MUCOLEX INJECTION 4MG/2ML (2 ML AMP)

DESCRIPTION:
MUCOLEX INJECTION is a clear, colourless solution.

COMPOSITION:
Bromhexine Hydrochloride 4 mg in 2 ml.

PHARMACODYNAMICS:
Bromhexine is a systematically active mucolytic agent. The onset of action clinically manifested by an increase in sputum production becomes evident within 15 minutes. The breakdown of acid mucopolysaccharide fibres makes the sputum thinner and less viscid and therefore more easily removed by coughing. Although sputum volume eventually decreases, its viscosity remains low as long as removed by coughing. Although sputum volume eventually decreases, its viscosity remains low as treatment with bromhexine is maintained. There is also an increased response to bronchodilator drugs.

PHARMACOKINETICS:
50-60% of the administered dose is excreted in the first 12 hours and a further 30-40% is excreted within 4 days. Total excretion amount to about 90% of the administered dose, most of which is excreted in the urines as metabolites.

INDICATION:
Secretolytic therapy in acute and chronic bronchopulmonary disease with abnormal mucus secretion and impaired mucus transport.

RECOMMENDED DOSAGE:
The administration of Bromhexine ampoules is recommended for the treatment of the most severe cases as well as for reducing post-operative complications. In severe cases as well as before and after surgical intervention, 1 amp. intravenously (duration of injection 2–3 minutes) or deep intramuscularly, 2–3 times a day.
The injection solution can also be given as an i.v. infusion together with glucose, levulose or Ringer's solution.

ROUTE OF ADMINISTRATION:
By i.m, i.v or infusion.

CONTRAINDICATIONS:
Should not be used in patients known to be hypersensitive to bromhexine.

WARNINGS & PRECAUTIONS:
Very rare cases of chronically associated severe skin impairments such as Stevens 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, and sore throat. If skin or mucous membrane damage occurs, seek medical advice immediately and discontinue treatment as a precaution.
Precautions: Use with caution in patients with gastric ulceration. When patients under treatment for tuberculosis are receiving Bromhexine, continue the sputum culture for the tubercle bacilli for at least three months before assuming a negative result.
Warning for Sodium Metabisulphite: This preparation contains sodium metabisulphite, a sulphite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulphite sensitivity in the general population is unknown and probably low. Sulphite sensitivity is seen more frequently in asthmatic than non-asthmatic people. This preparation contains Sodium metabisulphite that may cause serious allergic type reactions in certain susceptible patients. Do not use if known to be hypersensitive to bisulphites.

INTERACTION WITH OTHER MEDICAMENTS:
Administration of Bromhexine together with antibiotics (amoxicillin. cefuroxime, erythromycin, and doxycycline) leads to higher antibiotic concentration in the lung tissue. No clinical relevant unfavourable interaction with other medications has been reported.

USE IN PREGNANCY & LACTATION:
Use in Pregnancy: Dysmorphogenicity studies in animals have given no suggestion that Bromhexine has any teratogenic potential in humans. Nevertheless, as with any drug, it is advisable its use during the first trimester of pregnancy.

Use in Lactation: No information of lactating women is available but excretion of the drug into breast milk cannot be excluded. Hence, bromhexine should not be given during the lactating period.

SIDE EFFECTS:
Occasional gastrointestinal side effects, like nausea, diarrhoea, indigestions and abdominal fullness may occur but these are mild and do not necessitate withdrawal of treatment. Isolated instances of headache, vertigo, perspiration and skin rash have also been reported. In a very few patients, a transient rise in serum transaminase levels may be observed but these fall again with continuation of bromhexine treatment.
Note: Patients being treated with Bromhexine should be warned to expect an increase in the flow of secretions.

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:
Over dosage in man has not been reported. Should over dosage occur, symptomatic treatment is recommended.

INCOMPATIBILITIES:
Bromhexine should not be mixed with alkaline solution as the acid character of Bromhexine solution (pH 2.8) may cause cloudiness or flocculation.

STORAGE CONDITIONS:
Store below 30˚C. Protect from light.
KEEP OUT OF REACH OF CHILDREN. *JAUHKAN DARIPADA CAPAIAN KANAK-KANAK.*

[Revision Date: 08.12.2020]

SHELF LIFE:
Please refer to outer package.

PACK SIZE:
Pack in box of 10 ampoules x 2 ml

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