Black

178 mm.

FluiFort® 2.7 g

Sachet

International Non-proprietary Name
Carbocysteine Lysine Salt Monohydrate.

Composition
Each Sachet contains Carbocysteine Lysine Salt Monohydrate 2.86 g, equivalent to Carbocysteine Lysine Salt 2.7 g.

Description
Straw-yellow coloured powder, with orange smell and without foreign bodies.

Therapeutic Properties
FluiFort® (Carbocysteine Lysine Salt Monohydrate) is a muco-regulator which exerts a specific *metabolic action* on the serous and mucous cells of the respiratory epithelium. It has no effect on the mucus itself.

The main demonstrated effect of **FluiFort**® is the increase of sialomucin contents in the mucus, restoring the proper sialo- to fuco-mucin proportion. This directly results in restored physiological mucus viscosity, elasticity and adhesion, and indirectly in restoring mucus hydration and mucociliary clearance.

The salification of Carbocysteine with Lysine results in greater solubility and biological availability, which allows to decrease the number of daily administrations while maintaining the wanted effects, and with an increase of the post-dosing effect typical of metabolic agents.
Once the metabolic mechanism is activated - that is, after one or a few days of administration, depending on the specific condition of the patient - it remains in effect even in the absence of drug administration (post-dosing carry-over effect).

Pharmacokinetics
Carbocysteine Lysine Salt Monohydrate has a greater water solubility and hence improved bio-availability. Therefore it is possible to administer **FluiFort**® once daily.
The active ingredient is rapidly and completely absorbed after oral administration (plasma half-life 1.5 hour). It is mainly excreted via the urinary route; 30-60% is excreted unmodified; the remainder in the form of various metabolites. Bioavailability studies have shown that up to 17.5% of the administered dose can be found in the bronchial secretions.

Indications
FluiFort® is a mucolytic and fluidifying agent indicated for the symptomatic treatment of acute and chronic respiratory tract disease accompanied by excessive mucous production.

Recommended Dose
One Sachet contains 2.7 g Carbocysteine Lysine salt.
Adults: 1 Sachet daily or according to medical prescription.
In view of the pharmacokinetic properties and the tolerability of Carbocysteine Lysine Salt Monohydrate, such posology can be maintained even in patients with impaired renal or liver function.
FluiFort® Sachet may be used for diabetic patients.
Directions for use:
Dissolve the contents of the sachet in half a glass of water, mixing well, and stir before drinking.

FluiFort® Sachet can be taken before, with or after food.

Duration of Treatment can range from 4-10 days to 20-30 days and, in chronic pathologies, for relatively long periods (15-30 days and up to 6 months or every day up to 12 months).

Children: FluiFort® Sachet is not suitable for use in children.
FluiFort® Syrup is available for use in children.

Contraindications
History of ascertained hypersensitivity to the product; gastric or duodenal ulcer.
Contraindicated in children under 2 years of age.

Warning and Precautions
Unsuitable for phenylketonurics.
Carbocysteine should be used with caution in patients with a history of peptic ulcer disease because of the risk that mucolytics may disrupt the gastric mucosal barrier.
From the first days of treatment, there is an increase in the expectorate, due to improved elimination of secretions.
Addiction or dependence is not known. Even though the product is neither teratogenic nor mutagenic, and has shown no adverse effects on the reproductive function of animals, its use during the first three months of pregnancy is not recommended.
Since no data is available on excretion of carbocysteine into mother's milk, its use during breast-feeding should be avoided.

Use During Pregnancy and Lactation
Although the product is neither teratogenic nor mutagenic, and did not appear to have negative effects on the reproductive function in animal studies, it is not recommended for use during the first trimester of pregnancy.
As it is not known whether carbocysteine is excreted in milk, its use during lactation is not advised.

Overdosage
In case of overdosage with enhancement of side effects, gastric lavage may be useful, followed by additional treatment under medical supervision. No specific antidote exists.

Side Effects
The clinical trials and pharmacovigilance initiatives conducted after commercialisation show that **FluiFort**® is well tolerated.
Gastritis, diarrhoea, vomiting, nausea, and gastrointestinal discomfort were reported after administration of carbocysteine and its lysine salt and were mild to moderate in nature.
These side effects disappear upon reduction of the dosage.
Gastrointestinal bleeding has occasionally occurred with carbocysteine. Skin rashes have also been reported. Carbocysteine should be used with caution in patients with a history of peptic ulcer disease because of the risk that mucolytics may disrupt the gastric mucosal barrier. Effects on endocrine function.
Transient hypothyroidism associated with the use of carbocysteine developed in a patient with compromised thyroid function.
Immune System Disorders:
Anaphylactic / anaphylactoid reaction

Skin and Subcutaneous Tissue Disorders:
Severe cutaneous adverse reactions (SCAR) e.g. erythema multiforme, Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN).

In most of these cases reported at least one other drug was administered at the same time, which may have possibly enhanced the described mucocutaneous effects.

Drug Interactions
No incompatibilities are known between **FluiFort**® and the most commonly used medications for the treatment of disorders of the upper and lower airways.

Packaging
Sachet containing 5g powder
Boxes of 6's and 50's Sachets.

Storage Conditions
Store in a dry place below 30°C.

Keep out of reach of children /
Jauhi dari kanak-kanak

Manufactured under licence for:
Eurodrug Laboratories S.A. (Belgium)
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