SUMMARY OF PRODUCT CHARACTERISTICS

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Rhinathiol Expectorant Carbocisteine 2% Enfants syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Carbocisteine.....2 g

For 100 ml of syrup

One 5 ml measuring spoon contains 100 mg of carbocisteine.

Excipient(s) with known effect: 3.5 g of sucrose and 13 mg of sodium per 5 ml measuring spoon. Methyl parahydroxybenzoate (E218). Ponceau 4R (E124).

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, particularly in acute bronchial disease: acute bronchitis and acute episodes of chronic obstructive pulmonary disease.

4.2. Posology and method of administration

One 5 ml measuring spoon contains 100 mg of carbocisteine.

Children aged 2 to 5 years: 200 mg per day, divided into 2 doses, i.e. one 5 ml measuring spoon twice daily.

Children aged over 5 years: 300 mg per day, divided into 3 doses, i.e. one 5 ml measuring spoon three times daily.

Duration of treatment

Treatment duration should be short and not exceed 8 to 10 days.

4.3. Contraindications

- History of hypersensitivity to any of the ingredients (particularly methyl parahydroxybenzoate and other parahydroxybenzoate salts).
- Infants (under two years of age) (see section 4.4).

4.4. Special warnings and precautions for use

Special warnings

In patients with thick and purulent sputum, fever or chronic bronchial and pulmonary disease, the clinical situation should be reassessed.

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.

Mucolytic agents may induce severe bronchial congestion in infants. Infant bronchial mucus drainage capacities are limited due to the physiological characteristics of their bronchial tree. Mucolytics should therefore not be used in infants (see sections 4.3 and 4.8).

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Treatment should be re-evaluated if the symptoms or disease persist or worsen.

This medicinal product contains sucrose. It is therefore not recommended in patients with fructose intolerance, glucose and galactose malabsorption syndrome or sucrase-isomaltase deficiency.

Precautions for use

Caution is recommended in patients with gastroduodenal ulcers.

This medicinal product contains 3.5 g of sucrose per measuring spoon; this should be taken into account in patients on a low-sugar diet or with diabetes mellitus.

This medicinal product contains sodium. This medicinal product contains 13 mg of sodium per 5 ml measuring spoon of syrup. This should be taken into consideration in patients on a strict low-sodium diet.

This medicinal product contains methyl parahydroxybenzoate (E218) and an azo dye (Ponceau 4R (E124)) 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. As no teratogenic effects have been observed in animals, no malformative effects are expected in humans. To date, substances causing malformations in humans have been shown to be teratogenic in animals during well-conducted studies in two species.

No particular teratogenic or fetotoxic effects have been reported to date in clinical practice.

Nevertheless, there is insufficient data on pregnancies exposed to carbocisteine to completely rule out any risk. Therefore, use of carbocisteine should only be considered during pregnancy if necessary.

Breastfeeding

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

However, in view of its low toxicity, potential risks to infants appear negligible during treatment with this medicinal product. Breastfeeding is therefore possible.

4.7. Effects on ability to drive and use machines

Not applicable.

4.8. Undesirable effects

- Risk of severe bronchial congestion in infants (see sections 4.3 and 4.4).
- Allergic skin reactions such as pruritus, erythematous eruption, urticaria and angioedema.
- Some cases of fixed drug eruption have been reported.
- Gastrointestinal disorders (gastric pain, nausea, vomiting, and diarrhea). If these occur, the dose should be reduced.
- Gastrointestinal bleeding. Treatment should be discontinued.
- Isolated cases of bullous dermatoses, 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, i.e. "*Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM)*" under "*Réseau des Centres de Pharmacovigilance*" (Network of Pharmacovigilance Centers) - website: www.ansm.sante.fr.

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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

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

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 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

Sucrose, methyl parahydroxybenzoate (E218), vanillin, Ponceau 4R (E124), raspberry flavoring (raspberry and vanilla tincture, raspberry and lemon alcohol extracts), cherry flavoring (cherry tincture, marasca cherry, raspberry and lemon alcohol extracts), sodium hydroxide, purified water.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years

6.4. Special precautions for storage

Do not store above 25°C.

6.5. Nature and contents of container

- 125 ml in a (glass) bottle with an aluminum cap and a 5 ml (polystyrene) measuring spoon.
- 200 ml in a (glass) bottle with an aluminum cap and a 5 ml (polystyrene) measuring spoon.
- 125 ml in a (glass) bottle with a (polypropylene) child-resistant cap and a 5 ml (polystyrene) measuring spoon.
- 200 ml in a (glass) bottle with a (polypropylene) child-resistant cap and a 5 ml (polystyrene) measuring spoon.

6.6. Special precautions for disposal and other handling

No special requirements.

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7. MARKETING AUTHORIZATION HOLDER

sanofi-aventis France
82 Avenue Raspail
94250 Gentilly
France

8. MARKETING AUTHORIZATION NUMBER(S)

- 34009 309 093 7 9: 125 ml in (glass) bottles + (polystyrene) measuring spoon
- 34009 363 705 7 9: 200 ml in (glass) bottles + (polystyrene) measuring spoon
- 34009 219 020 0 6: 125 ml in (glass) bottles with (polypropylene) child-resistant cap + (polystyrene) measuring spoon
- 34009 219 021 7 4: 200 ml in (glass) bottles with (polypropylene) child-resistant cap + (polystyrene) measuring spoon

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

[to be filled in by the MA holder]

10. DATE OF REVISION OF THE TEXT

[to be filled in 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.

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