

# VASICAN

## PRODUCT DESCRIPTION:

- 1) Tablet : Green, round and flat tablets, with 8 mm diameter, score-line on one side and 'DHA' logo on the other side.  
2) 4mg/5mlsyrup : Clear light green syrup, sweet taste with banana flavour.

## COMPOSITION:

Each Vasican tablet contains :Bromhexine HCl BP 8mg/tablet

Excipients :

Corn Starch, Lactose Mesh, Acacia Powder, FDC Blue No.1 Aluminum Lake HT, Quinoline Yellow E104, Magnesium Stearate.

Each 5ml:

Vasican 4mg/5ml syrup contains : Bromhexine HCl BP 4mg/5ml

Preservative : Benzoic Acid 0.1%w/v

Excipients : Granulated Fine White Sugar, Glycerin, Propylene Glycol, Alcohol 96%, Banana Flavor, Quinoline Yellow E104, Edicol Brilliant Blue FCF, Citric Acid Monohydrate, Sodium Citrate Dihydrate, Di-Sodium EDTA, Purified Water.

## PHARMACOLOGY :

VASICAN contains bromhexine HCl which is a mucolytic agent. It acts on the mucous gland in the respiratory tract to change the structure of bronchial secretion and to increase the volume and reduce the viscosity of the sputum.

## PHARMACOKINETICS:

Oral administration Bromhexine HCl is absorbed rapidly from the gastro-intestinal tract, with peak plasma concentration achieved in about one hour. It undergoes extensive first-pass metabolism in the liver and has an elimination half-life of 6.5 hours.

## INDICATIONS:

For the reduction of sputum viscosity.

## RECOMMENDED DOSAGE:

Tablets:

Adult and children over 12 years : 8mg (1 tablet) 3 times a day  
Children : 6 to 12 years : 4 mg (half tablet) 3 times a day

Syrup

Adults and children over 12 years : 8 mg (10ml) 3 times a day  
Children : 6 to 12 years : 4 mg (5ml) 3 times a day  
2 to 6 years : 4 mg (5ml) 2 times a day

## WARNINGS AND PRECAUTIONS :

Bromhexine HCl should be given with caution to patient with gastric ulceration. In very few cases, severe skin disorders such as Stevens-Johnson's syndrome and toxic epidermal necrolysis (TEN) have been reported after administration of mucolytic substances (e.g. bromhexine), which in most cases could be explained by the patients underlying disease and/or the concomitant medication. In addition during the early phase of a Steven-Johnson Syndrome or TEN a patient may find experience non-specific influenza-like prodromes (e.g. fever, aching body, rhinitis, cough and sore throat). It is possible that a symptomatic treatment is started with a cough and cold preparation due to these misleading nonspecific influenza-like prodromes. Therefore if new skin or mucosal lesions occur, medical advice should be sought immediately and treatment with bromhexine discontinued as a precaution.

#### USE IN PREGNANCY AND LACTATION :

It is advisable to avoid use during the first three months of pregnancy and during lactation, Bromhexine HCl is excreted in breast milk.

#### DRUG INTERACTION :

Bromhexine HCl enhance the penetration of antibiotic (e.g.amoxycillin, cefuroxime, erythromycin and doxycycline) into the lung tissues. In elderly patients with acute exacerbation of chronic bronchopulmonary disease, a combination of cephalexin and bromhexine HCl shows that the symptoms and ventilatory functions were improved to a greater extent in the group treated with antibiotic and mucolytic combination than with the antibiotic alone. No other clinically unfavourable interaction with medication have been reported.

#### CONTRA-INDICATIONS :

Known hypersensitivity to bromhexine.

#### SIDE EFFECTS :

Gastro-intestinal irritations, allergic reactions including skin rashes, bronchospasm, an-gio-oedema and anaphylaxis, transient increased serum amino transaminase.

#### OVERDOSAGE AND TREATMENT :

To date, no symptoms of overdosage have been reported.

#### STORAGE :

Protect from light

Store below 30°C.

#### EXPIRY PERIOD :

Do not use after the expiry date stated on the label.

#### AVAILABILITY

Tablets : 10x10x10's in blister pack

Syrup : Bromhexine HCl 4mg/5ml: 100 ml in amber glass bottle and 3.8 Litres in plastic container

DATE OF REVISION : May 2021

For further Information, please consult your physician or pharmacist.

Manufactured By:

PT Actavis Indonesia

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