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(Betahistine Dihydrochloride)

COMPOSITION: Exics® 8mg Tablets Each tablet contains:

Betahistine Dihydrochloride BP......8mg

Enies® 16mg Tablets Each tablet contains Betahistine Dihydrochloride BP......16mg Enies® 24mg Tablets Betahistine Dihydrochloride BP......24mg

## PHARMACOLOGICAL ACTION:

Betainstine diffyorhorhoride is an analogue of histamine. It is completely absorbed after oral administration. The mean plasma half-life is 3-4 hours and excretion is virtually complete in the urine within 24 hours in the form of the metabolite 2 pyridylacetic acid

### MODE OF ACTION:

The mechanism of action of betahistine is not known. Pharmacological testing in animals has shown that the blood circulation in the striae vascularis of the inner ear improves, probably by means of a relaxation of the precapillary sphincters of the microcirculation of the inner ear

The mode of action of betahistine was believed to be a direct stimulating (agonistic) effect on H1 receptors located on blood vessels in the inner ear. This would give rise to

local vascodiation and increased permeability, which would help reverse the underlying problem of endolympathic hydrops
In addition, betahistine has a antagonistic effects at H3 receptors, and increases the levels of neurotransmitters released from the nerve endings

### INDICATIONS:

- Symptomatic treatment of:

   Vertigo associated with Ménière's Syndrome
- Vestibular vertigo

### CONTRA-INDICATIONS:

- Hypersensitivity to any of the ingredients
   Patients with active peptic ulcer
   Patients with phaeochromocytoma

## Adult dosage

The dosage for adults is 24-48mg in divided doses

### Three times daily dosing

8mg tablets: 1-2 tablets three times a day 16mg tablets: ½-1 tablets three times a day

Twice daily dosing 24mg tablets: 1 tablet twice a day

OR As directed by the physician

Gastro-intestinal disturbances, headache and skin rashes have been reported

Caution should be exercised when betahistine dihydrochloride is given to patients with a history of peptic ulcer or asthmatic patients Concomitant use with antihistamines should be avoided

# PREGNANCY:

There are no well-controlled studies of betahistine use by pregnant women. Therefore, this medication should be used during pregnancy or in women of childbearing potential only if benefits outweigh potential risk

# BREAST-FEEDING:

It is not known whether betahistine passes into breast milk. It should be used during breast-feeding only if the potential benefits outweigh the possible risks

## CHILDREN:

This medication is not recommended for use by children

## OVERDOSAGE AND ITS TREATMENT:

Nausea, vomitting and headache are the more common symptoms. Hypotension could possibly occur. There is no specific antidote. Treatment could include stomach emptying by inducing emesis or by lavage. Further treatment is symptomatic and supportive

## STABILITY:

See expiry on the pack

PRESENTATION:

Ener 8 mg tablets in a pack of 30's

Ener 16 mg tablets in a pack of 30's Enies® 24mg tablets in a pack of 30's

## INSTRUCTIONS:

Keep out of reach of children. Avoid exposure to heat, light and humidity Store between 15 to 30°C. Improper storage may deteriorate the medicine

خوراک: ڈاکٹر کی ہدایت کےمطابق استعال کریں ہدایات: بچوں کی پہنچ سے دور رکھیں دواکودھوپ، گرمی اورنمی ہے محفوظ ۱۵ سے ۱۳ ڈگری سنٹی گریٹر

کے درمیان میں رکھیں ورنہ دواخراب ہوجائیگی

Manufactured by: SAMI Pharmaceuticals (Pvt.) Ltd. F-95, S.I.T.E., Karachi-Pakistan www.samipharmapk.com

R.N-04/HA/03/16/Pampac