Revised:
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SUMMARY OF PRODUCT CHARACTERIZATION

1. NAME OF MEDICINAL PRODUCT

BRONGO

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains carbocisteine lysine 450 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Syrup

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4. CLINICAL PARTICULARS

4.1 Indication

BRONGO is a muco-regulator having mucolytic and fluidifying effect.
BRONGO is effective in conditions with either hyperviscous or hypoviscous mucus.
BRONGO is indicated for the treatment of acute and chronic disorders of the upper and lower respiratory tract, such as chronic obstructive pulmonary disorders (COPD) and the prevention of acute exacerbations associated with chronic obstructive bronchitis.
BRONGO is also indicated for the treatment of ear, nose and throat (ENT) disorder, such as pharyngitis, tonsilitis, laryngitis, rhinopharyngitis, otitis, sinusitis.

4.2 Posology and method of administration

Posology:
Adults:
30 ml (equivalent to carbocisteine lysine salt 2.7 g) once daily or 15 ml twice daily.
Children:
- Not recommended in neonates and infants.
- 1 to 5 years of age: 2.5 ml twice daily
- over 5 years of age: 5 ml twice daily.

Administration in children should be done under careful medical monitoring.
The dosage may be increased to administration three times daily (t.i.d.) in both children and adults according to medical prescription.
Method of administration:
Use the measuring device to measure the appropriate amount, whether its use is for an adult or a child.

4.3 Contraindications

Hypersensitivity to carbocisteine or any component of the formulation. Active peptic or duodenal ulcer.

4.4 Special warnings and precautions for use

Precautions should be exercised in the following cases:

- Asthmatic patients with a history of bronchospasm; severe respiratory failure; and debilitated patients.
- The use of carbocisteine can lead to an increase of cough and sputum. This association of this medicine with antitussive medication is not recommended.
- Individuals susceptible to gastroduodenal ulcers, as mucolytics have the capacity to destroy the gastric mucosal barrier.
- Pregnant women in the first trimester and breastfeeding women.

4.5 Interaction with other medicinal products and other forms of interaction

No drug interactions have been identified.

4.6 Fertility, pregnancy and lactation

Pregnancy:

Although teratogenic effects have not been observed in animal reproduction studies, it is not recommended during the first trimester of pregnancy.

Lactation:

It is not known if carbocisteine is present in breast milk; use caution.

4.7 Effects on ability to drive and use machine

Carbocisteine has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Significant: Gastrointestinal bleeding.

Gastrointestinal disorders: Nausea, vomiting, diarrhoea, epigastric discomfort.

Immune system disorders: Anaphylactic reactions, fixed drug eruption.

Skin and subcutaneous tissue disorders: Rash. Rarely, bullous dermatitis (e.g. Stevens-Johnson syndrome, 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 HPVC at https://hpvcth.fda.moph.go.th/

4.9 Overdose

Symptoms: Gastrointestinal disturbances such as gastralgia, nausea, and vomiting.

Treatment: Supportive treatment. May perform gastric lavage, then closely observe the patient.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Mucolytic
ACT code: R05CB03

5.1 Pharmacodynamics properties

Carbocisteine (S-carboxymethyl L-cysteine) is a mucolytic agent. It has been shown in normal and bronchitic animal models to affect the nature and amount of mucus glycoprotein which is secreted by the respiratory tract. An increase in the acid:neutral glycoprotein ratio of the mucus and a transformation of serous cells to mucus cells is known to be the initial response to irritation and will normally be followed by hypersecretion. Carbocisteine serves to restore equilibrium between sialomucins and fucomucins, likely by intracellular stimulation of sialyl transferase enzyme, thus reducing mucus viscosity.

Several studies have demonstrated that carbocisteine reduces goblet cell hyperplasia. Carbocisteine can therefore be demonstrated to have a role in the management of disorders characterised by abnormal mucus.

5.2 Pharmacokinetics properties

Absorption

Carbocisteine is rapidly absorbed in the gastrointestinal tract when taken orally with peak serum concentrations achieved within 1 to 1.7 hours (plasma half-life 1.33 hour).

Distribution

$V_{d:}$: ~60 to 105 L; distributed to lung and respiratory mucous

Metabolism

Multiple metabolic pathways leading to multiple metabolites may be involved, including glucuronidation, N-acetylation, and sulfoxidation. Metabolism may vary due to circadian rhythm and genetic polymorphisms

Excretion

Excrete via urine as a primary route; about 30% to 60% of an orally administered dose is detected unchanged.

Bioavailability

Up to 17.5% of administered dose can be found in the bronchial secretions.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Dibasic Sodium Phosphate, Dodecahydrate
- Monobasic Sodium Phosphate, Dihydrate
- Propylparaben Sodium

- Sucralose
- Ammonium Glycyrrhizate
- Pyridoxine Hydrochloride
- Maltitol Solution
- Sorbitol Solution
- Caramel
- Natural Cherry Flavor
- Purified Water

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6.2 Major incompatibilities

Not applicable

6.3 Shelf-life

2 years

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6.4 Special precautions for storage

Store at temperature not above 30°C. Protect from light.

6.5 Natural and composition of immediate packaging

An amber PET 40 Bottle, packed in a carton with or without measuring cup.

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7. MARKETING AUTHORISATION HOLDER

Manufactured by
BIOLAB CO., LTD.
SAMUTPRAKARN, THAILAND

Manufactured under license for:
Interpharmacare Co., Ltd.

8. MARKETING AUTHORISATION NUMBER

Not applicable

9. DATE OF FIRST AUTHORISATION

Not applicable

10. DATE OF REVISION OF THE TEXT

September 2024