เอกสารกำกับยาสำหรับบุคลากรทางการแพทย์
Summary of Product Characteristics (SmPC)

1. **Name of the Medicinal Product**

   1.1. Product Name

   CARBOSOL SYRUP

   1.2. Strength

   Each 5 mL contains Carbocisteine 250 mg

   1.3. Pharmaceutical Dosage Form

   Syrup

2. **Quality and Quantitative Composition**

   2.1 Qualitative Declaration

   Carbocisteine

   2.2 Quantitative Declaration

   Each 5 mL contains Carbocisteine 250 mg

3. **Pharmaceutical Form**

   Product description: Clear orange syrup

   Pharmaceutical form: Syrup

4. **Clinical Particulars**

   4.1 Therapeutic indication

   A mucolytic agent indicated in adults and children 2 years and above for the adjunctive therapy of respiratory tract disorders characterised by excessive, viscous mucus, including chronic obstructive airways disease.

   4.2 Posology and method of administration

   4.2.1 Posology

   Adults including the elderly:

   Initially 15 mL 3 times daily, reducing to 10 mL 3 times daily, as condition Improves.

   Children:

   Children 2 – 5 years: The usual dose is 1.25 mL – 2.5 mL four times daily

   Children 5 – 12 years: The usual dose is 5 mL three times daily

   4.2.2 Mode of administration

   Oral use

   4.3 Contraindication

   – Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

   – Active peptic ulceration

4.4 Special warning and precautions for use

- The use of Carbocisteine will result in less viscous mucus, requiring clearance via epithelial ciliary action and an intact cough reflex. The concomitant use of antitussives is therefore not recommended (see 4.5).
- The use of bronchial mucous modifiers with anti-cough medicines and/or substances that dry out secretions (atropinic) is not recommended.
- This medicine contains methylparaben and propylparaben which may cause allergic reactions (possible delayed).
- Caution is recommended in the elderly, in those with a history of gastroduodenal ulcers, or those taking concomitant medications known to cause gastrointestinal bleeding. Since mucolytics may disrupt the gastric mucosal barrier, caution should be taken in patients with a history of peptic ulcers. If gastrointestinal bleeding occurs, patients should discontinue medication.

4.5 Interaction with other medicinal products and other forms of interactions The combination of mucolytics with antitussives and/or substances that dry out secretions (atropinic) is not recommended.

4.6 Pregnancy and lactation

- **Pregnancy:**

  There are no available data on Carbocisteine use in pregnant women. No conclusions can be drawn regarding whether or not Carbocisteine is safe for use during pregnancy. The use of Carbocisteine in pregnant women is not recommended, especially during the first trimester.
- **Lactation:**

  There are no available data on the presence of Carbocisteine in human milk, milk production, or the effects on the breastfed infant. No conclusions can be drawn regarding whether or not Carbocisteine is safe for use during breastfeeding. The use of Carbocisteine in breastfeeding women is not recommended.
- **Fertility:**

  There are no fertility data available.

4.7 Effects on ability to drive and use machine

The medicinal product has negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions listed by System Organ Class:

- **Gastrointestinal disorders**

  Very common: stomach pains, nausea, diarrhea

Uncommon: vomiting

Very rare: There have been reports of gastrointestinal bleeding occurring during treatment with carbocisteine.

– **Immune system disorders**

Rare: There have been reports of anaphylactic reactions and fixed drug eruption.

Not known: Allergic skin eruption.

– **Skin and subcutaneous tissue disorders**

Rare: itching, rash, erythematous rash, or swelling in the face.

Not known: Isolated cases of bullous dermatitis such as Stevens-Johnson syndrome have been reported.

4.9 Overdose

Symptoms:

The most likely symptoms associated with overdose are gastrointestinal (gastralgia, nausea and vomiting).

Treatment:

Supportive therapy should be instituted, and gastric lavage could be considered.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

5.1.1 Pharmacotherapeutic group:

Mucolytics

ATC Classification: R05CB03

5.1.2 Mechanism of action:

Carbocisteine (S-carboxymethyl L-cysteine) is a mucolytic agent that modifies mucous secretions. It acts during the gel phase of the mucus, most likely by breaking up the disulfide bonds of the glycoproteins, and thus favouring expectoration. Moreover, carbocisteine has effects on bronchial secretion by normalization of mucus hyperviscisity.

5.2 Pharmacokinetic properties

After oral administration, carbocisteine is rapidly absorbed; maximum plasma concentration is reached in two hours. Its bioavailability is low, less than 10% of the administered dose, which is probably due to intraluminal metabolism and a marked liver first pass effect. Elimination half-life is about 2 hours. Carbocisteine and its metabolites are mainly eliminated via the kidneys.

5.3 Preclinical safety data

Tests in a wide range of animal species have revealed no significant toxicity. Serious adverse events associated with the use of carbocisteine have not been reported. Even symptomatic adverse events are very rare.

6. Pharmaceutical Particulars

6.1 List of excipients

CARBOSOL SYRUP contains alcohol, glycerin, sorbitol solution, sucrose, saccharin sodium, methylparaben, propylparaben, sodium hydroxide, raspberry flavor, menthol, ponceau 4R, tartrazine and purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Tentative shelf life: 2 years

After opening, use within 14 days then discard any unused.

6.4 Special precautions for storage

Keep in tight containers, protected from light and heat, Store below 30°C.

6.5 Nature and contents of container

- 60 mL of amber glass type III with aluminium cap having high sheer foam as inner liner and then be closed in secondary paper box containing 1 bottle.
- 60 mL of amber glass type III with aluminium cap having high sheer foam as inner liner and then be closed in carton containing 50 bottles.

7. Marketing Authorization Holder

Manufactured by:

SEVEN STARS PHARMACEUTICAL CO., LTD.

18/5 Phetkasem Road, Moo 1, Ban Mai, Sam Phran, Nakhon Pathom, 73110 Thailand

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8. Marketing Authorization Numbers

9. Date of authorization

10. Date of revision of the text

13 March 2024