SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

FINATUX 50 mg/ ml syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

100 ml of syrup contains 5.0 g of carbocisteine

Excipients with known effect:
Methylparaben (E218) - 0.0015 g/ml
Sucrose - 577.50 mg/ml
Sodium - 6.71mg/ml (as Sodium hydroxide)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup.
Yellow-amber syrup with currant flavour and sweetish taste.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

FINATUX is indicated as mucolytic adjuvant in the antibacterial treatment of respiratory infections with bronchial hypersecretion.

4.2 Posology and method of administration

Adults: 15 ml 2 to 4 times daily.
Children:
Up to 5 years old: 5 ml 2 to 4 times daily.
6 to 12 years old: 10 ml 2 to 4 times daily in properly spaced intervals.
Use the measuring device in order to measure the appropriate quantity, depending on whether an adult or a child is being treated.

4.3 Contraindications

Gastroduodenal ulcers.
Hypersensitivity to carbocisteine or to any of the excipients.

4.4 Special warnings and precautions for use

Special warnings:
Patients with asthma and with a history of bronchospasm
Severe respiratory insufficiency
Debilitated patients. Due to the decrease of the cough reflex, there is risk of obstruction of the airway as a consequence of the increase of the quantity of secretions.

Warnings:
The use of the mucolytic implies a decrease of the mucus viscosity and its removal, either through the ciliary activity of the epithelium, either through the cough reflex, therefore an increase of the expectoration and cough should be expected. Do not associate with an antitussive.
Mucolytics, as they have the ability to destroy the gastric mucosa barrier, should be used with caution in individuals susceptible to gastroduodenal ulcers.
Data on the use of carbocisteine in children up to 12 years old are limited, so the use of FINATUX in this age group should be avoided.
In diabetic patients, the sucrose present should be considered.

This medicinal product contains methylparaben. May cause allergic reactions (possibly delayed).
This medicine contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
This medicinal product contains sodium. This medicinal product contains 4.37 mmol (or 100.51 mg) of sodium per dose (15 ml). To be taken into consideration by patients on a controlled sodium diet.

4.5 Interaction with other medicinal products and other forms of interaction

A cough suppressant agent or a secretion-drying agent has an effect contrary to that intended.

4.6 Fertility, pregnancy and lactation

Pregnancy
It is not recommended to use in pregnant women, especially during the first 3 months of pregnancy, even though no teratogenic effects were detected.

Breast-feeding
It is not recommended to use during breastfeeding because there are no safety date, concerning the passing of carbocisteine into breast milk.
Considering its low toxicity, if the mother is treated with this product, the potential risks for the child seem negligible.

4.7 Effects on ability to drive and use machines
Not relevant.

4.8 Undesirable effects

Occasionally:
Digestive disturbances: nausea, vomiting and diarrhoea.

Rarely:
Severe hypersensitivity reactions, such as urticaria and bronchospasm. Special attention in the patients with asthma as bronchoconstriction may occur. In these cases treatment should be stopped.
Headaches, myalgia, dizziness, urinary incontinence, palpitations and dyspnoea.
There are very rare reports of digestive haemorrhage and skin rash.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation 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 directly to INFARMED, I.P.:

INFARMED, I.P.
Direção de Gestão do Risco de Medicamentos
Parque da Saúde de Lisboa, Av. Brasil 53
1749-004 Lisboa
Tel: +351 21 798 71 40
Fax: + 351 21 798 73 97
Internet website: http://extranet.infarmed.pt/page.seram.frontoffice.seramhomepage
E-mail: farmacovigilancia@infarmed.pt

4.9 Overdose

It is shown as gastralgias, nausea and vomiting.
In these cases, suspend the administration of the drug and see the doctor.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Respiratory system. Cough and cold preparations. Mucolytics, ATC code: R05 C B03

FINATUX acts as fluidizing and expectorant. It is selectively fixed on the bronchopulmonary tissue and its specific activity on the muco-secretory cells allows recovering the qualitatively and quantitatively normal mucus production and in particular of one of its essential constituents - sialomucines.
The role of the acid sialomucines is fundamental under a triple point of view:
– Restore the mucus viscosity and elasticity, properties needed to the mobilization and expectoration of the pathological secretions;

– Make the bronchial epithelium functional again, and able to segregate a protective film of the normal mucosa not preventing the ciliary movements of clearance;
– Antagonize the locally produced quinines, factors of bronchial spasm and mucosa inflammation.

5.2 Pharmacokinetic properties

Absorption
After oral administration, carbocisteine is well-absorbed by the gastrointestinal tract. The maximum concentrations in serum are reached within 1.1 hours, approximately. The plasma half-life was estimated in 1.3 hours.

Distribution
Carbocisteine seems to penetrate well in the pulmonary tissue and in the breathing mucosa.

Biotransformation/ Elimination
There is no information available on the degree of first-passage metabolism or on proteins binding. Acetylation, decarboxylation and sulphoxidation have been identified as the main metabolic routes in the humans. In the detected levels of sulphoxide metabolites, inter-individual variation, of up to 100 times, was seen, which seems genetic. There is no record of pharmacologically important activity in these metabolites. Carbocisteine is excreted in urine unchanged and as its metabolites.

5.3 Preclinical safety data

Pharmaco-toxicological studies of carbocisteine allowed concluding that LD50 is higher than the maximum administered dose (5 g/Kg) to rats, mice and rabbits as this dose did not allow determining with accuracy LD50.
Also chronic toxicity studies for 160 days in the dog in doses 5-10 times higher than the maximum daily dose foreseen in the Man, did not cause significant changes of the studied parameters (body weight, no. of red blood cells, no. of white blood cells, haematocrit, percentage of haemoglobin, leucocyte form, GOT, GPT, azotaemia, proteinaemia, glycosuria, proteinuria, urinary pH, weight of the main organs), or anatomo-pathological changes on the examined organs.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Caramel (E150),
Currant flavour
Sodium hydroxide
Methylparaben (E218)
Purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25ºC.
Keep the container tightly closed.

6.5 Nature and contents of container

Type III amber glass bottles with 100, 125 or 200 ml of syrup (5%) with a measuring device.

6.6 Special precautions for disposal

No special requirements for disposal.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Laboratórios Basi – Indústria Farmacêutica, S.A.
Parque Industrial Manuel Lourenço Ferreira, Lote 15
3450-232 Mortágua
Portugal
Tel: + 351 231 920 250
Fax: + 351 231 921 055
E-mail: basi@basi.pt

8. MARKETING AUTHORISATION NUMBER

Registration no. 3016094 - 100 ml syrup, 50 mg/ml, Bottle
Registration no. 9484220 - 200 ml syrup, 50 mg/ml, Bottle
Registration no. 5711023 - 125 ml syrup, 50 mg/ml, Bottle

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26 December 1978

Date of latest renewal: 23 July 2004

10. DATE OF REVISION OF THE TEXT