SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE DRUG

SOLUCIS 50 mg/ml Syrup
SOLUCIS 100 mg/ml Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

SOLUCIS 50 mg/ml Syrup
100 ml of syrup contain:
Active substance
Carbocysteine g 5
Excipients with known effects: methyl p-hydroxybenzoate; ethyl p-hydroxybenzoate; propyl p-hydroxybenzoate; sucrose, sodium, sodium benzoate
For a full list of excipients, see paragraph 6.1

SOLUCIS 100 mg/ml Syrup
100 ml of syrup contain:
Active substance
Carbocysteine g 10
Excipients with known effects: methyl p-hydroxybenzoate; ethyl p-hydroxybenzoate; propyl p-hydroxybenzoate; sucrose, sodium, sodium benzoate
For a full list of excipients, see paragraph 6.1

3. PHARMACEUTICAL FORM

Syrup

4. CLINICAL INFORMATION

4.1. Therapeutic Indications

Mucolytic, fluidifying in acute and chronic infections of the respiratory apparatus.

4.2. Dosage and administration method

SOLUCIS 50 mg/ml Syrup
Adults : 1 spoon 3 times a day.
Children over 5 years: 1 teaspoon 2-3 times a day depending on the age.

SOLUCIS 100 mg/ml Syrup
Its use is restricted to adults
1 spoon 2 times a day, morning and evening.

Duration of recommended treatment
Acute infections of the respiratory tracts: from 8 to 10 days.
Chronic and recurrent infections of the E.N.T. or bronchial sphere: from 10 days to 3 weeks several times a year.

4.3. Contraindications

Hypersensitivity to the active substance or to any one of the excipients.
Gastro-duodenal ulcer.
Pregnancy and lactation.
SOLUCIS 50 mg / ml Syrup: the medicinal is contraindicated in children aged less than or equal to 5 years.

4.4. Special warnings and use precautions

Gastrointestinal bleeding

Cases of gastrointestinal bleeding have been reported with the use of carbocysteine. Caution is advised in the elderly, in patients with a history of gastroduodenal ulcers or in patients taking concomitant medications known to increase the risk of gastrointestinal bleeding. In case of gastrointestinal bleeding, the patient must stop carbocysteine treatment.

Asthmatic and debilitated patients

It is recommended that specific precautions be taken in patients with severe respiratory insufficiency, in patients with asthma and a history of bronchospasm, as well as in debilitated patients. The use of carbocysteine causes a decrease in mucus viscosity and an increase in mucus removal, both through the ciliary activity of the epithelium, and through the cough reflex. Therefore, an increase in cough and sputum is expected. The use of antitussive medicines inhibits the cough reflex and increases the risk of airway obstruction, due to increased mucus accumulation in the airways. The concomitant use of this medicinal product with cough suppressant medicinal products and / or medicinal products that inhibit bronchial secretion (e.g. anti-muscarinic medicinal products) is not recommended.

The increase in expectorate which may occur in the initial days of treatment attenuates rapidly afterwards.

SOLUCIS contains: methyl p-hydroxybenzoate; ethyl p-hydroxybenzoate; propyl p-hydroxybenzoate which can cause allergic reactions (also delayed).

SOLUCIS contains: 6.3 g of sucrose per 15 ml of syrup (1 spoon) and 2.1 g of sucrose per 5 ml of syrup (1 teaspoon). Patients with rare hereditary problems of fructose intolerance, or glucose-galactose malabsorption, or sucrase isomaltase insufficiency, should not take this medicine.
The daily dosage of 3 spoons per day (equal to 45 ml of syrup) contains 18.9 g of sucrose, while the dosage of 3 teaspoons per day (equal to 15 ml of syrup) contains 6.3 g of sucrose. It should be remembered in case of diabetes or low-calorie diets.

SOLUCIS 100 mg / ml contains 192.4 mg of sodium per 15 ml of syrup (1 spoon), equivalent to 10% of the maximum daily intake recommended by the WHO which corresponds to 2 g of sodium for an adult.
The maximum daily dose of this product is equivalent to 20% of the maximum daily intake recommended by WHO. SOLUCIS 100 mg / ml is therefore considered to be high

in sodium. This aspect should be particularly taken into consideration for those on a low salt diet.

SOLUCIS 50 mg / ml contains 97.4 mg of sodium per 15 ml (1 spoon) and 32,5 mg per 5 ml (1 teaspoon) equivalent to 5% and 1.6% of the maximum daily intake recommended by the WHO which corresponds to 2 g of sodium for an adult.

4.5. Interactions with other medicines and other forms of interaction

There are no known interactions in the literature and incompatibility with other drugs.

4.6. Pregnancy and lactation

Pregnancy

Although the active substance is not teratogenic or mutagenic and has shown no adverse effects on reproductive function in animals, there are no data on the use of carbocysteine in pregnant women. Therefore, the use of the medicine is contraindicated in pregnancy.

Lactation

Since no data are available on the passage of carbocysteine into breast milk, the use of the medicine is contraindicated during breastfeeding.

4.7. Effects on the ability to drive vehicles and use machinery

SOLUCIS does not alter the ability to drive vehicles or use machinery.

4.8. Undesired effects

Frequency of the adverse events is classfied for System Organ Class and frequency: as follows: very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1000, <1/100); rare (≥1/10.000, <1/1.000); very rare (<1/10.000), unknown (it cannot be determined on the basis of the availabe data).

Skin and subcutaneous tissue disorders

Unknown frequency: Steven-Johnson syndrome, bullous dermatitis, Erythema multiforme, Toxic rash.

Gastrointestinal disorders

Unknown frequency: gastrointestinal bleeding.

It can also occur dizziness and digestive phenomena such as stomach pain, nausea and diarrhoea. In these cases it is necessary to reduce the dose or discontinue therapy. There can also be allergic rashes and anaphylactic reactions, fixed erythema. In this case, stop treatment and consult your doctor to institute an appropriate therapy.

Reporting suspected adverse reactions

Reporting suspected adverse reactions occurring after the authorization of the medicine is important as it allows continuous monitoring of the benefit/risk ratio of the medicine.

Healthcare professionals are required to report any suspected adverse reactions through the national reporting system at:
http://www.aifa.gov.it/content/segnalazioni-reazioni-avverse.

4.9. Overdose

Symptoms due to overdose include: headache, nausea, diarrhoea, stomach pain. In case of overdose, induce vomiting and if necessary practice gastric lavage.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic class: Mucolytic – Mucoregulator, ATC code R05CB03

Mechanism of action:
Breakage of the disulfide bonds of mucoglycoproteins, mucus depolymerization and consequent reduction in viscosity.
Normalization of the production of sialomucin, considerably reduced in inflammatory processes.

5.2. Pharmacokinetic properties

Carbocysteine, orally administered, is rapidly absorbed, has good tissue distribution and is mainly excreted as such in urine.
Peak plasma concentrations are reached in about 2 hours.

5.3. Preclinical safety data

The preclinical data demonstrate no risks for human beings on the basis of the conventional studies of pharmacological safety, toxicity from repeated administrations, genotoxicity, carcinogenic potential, reproductive toxicity.

6. PHARMACEUTICAL INFORMATION

6.1. List of excipients

Sodium benzoate; sodium hydroxide; methyl p-hydroxybenzoate; ethyl p-hydroxybenzoate; propyl p-hydroxybenzoate; Sucrose; Flavours: Caramel, Vanillin, Bur caramel, purified water.

6.2. Incompatibilities

Incompatibilities with other drugs are not known in the literature.

6.3. Shelf life

SOLUCIS 50 mg/ml Syrup: 5 years
SOLUCIS 100 mg/ml Syrup: 5 years

6.4. Special precautions for conservation

This medicine does not require any special storage condition.

6.5. Nature and content of container

Dark glass bottle with child-proof capsule, containing a clear brown solution.

200 ml bottle

6.6. <u>Special precautions for disposal and handling</u>

The unused product and the waste deriving from this product must be disposed of of in accordance with the requirements of local laws.

7. MARKETING AUTHORIZATION HOLDER

AESCULAPIUS FARMACEUTICI S.r.l. - Via Cefalonia, 70 - 25124 BRESCIA (ITALY)

8. MARKETING AUTHORIZATION HOLDER NUMBERS

SOLUCIS 50 mg/ml Syrup

200 ml bottle M.A.H. n° 025979030

SOLUCIS 100 mg/ml Syrup

200 ml bottle M.A.H. n° 025979055

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORIZATION

Date of first authorization: October 1991

Renewal date: June 2010

10. DATE OF REVISION OF THE TEXT

January 2022