

Dysolvon Syrup (Raspberry)

MAL07091035XZ

DESCRIPTION:

Colourless, raspberry flavour syrup.

EACH 5 ML CONTAINS:

Bromhexine Hydrochloride..... 4 mg

PHARMACODYNAMICS:

Bromhexine Hydrochloride has been reported to change the structure of bronchial secretions and to increase the volume and reduce the viscosity of sputum.

PHARMACOKINETICS:

Bromhexine Hydrochloride is absorbed from the gastrointestinal tract and peak plasma concentrations have occurred after 1 hour. Most of a dose is excreted in the urine mainly as metabolites; only a small amount is excreted in the faeces. Ambroxol is a metabolite of Bromhexine.

INDICATION:

Administered in bronchitis and other respiratory conditions to aid expectoration. Reduction of sputum-viscosity.

RECOMMENDED DOSAGE:

Adults: 2 - 4 teaspoonfuls (10 ml - 20 ml), 3 times daily.
Children under 5 years: 1 teaspoonful (5 ml), twice daily.
Children 5 to 10 years: 1 teaspoonful (5 ml), four times daily.

ROUTE OF ADMINISTRATION:

FOR ORAL USE ONLY

CONTRAINDICATION:

Bromhexine should not be given to patients known to be hypersensitive to Bromhexine or other ingredients of the formulation.

WARNING AND PRECAUTIONS:

Bromhexine should be given cautiously to patient with gastric ulceration.

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.

INTERACTIONS WITH OTHER MEDICAMENTS:

Administration of Bromhexine together with antibiotics (Amoxycillin, Cefuroxime, Erythromycin, Doxycycline) leads to higher antibiotic levels in the lung tissue.

No clinically relevant unfavourable interactions with other medications have been reported.

PREGNANCY AND LACTATION:

No evidence suggests ill effects concerning usage of Bromhexine during pregnancy. However, the usual caution regarding drug usage during pregnancy should be practiced.

Bromhexine is expected to enter breast milk, and should be avoided during lactation.

SIDE EFFECTS:

Gastrointestinal side effects may occur occasionally a transient rise in serum transaminase values has 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)).

PACKAGING/PACK SIZE(S):

Plastic bottle of 60 ml.

JAUHI UBAT DARIPADA KANAK-KANAK

KEEP OUT OF REACH OF CHILDREN

Keep Container Tightly Closed

Do Not Store Above 30°C

Protect From Light

SHAKE WELL BEFORE USE

MANUFACTURER/PRODUCT REGISTRATION HOLDER:

DYNAPHARM (M) SDN. BHD. 198001011897 (65683-V)

2497, Mk. 1, Lorong Perusahaan Baru 5,

Kawasan Perusahaan Perai 3,

13600 Perai, Pulau Pinang, Malaysia.

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