SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

TREVIGO 24 mg TABLETS

COMPOSITION

Each uncoated tablet contains betahistine dihydrochloride 24 mg.

Excipients: Cellulose microcrystalline, mannitol, povidone, crospovidone, anhydrous citric acid, colloidal anhydrous silica, talc and stearic acid.

Contains mannitol 18,75 mg.

Sugar free.

PHARMACOLOGICAL CLASSIFICATION

A.5.6 Histamine.

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

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

Betahistine was found to have weak H_1 receptor agonistic and considerable H_3 antagonistic properties in the autonomic nervous system and Central Nervous System (CNS) in pharmacological studies. Betahistine was also found to have a dose-dependent inhibiting effect on spike generation of neurons in lateral and medial vestibular nuclei. However, the importance of this observation in the action against Ménière's syndrome or vestibular vertigo remains unclear.

Pharmacokinetic properties

After oral administration, betahistine is completely absorbed. Only one metabolite, 2-pyridyl-acetic acid which is excreted in the urine, is known.

INDICATIONS

TREVIGO 24 mg TABLETS are indicated for the symptomatic treatment of the vertigo associated with Ménière's syndrome.

CONTRAINDICATIONS

Hypersensitivity to any of the ingredients.

Patients with active peptic ulcer.

Patients with pheochromocytoma.

WARNINGS and SPECIAL PRECAUTIONS

TREVIGO 24 mg TABLETS should be administered with caution to patients with bronchial asthma as clinical intolerance has been shown in relatively few patients. Caution is advised in patients with a history of peptic ulcers.

Concomitant use with antihistamines should be avoided (see **"INTERACTIONS"**).

Effects on the ability to drive and use machines

On the basis of the pharmacodynamics profile and reported adverse reactions (see **"SIDE EFFECTS"**), **TREVIGO 24 mg TABLETS** have no or negligible effects on the ability to drive and use machines.

INTERACTIONS

Concomitant use with antihistamines should be avoided (See **"WARNINGS and SPECIAL PRECAUTIONS"**).

HUMAN REPRODUCTION

There is insufficient data on the use of this medicine during pregnancy and lactation. Therefore **TREVIGO 24 mg TABLETS** should not be used during pregnancy and lactation.

DOSAGE AND DIRECTIONS FOR USE

Adults (including the elderly): Initially 16 mg three times daily taken preferably with meals. Maintenance doses are generally in the range of 24 to 48 mg daily, in divided doses.

TREVIGO 24 mg TABLETS

1 tablet 2 times/day.

The dosage should be individually adapted according to the response.

Children: No dosage recommendations are made for children.

SIDE EFFECTS

TREVIGO 24 mg TABLETS may cause the following side effects:

Immune system disorders

Less frequent

Hypersensitivity reactions e.g., anaphylaxis

Nervous system disorders

Less frequent

Headache.

Gastrointestinal disorders

Frequent

Gastrointestinal disturbances. These can normally be dealt with by lowering the dose or by taking the dose during meals.

Skin and subcutaneous tissue disorders

Less frequent

Cutaneous hypersensitivity reactions have been reported, in particular rash, pruritus and urticaria.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

See **"SIDE EFFECTS"**. The most common symptoms are nausea, vomiting and headache. Hypotension may occur. There is no specific antidote. Treatment may include stomach emptying by inducing emesis or by lavage. Further treatment is symptomatic and supportive.

IDENTIFICATION

White to off–white round, uncoated tablets, debossed with ‘X’ and a break line on one side and ‘89’ on the other side.

PRESENTATION

Blister Pack

Tablets are packed in blister packs (composed of OPA / aluminium foil / PVC film and printed aluminium foil).

Each blister contains 10 tablets.

The blisters will be further packed in pre-printed cartons with a package leaflet.

Pack size: 20’s – Each carton contains 2 blisters of 10 tablets each.

HDPE Container Pack

Tablets are packed in 40 ml white opaque round HDPE containers with white opaque polypropylene ribbed stock closures with a wad having an induction sealing liner, containing cotton coil.

The HDPE containers will be further packed in pre-printed cartons with a package leaflet.

Pack size: 20’s - One HDPE container contains 20 tablets.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Do not remove the blisters from the carton until required for use.

Keep the containers tightly closed.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

TREVIGO 24 mg TABLETS: 45/5.6/0579

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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