1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

MENIVERT 24 mg TABLETS

COMPOSITION

Each tablet of MENIVERT 24 mg TABLETS contains 24 mg of betahistine dihydrochloride.

Excipients:

Citric acid anhydrous, crospovidone, hydrogenated vegetable oil, lactose monohydrate, maize starch, microcrystalline cellulose, povidone

Contains sugar: Lactose monohydrate 150 mg

CATEGORY AND CLASS

A 5.6 Histamine

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Betahistine is an analogue of histamine. It improves the microcirculation of the labyrinth resulting in reduced endolymphatic pressure. 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.

In pharmacological studies, betahistine was found to have weak H_1 receptor agonistic and considerable H_3 antagonistic properties in the central nervous system and the autonomic nervous system.

Betahistine was also found to have a dose dependant inhibiting effect on spike generation of neurons in lateral and medial vestibular nuclei.

Pharmacokinetic properties

Absorption

Following oral administration betahistine is well absorbed.

Distribution

There is little or no binding to plasma proteins.

Metabolism

Betahistine undergoes hepatic biotransformation, with evidence for the formation of 2-pyridylacetaldehyde and 2-(2-aminoethyl)pyridine.

Elimination

It is excreted in urine as the metabolite 2-pyridylacetic acid within 24 hours. No unchanged betahistine has been detected.

Betahistine is excreted in breast milk at approximately the same level as found in plasma.

INDICATIONS

MENIVERT 24 mg TABLETS is indicated for the symptomatic treatment of the vertigo

associated with Ménière's syndrome.

CONTRAINDICATIONS

MENIVERT 24 mg TABLETS is contraindicated in:

- Patients with hypersensitivity to betahistine or to any of the ingredients contained in MENIVERT 24 mg TABLETS (see COMPOSITION).
- Patients with phaeochromocytoma. As betahistine is a synthetic analogue of histamine it may induce the release of catecholamines from the tumour resulting in severe hypertension.

WARNINGS AND SPECIAL PRECAUTIONS

Caution is advised in the treatment of patients with peptic ulcer or a history of peptic ulceration, because of the occasional dyspepsia encountered in patients on MENIVERT 24 mg TABLETS.

Patients with bronchial asthma should be monitored carefully during the treatment with MENIVERT 24 mg TABLETS.

Caution is advised in prescribing MENIVERT 24 mg TABLETS to patients with either urticaria, rashes or allergic rhinitis, because of the possibility of aggravating these symptoms.

Caution is advised in patients with severe hypotension.

Caution is advised in patients with porphyria.

If MENIVERT 24 mg TABLETS are to be administered subsequent to the treatment with an antihistamine and this treatment is stopped abruptly, withdrawal symptoms such as sleep disorders and agitation could appear because of the sedative action of antihistamines. Treatment with the antihistamine should be tapered over approximately six days.

Effects on ability to drive and use machines

Since adverse reactions such as drowsiness have been reported in patients receiving MENIVERT 24 mg TABLETS, patients should not drive, use machinery or perform any tasks that require concentration, until they are certain that MENIVERT 24 mg TABLETS does not adversely affect their ability to do so (see SIDE EFFECTS).

Excipients

Lactose warning:

MENIVERT 24 mg TABLETS contain lactose which may have an effect on the glycaemic control of patients with diabetes mellitus. Patients with rare hereditary problems of galactose intolerance e.g. galactosaemia, the Lapp lactase deficiency or glucose-galactose malabsorption should not take MENIVERT 24 mg TABLETS.

INTERACTIONS

There are no studies on the interactions with the following medicines: vasodilators, psychotropic medicines, in particular sedatives, tranquillisers and neuroleptics, parasympatholytics, and vitamins.

MENIVERT 24 mg TABLETS should not be concomitantly administered with antihistamines.

MENIVERT 24 mg TABLETS metabolism may be inhibited by medications that inhibit

monoamine-oxidase (MAO) including MAO subtype B (e.g. selegiline). Caution is recommended when using MENIVERT 24 mg TABLETS and MAO inhibitors (including MAO-B selective) concomitantly.

HUMAN REPRODUCTION

The safety of MENIVERT 24 mg TABLETS during pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

The usual daily dose is 24 mg to 48 mg of MENIVERT 24 mg TABLETS in divided doses. One 24 mg tablet can be administered twice daily.

The dosage should be individually adapted according to the response.

MENIVERT 24 mg TABLETS are not recommended for use in children and adolescents below the age of 18 years due to a lack of data on safety and efficacy.

SIDE EFFECTS

MENIVERT 24 mg TABLETS can cause the following side effects:

Immune system disorders

Frequency unknown: Hypersensitivity reactions, e.g. anaphylaxis

Nervous system disorders

Frequent: Headache

Less frequent: Head pressure

Frequency unknown: Occasional drowsiness

Cardiac disorders

Less frequent: Palpitations, tightness of the chest

Respiratory, thoracic and mediastinal disorders

Less frequent: Exacerbation of pre-existing bronchial asthma

Gastrointestinal disorders

Frequent: Nausea, dyspepsia

Less frequent: Retching, heartburn, gastric discomfort and pain, flatulence

Gastric disorders can normally be avoided by taking MENIVERT 24 mg TABLETS with or after a meal, or by reducing the dosage.

Skin and subcutaneous tissue disorders

Frequency unknown: Cutaneous and subcutaneous hypersensitivity reactions, in particular angioneurotic oedema, urticaria rash, and pruritus

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

In case of overdose, the following symptoms, analogous to histamine overdose, might occur: headache, redness of the face, vertigo, tachycardia, hypotension, bronchial spasm, oedema, in particular oedema of the mucosa of the upper respiratory tract (Quincke's oedema).

Treatment

There is no specific antidote to MENIVERT 24 mg TABLETS.

IDENTIFICATION

MENIVERT 24 mg TABLETS are white, round, flat tablets with bevelled edges, breakline on one side. The tablets can be divided into equal halves.

PRESENTATION

20 tablets are packed in a polyvinylchloride, polyethylene, polyvinylidene chloride film sealed with aluminium foil backing. There are 10 tablets per blister strip and two blister strips are packed into an outer cardboard carton.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

46/5.6/0960

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

PHARMACARE LIMITED

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