

•ALVIGO•[®] Tablets

(Betahistine dihydrochloride)

DESCRIPTION

Betahistine dihydrochloride is a synthetic and orally active analogue of histamine.

Each tablet available for oral administration contains 8 mg or 16 mg betahistine dihydrochloride.

Inactive ingredients: Microcrystalline cellulose, lactose, croscarmellose sodium, povidone, colloidal silicone dioxide, stearic acid.

Tablet Description:

8 mg : White round tablet plain on both sides

16 mg: White round tablet, quadrisection on one side, plain on the other.

INDICATIONS AND USAGE

Meniere's disease and Meniere-Like syndromes characterized by attacks of vertigo, tinnitus and/or progressive loss of hearing.

CONTRAINDICATIONS

Several patients with a history of peptic ulcer have experienced an exacerbation of symptoms while using betahistine. Although no causal relation has been established, betahistine is contraindicated in the presence of peptic ulcer.

Hypersensitivity to any of the ingredients contained in the tablets.

PRECAUTIONS

Caution should be exercised in patients with bronchial asthma if this drug is to be used due to the risk of bronchoconstriction.

Pregnancy

Safety in pregnant women has not been established; therefore, its use in pregnancy or in women of child bearing potential requires that its potential benefits be weighed against its possible risks.

Nursing Mothers

It is not known whether betahistine is excreted in human breast milk; therefore, its use in lactating women should be weighed against its possible risks.

Pediatric Patients

Betahistine is not recommended for use in children. As with all drugs, betahistine should be kept out of the reach of children.

ADVERSE REACTIONS

- Upset stomach, nausea, vomiting, dryness of the mouth and diarrhea.

- Headache.

- Less frequently: somnolence and hypersensitivity reactions.

- Rarely elevation of liver enzymes.

Concomitant Therapy

Betahistine should not be used concurrently with antihistamine agents since no information is available with regards to the possible interaction of these drugs.

OVERDOSAGE

In the case of overdosage, symptoms similar to the ones elicited by histamine have been observed.

Overdosage with betahistine is treated with the administration of antihistamines.

DOSAGE AND ADMINISTRATION

8 to 16 mg as recommended administered 3 times a day preferably with meals.

PRESENTATION

Alvigo[®] is available as 8 mg tablets in blister packs of 100 s and 16 mg tablets in blister packs of 60 s.

STORAGE CONDITIONS

Store in a dry place below 25°C, protected from light.

Do not refrigerate.

Do not use after expiry date.

Keep medicament out of reach of children.

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.

- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are experts in medicine, its benefits and risks.

- Do not by yourself interrupt the period of treatment prescribed.

- Do not repeat the same prescription without consulting your doctor.

Manufactured in Zouk Mosbeh, Lebanon, by

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Rev. No: 05/06