

SCITIN™

[BETAHISTINE DIHYDROCHLORIDE]

8mg & 16mg Tablets

DESCRIPTION

SCITIN (Betahistine dihydrochloride) is an analogue of Histamine and is claimed to improve the microcirculation of the labyrinth resulting in reduced endolymphatic pressure. Its chemical name is 2-[2-(Methylamino-ethyl)pyridine dihydrochloride and the molecular formula is $C_8H_{12}N_2 \cdot 2HCl$.

COMPOSITION

SCITIN (Betahistine dihydrochloride) Tablets are available for oral administration as:

1. SCITIN Tablets 8mg
Each tablet contains:
Betahistine dihydrochloride USP.... 8mg
2. SCITIN Tablets 16mg
Each tablet contains:
Betahistine dihydrochloride USP.... 16mg

CLINICAL PHARMACOLOGY

Mechanism of Action

Betahistine dihydrochloride is a specific histamine agonist with virtually no H₂-activity. It appears to act on the precapillary sphincter in the stria vascularis of the inner ear, thus reducing the pressure in the endolymphatic space.

Pharmacokinetics

Betahistine dihydrochloride is rapidly and completely absorbed after oral administration of the drug from gastro intestinal tract. The drug is rapidly metabolized to one major metabolite, 2-pyridylacetic acid. The mean plasma half life is 3 - 4 hours. Excretion is virtually complete in urine within 24 hours. It is excreted almost quantitatively in urine as 2-pyridylacetic acid within 24 hours after administration. No unchanged Betahistine has been detected.

THERAPEUTIC INDICATIONS

SCITIN (Betahistine dihydrochloride) Tablets are indicated in;

- Vertigo
- Tinnitus
- Hearing loss associated with Meniere's disease.

DOSAGE AND ADMINISTRATION

Adults (including the elderly):
Initially 16mg (two tablets of Scitin Tablets 8mg or one tablet of Scitin Tablets 16mg) three times daily taken preferably with meals. Maintenance doses are in the range 24-48mg daily.

CONTRAINDICATIONS

Betahistine dihydrochloride is contraindicated in patients with:

- Known hypersensitivity to Betahistine dihydrochloride or to any of the excipients in the tablet.
- Phaeochromocytoma.

PRECAUTIONS

Betahistine dihydrochloride should be given with care to patients with:

- Asthma
- Peptic ulcer disease
- A history of peptic ulcer disease

سائٹین

These patients need to be carefully monitored during the therapy.

Pregnancy

There are no adequate data from the use of Betahistine dihydrochloride in pregnant women. The potential risk for humans is unknown. Betahistine dihydrochloride should not be used during pregnancy unless clearly necessary.

Nursing Mothers

It is not known whether Betahistine dihydrochloride is excreted in human milk. The importance of the drug to the mother should be weighed against the benefits of nursing and the potential risks for the child.

ADVERSE REACTIONS

Following adverse reactions have been reported during use of Betahistine dihydrochloride:
Gastrointestinal disturbances, headache, skin rashes and pruritis.

Drug Interactions

An antagonism between Betahistine dihydrochloride and antihistamines could be expected on a theoretical basis no such interactions have been reported.

OVERDOSAGE

Some patients may experienced mild to moderate symptoms with doses up to 728mg (e.g., nausea, somnolence, abdominal pain). More serious complications (e.g., convulsion, pulmonary or cardiac complications) were observed in cases of intentional overdose of Betahistine dihydrochloride especially in combination with other overdosed drugs. Treatment of overdose should include standard supportive measures.

STORAGE

Store at 25°C (Excursions permitted between 15°C to 30°C).

Protect from sunlight and moisture.

The expiration date refers to the product correctly stored at the required conditions.

HOW SUPPLIED

SCITIN (Betahistine dihydrochloride) Tablets 8mg are available in blister pack of 30's.

SCITIN (Betahistine dihydrochloride) Tablets 16mg are available in blister pack of 30's.

Keep out of reach of children.

To be sold on prescription of a registered medical practitioner only.

Please read the contents carefully before use.
This package insert is continually updated from time to time.

Manufactured by: Getz Pharma (Pvt.) Limited
29-30/27 K.I.A., Karachi - 74900, Pakistan.

Marketed by:

SCILIFE

SciLife Pharma (Pvt.) Ltd.,
16- K.O.C.H.S., Amir Khusro Road,
Karachi - 75350, Pakistan.

L00-20006279