posology

FOR ADULTS AND ADOLESCENTS OVER 15 YEARS OF AGE ONLY.

This proprietary medicinal product is suitable for patients on a low-carbohydrate or low-calorie diet.

One 15 mL measuring cup = 750 mg carbocisteine.
Take one 15 mL measuring cup 3 times a day, preferably without meals.

Duration of treatment

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

Method of administration

Oral use.

4.3. Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- In case of active gastroduodenal ulcer.

4.4. Special warnings and precautions for use

Special warnings

Productive cough, which is a fundamental bronchopulmonary defense mechanism, should not be suppressed.

Combining drugs that affect bronchial secretions with cough suppressants and/or substances that dry up secretions (atropine-like agents) is irrational.

Precautions for use
Caution is recommended in the elderly, in those with a history of gastroduodenal ulcers, in the event of concomitant administration of medications known to cause gastrointestinal bleeding. If gastrointestinal bleeding occurs, patients should discontinue treatment.

This medicine contains sodium. This medicine contains 90 mg sodium per 15 mL measuring cup. This should be taken into account in patients following a strict low-sodium diet.

This medicine contains sodium methyl p-hydroxybenzoate (E 219) and may cause allergic reactions (possibly delayed).

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

Not applicable.

4.6. Fertility, pregnancy and lactation

Pregnancy

Animal studies do not indicate any teratogenic effect.

There are no available data on carbocisteine use in pregnant women.

The use of carbocisteine in pregnant women is therefore not recommended.

Breast-feeding

There are no data available on the excretion of carbocisteine in human milk.

The use of carbocisteine in breast-feeding women is therefore not recommended.

4.7. Effects on ability to drive and use machines

Not applicable.

4.8. Undesirable effects

- Gastrointestinal disorders (gastric pain, nausea, vomiting, diarrhea). If these occur, the dose should be reduced.
- Gastrointestinal bleeding. Treatment should be discontinued.
- Allergic skin eruption and anaphylactic reactions such as urticaria, angioedema, pruritus and erythematous rash.

Some cases of fixed drug eruption have been reported.
Isolated cases of dermatitis bullous, such as Stevens-Johnson syndrome and erythema multiforme.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization 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) and *réseau des Centres Régionaux de Pharmacovigilance* [Network of Regional Pharmacovigilance Centers] - Website: www.signalement-sante.gouv.fr

4.9. Overdose

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: MUCOLYTICS, ATC Code: R05CB03.

(R: Respiratory system).

Carbocisteine has a mucolytic effect on bronchial secretions. It acts on the gel phase of mucus production, most likely by breaking down the disulfide bonds in the glycoproteins, thus promoting expectoration.

5.2. Pharmacokinetic properties

Absorption

Orally administered carbocisteine is rapidly absorbed; peak plasma concentrations are reached in two hours.

Biotransformation

Bioavailability is low (less than 10% of the administered dose), probably as a result of intraluminal metabolism and a marked liver first-pass effect.

Elimination

Elimination half-life is approximately 2 hours. Carbocisteine and its metabolites are eliminated primarily in the urine.

5.3. Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Glycerol, hydroxyethylcellulose, sodium saccharin, sodium methyl p-hydroxybenzoate (E 219), caramel powder (E 150), aromatic elixir*, sodium hydroxide, purified water.

*Composition of aromatic elixir: Vanillin, esters of ethyl, propyl, butyl, isoamyl, allylic alcohol, esters of acetic, propionic, butyric, isovaleric, caprylic, capric, lauric acid, propylene glycol, glycerol.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

2 years before opening.

15 days after opening.

6.4. Special precautions for storage

Do not store above 25°C.

6.5. Nature and contents of container

125 mL or 200 mL or 250 mL in a (colorless glass, type III) bottle, with an aluminum stopper and a (polypropylene) measuring cup.

6.6. Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORIZATION HOLDER

SANOFI-AVENTIS FRANCE
82 AVENUE RASPAIL
94250 GENTILLY
FRANCE

[Tel., fax, email: to be completed later by the MA holder]

8. MARKETING AUTHORIZATION NUMBER(S)

05688/07585/REN/2020

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

Feb 22, 2021

10. DATE OF REVISION OF THE TEXT

[to be completed later by the MA holder]

11. DOSIMETRY

Not applicable.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product not subject to medical prescription.