ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Rhinathiol Expectorant Carbocisteine 5% syrup for Adults

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Carbocisteine..... 5 g
For 100 ml of syrup
One 15 ml measuring cup contains 750 mg of carbocisteine, 6 g of sucrose, 0.2 g of ethanol and 97 mg of sodium.
Alcohol content (v/v): 1.64°.
Excipients with known effet: sucrose, sodium, methyl parahydroxybenzoate (E218), ethanol (Alcohol content (v/v): 1.64°)
For the full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Syrup.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

This medicine is intended for use in adults and adolescents over 15 years of age who have had a recent respiratory disorder with difficulty expectorating.

4.2. Posology and method of administration

Oral use.
FOR ADULTS AND ADOLESCENTS OVER 15 YEARS OF AGE ONLY.
- One 15 ml measuring cup = 750 mg of carbocisteine.
- One 15 ml measuring cup to be taken 3 times daily, preferably not during mealtimes.

Treatment duration:

The duration of treatment should be short and not exceed 5 days.

4.3. Contraindications

Hypersensitivity to any of the ingredients,

4.4. Special warnings and precautions for use

Special warnings

WARNING: THE ALCOHOL CONTENT OF THIS MEDICINAL PRODUCT IS 1.64°, i.e. 0.2 g OF ALCOHOL PER 15 ml MEASURING CUP, which is equivalent to 4.92 ml of beer or 2.05 ml of wine per 15 ml dose.

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Use of this medicinal product is dangerous in alcoholics and the alcohol content should be taken into account in pregnant or breast-feeding women, in children or high-risk populations such as patients with liver failure or epilepsy.

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

Using drugs that affect bronchial secretions in combination with antitussives and/or substances that dry up secretions (atropine-like agents) is not logical.

This medicine contains sucrose. Its use is not recommended in patients with fructose intolerance, glucose and galactose malabsorption syndrome, or sucrase/isomaltase deficiency.

Special precautions for use

Caution should be exercised in patients with peptic ulcers.

This medicine contains 6 g of sucrose per 15 ml measuring cup; this must be taken into account in the daily allowance in patients on a low-sugar diet or with diabetes.

This medicinal product contains 97 mg of sodium per 15 ml measuring cup. This should be taken into account in patients following a strict low-sodium diet.

This medicinal product contains methyl parahydroxybenzoate (E218) and can cause (possibly delayed) allergic reactions.

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

Combinations to be taken into account

Combinations to be taken into account due to the alcohol content of this medicinal product:

+ Medicines causing an antabuse reaction with alcohol (heat sensation, redness, vomiting, tachycardia): disulfiram, cefamandole, cefoperazone, latamoxef (cephalosporin antibacterials), chloramphenicol (phenicol antibacterial), chlorpropamide, glibenclamide, glipizide, tolbutamide (antidiabetic sulfonylureas), griseofulvin (antifungal agent), 5-nitroimidazoles (metronidazole, ornidazole, secnidazole, tinidazole), ketoconazole, procarbazine (cytostatic agent).

+ **Central nervous system depressants.**

4.6. Pregnancy and lactation

Pregnancy

Animal studies have revealed no evidence of teratogenic effects, therefore the drug is not expected to have a malformative effect 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 malformative or fetotoxic effects have been reported to date in clinical practice. Nevertheless, there are insufficient data on pregnancies exposed to carbocisteine to completely rule out a risk.
Therefore, use of carbocisteine should only be considered during pregnancy if necessary.

Lactation

There are no data available on the excretion of carbocisteine in breast milk. However, in view of its mild toxicity, potential risks to infants appear to be negligible during treatment with this medicine. Breast-feeding is therefore possible.

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4.7. Effects on ability to drive and use machines

Not applicable.

4.8. Undesirable effects

Possible gastrointestinal disorders (gastric pain, nausea, diarrhea). If these occur, the dose should be reduced.
Possible allergic skin reactions such as urticaria, angioedema, pruritus, erythematous eruption.
A few cases of fixed drug eruption have been reported.
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.

4.9. Overdose

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: **MUCOLYTICS**, ATC Code: **R05CB03**.
(R: Respiratory system)
Carbocisteine is a mucus modifying agent with a mucolytic effect on bronchial secretions. It acts on the gel phase of mucus production, probably by breaking down the disulfide bonds in mucus glycoproteins, thus promoting expectoration.

5.2. Pharmacokinetic properties

Orally administered carbocisteine is rapidly absorbed; peak plasma concentrations are reached within two hours.
The drug is poorly bioavailable (less than 10% of the administered dose), probably as a result of intraluminal metabolism and a marked hepatic 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 (E 218), caramel coloring agent (E 150) (glucose, fructose, dextrose, inverted sugar, sucrose, ammonium hydroxide), cinnamon essential oil, aromatic elixir (concentrated rum extract, rum distillate, ethyl, propyl, butyl and amyl alcohol esters; acetic, propionic and butyric acid), sodium hydroxide, purified water.

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6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years

6.4. Special precautions for storage

Store below 25°C.

6.5. Nature and contents of container

125, 200, 250 or 300 ml (glass) bottle with aluminum stopper and (polypropylene) measuring cup.
125, 200, 250 or 300 ml (glass) bottle with (polypropylene) child-resistant stopper and (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
www.sanofi.fr

8. MARKETING AUTHORIZATION NUMBERS

- 309 092-0 or 34009 309 092 0 1: 125 ml in a (glass) bottle + (polypropylene) measuring cup.
- 337 811-8 or 34009 337 811 8 5: 200 ml in a (glass) bottle + (polypropylene) measuring cup.
- 217 766-1 or 34009 217 766 5 2: 250 ml in a (glass) bottle + (polypropylene) measuring cup.
- 323 687-8 or 34009 323 687 8 7: 300 ml in a (glass) bottle + (polypropylene) measuring cup.
- 219 015-7 or 34009 219 015 7 3: 125 ml in a (glass) bottle + (polypropylene) child-resistant stopper and (polypropylene) measuring cup.
- 219 016-3 or 34009 219 016 3 4: 200 ml in a (glass) bottle + (polypropylene) child-resistant stopper and (polypropylene) measuring cup.
- 219 018-6 or 34009 219 018 6 3: 250 ml in a (glass) bottle + (polypropylene) child-resistant stopper and (polypropylene) measuring cup.
- 219 019-2 or 34009 219 019 2 4 : 300 ml in a (glass) bottle + (polypropylene) child-resistant stopper and (polypropylene) measuring cup.

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

10. DATE OF REVISION OF THE TEXT

July 2015/V1.

11. DOSIMETRY

Not applicable.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

GENERAL CLASSIFICATION FOR PRESCRIPTION AND SUPPLY

Medicinal product not subject to medical prescription.

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