MUCOXIN

DESCRIPTION:
MUCOXIN ELIXIR 4 MG/ ML: A clear, green syrup**.**
MUCOXIN TABLET 8 MG: A round scored tablet, blue in colour, 7 mm diameter with marking 'duo'

COMPOSITION:
MUCOXIN ELIXIR 4 MG/ ML: Each 5 ml syrup contains Bromhexine Hydrochloride 4 mg. **Preservatives:** Methyl Paraben 0.1%; Propyl Paraben 0.033%
MUCOXIN TABLET 8 MG: Each tablet contains Bromhexine Hydrochloride 8 mg.

PHARMACODYNAMICS:
Bromhexine hydrochloride is a mucolytic. It has been shown to enhance the transport of mucus by reducing its viscosity and by activating the ciliated epithelium (mucociliary clearance). Preclinical studies show that there is an increase in the amount of thin watery bronchial secretion.

PHARMACOKINETICS:
Enteric absorption of bromhexine in man is relatively rapid, with an absorption half-life of 0.4 hours. Peak blood levels are reached within approximately 1 hour after oral administration. Bromhexine undergoes extensive first-pass metabolism with at least ten metabolites identified. Food eaten before administration of bromhexine enhances bioavailability. Following oral administration, bromhexine shows dose-linearity in the dose range 8-32 mg. There is a high level of protein binding and a large distribution volume. Bromhexine accumulates in the lung rather than in the plasma. The dominant elimination half-life is 1 hour; the terminal elimination half-life is 13-40 hours. Following oral administration of 8 mg, the plasma levels fell after 8-12 hours to 1.5 ng/mL and 0.2 ng/mL, respectively. For the most part, bromhexine is excreted in the urine as metabolites that pass through the kidneys while only minor amounts of parent compound are found in unchanged form in the urine. After 24 hours and 5 days, 70 and 88% of the oral dose respectively is recovered in the urine, 4% is excreted with the faeces. Bromhexine does not accumulate, as the long terminal elimination half-life is not dominant. Steady state levels are reached after three days at the latest. Reduced clearance of bromhexine parent substance can be expected in the case of severe liver disease; in the case of severe renal insufficiency accumulation of metabolites cannot be ruled out; pharmacokinetic studies for these conditions are not available.

INDICATIONS:
For use as a mucolytic in conditions such as bronchitis and emphysema.

RECOMMENDED DOSAGE:

MUCOXIN ELIXIR 4 MG/ ML:
Adults:
10 mL (8 mg) three times a day. May be increased to 16 mg (20 mL) three times a day for the first seven days.

Children:
Over the age of three years: 10 mL (8 mg) three times a day.
1 - 3 years: 5 mL (4 mg) three times a day.
Not recommended for children under 1 year**.**

MUCOXIN TABLET 8 MG:
Adults:
Initially two tablets (16 mg) three times a day for the first seven days.

Maintenance:
One tablet (8 mg) three times a day.

Children:
Over the age of three years: one tablet (8 mg) three times a day.
1 - 3 years: Half a tablet (4 mg) three times a day.
Not recommended for children under 1 year.

ROUTE OF ADMINISTRATIONS: For oral use.

CONTRAINDICATIONS:
Hypersensitivity to Bromhexine or any ingredients of the tablet or elixir.

WARNINGS AND PRECAUTIONS:
Mucoxin should be used with caution in patients with severe liver disease and severe renal failure (refer Pharmacokinetics). Use with caution in patients with gastric ulceration. Patients should be advised to expect an increase in the flow of mucus secretions.

Very rare cases of chronically associated severe skin impairments such as Steven Johnson Syndrome, Toxic Epidermal Necrolysis (TEN), Erythema Multiforme (EM) and Acute Generalized Exanthematous Pustulosis (AGEP) have been reported. In most cases, these could be explained by the severity of the underlying disease or concomitant administration of another drug. In the early stages of such severe skin reactions, initially only nonspecific flu-like symptoms appear, e.g. fever, arthralgia, runny nose, cough, sore throat. If skin or mucous membrane damage occurs, seek medical advice immediately and discontinue treatment as a precaution.

INTERACTIONS WITH OTHERS MEDICAMENTS:
Bromhexine may increase the concentration of currently administered antibiotics (for example - amoxycillin, erythromycin, doxycycline and cefuroxime) in bronchial secretions and lung tissue. No clinically relevant unfavourable interactions with other indications have been reported.

USE IN PREGNANCY AND LACTATION:
Use in Pregnancy: Available preclinical studies as well as clinical experience to date have shown no evidence of ill-effects during pregnancy. However, the usual precautions regarding the use of drugs during pregnancy, especially during the first trimester, should be observed**.**
Use in Lactation: Bromhexine is expected to enter the breast milk. Therefore, Mucoxin should be avoided during the lactation period.

SIDE EFFECTS/ADVERSE EFFECTS:
Mucoxin may cause severe allergy and serious skin reactions. Stop using Mucoxin and seek medical assistance immediately if you experience any of the following symptoms:
1) severe allergy: breathing difficulties, light headedness, skin swellings or rash
2) severe skin reaction: skin reddening, blisters, rash, fever, sore throat or eye irritation.

Occasional gastrointestinal side effects like nausea, diarrhoea, indigestion and abdominal fullness may occur with bromhexine, but these are mild and do not necessitate withdrawal of treatment. Very rarely allergic reactions including skin rashes, bronchospasm, angio-oedema, and anaphylaxis have also been reported.

Immune System Disorders
Frequency not known: Anaphylactic reactions including anaphylactic shock.

Skin and Subcutaneous Skin Disorders
Frequency not known: Severe skin reactions (including Stevens Johnson syndrome, Toxic epidermal necrolysis (TEN), Erythema Multiforme (EM) and Acute Generalized Exanthematous Pustulosis (AGEP).

SYMPTOMS AND TREATMENT OF OVERDOSE:
Overdosage in humans has not been reported. Should overdosage occur, symptomatic treatment is recommended.

STORAGE CONDITION:
Store below 30°C. Protect from light. Keep out of reach of children. *Jauhkan daripada kanak-kanak.*

PACKING / PACK SIZES:

MUCOXIN ELIXIR 4 MG/ ML: Pack of 60ml

MUCOXIN TABLET 8 MG : Blister pack of 100 x 10's tablets in a box.

SHELF LIFE:
Please refer to outer package.

PRODUCT REGISTRATION HOLDER AND MANUFACTURER:
DUOPHARMA (M) SDN BHD
Lot 2599 Jalan Seruling 59 Kawasan 3, Taman Klang Jaya, 41200 Klang, Selangor, MALAYSIA

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