

VERGO 16



1. Product Name

Vergo 16, 16 mg, tablet.

2. Qualitative and Quantitative Composition

Each tablet contains 16 mg of betahistine dihydrochloride.

For the full list of excipients, see section 6.1.

3. Pharmaceutical Form

White, approximately 8.5 mm, round, flat bevel edged tablet marked 'BH' breakline '16' on one side and breakline on the reverse.

The tablet can be halved.

4. Clinical Particulars

4.1 *Therapeutic indications*

Ménière's syndrome as defined by the following core symptoms:

- vertigo (with nausea/vomiting)
- hearing loss (hardness of hearing)
- tinnitus

4.2 *Dose and method of administration*

Dose

The recommended starting dose is 8-16 mg taken three times a day. The maximum recommended daily dose is 48 mg.

The tablets may be taken with or without food. However, if gastrointestinal upset occurs, it is recommended that the tablets be taken with meals.

The dosage should be individually adapted according to the response. Improvement can sometimes only be observed after a couple of weeks of treatment.

4.3 *Contraindications*

Vergo 16 (betahistine dihydrochloride) tablets are contraindicated as follows:

- during pregnancy and lactation
- in children less than 18 years
- in patients suffering from phaeochromocytoma

- in patients with active peptic ulcer or a history of this condition
- in patients with hypersensitivity to any component of the product (see section 6.1).

4.4 Special warnings and precautions for use

Patients with bronchial asthma need to be carefully monitored during therapy.

Caution should be taken in the treatment of patients receiving antihistamines (see section 4.5).

Use in children

Due to lack of clinical experience, betahistine dihydrochloride should not be used in children less than 18 years (see section 4.3).

4.5 Interaction with other medicines and other forms of interaction

In vitro data indicate an inhibition of betahistine metabolism by medicines that inhibit monoamine-oxidase (MAO) including MAO subtype B (e.g. selegiline). Caution is recommended when using betahistine and MAO inhibitors (including MAO-B selective) concomitantly.

An antagonism between Vergo 16 and antihistamines could be expected on a theoretical basis. However, no such interactions have been reported.

4.6 Fertility, pregnancy and lactation

Pregnancy

Category B2

Betahistine dihydrochloride should not be used during pregnancy (see section 4.3) since there is insufficient data on the use of this drug during pregnancy to evaluate possible harmful effects.

Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of foetal damage.

Breast-feeding

Betahistine dihydrochloride should not be used during lactation (see section 4.3).

Fertility

Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of foetal damage.

4.7 Effects on ability to drive and use machines

Betahistine is presumed to be safe or unlikely to produce an effect on the ability to drive or use machinery.

4.8 Undesirable effects

Most of the reported adverse reactions pertain to the skin, gastrointestinal tract, body as a whole, nervous system, respiratory system and cardiovascular system.

Events are listed within body systems and categorised by frequency according to the following definitions:

Common (frequency ≥ 1 and $<10\%$)

Uncommon (frequency $\geq 0.1\%$ and $<1\%$)

Rare (frequency $\geq 0.01\%$ and $<0.1\%$)

Very rare (frequency $<0.01\%$)

Skin and subcutaneous tissue disorders: *Rare:* various types of rash, pruritis and urticaria/angioneurotic oedema. These reactions are probably related to the histamine like structure of betahistine.
There was a single case of Stevens Johnson syndrome.

Body as a whole: *Common:* headache
Rare: tiredness and malaise.

Gastrointestinal system: *Common:* nausea and dyspepsia
Rare: vomiting, diarrhoea, abdominal distension, bloating and epigastric pain have been reported. These symptoms were usually mild.
Gastrointestinal disturbances may be relieved by reducing the dose or by taking betahistine with meals.

Nervous system: *Rare:* dizziness
Very rare: convulsions, somnolence, confusion and hallucinations. Some of these symptoms may also be observed as part of the disease condition and are usually resolved without changes to the treatment schedule.
Patients with neurological events usually presented with confounding factors.

Cardiovascular system: *Very rare:* vasodilation, postural hypotension and tachycardia.

Respiratory system: *Very rare:* dyspnoea, asthma and bronchospasms (see section 4.4)

Immune system disorders Hypersensitivity reactions, e.g. anaphylaxis have been reported

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://nzphvc.otago.ac.nz/reporting/>.

4.9 Overdose

Symptoms: There have been a few cases of overdosage reported. Although in most cases no overdose symptoms were reported, some patients have experienced mild to moderate symptoms of overdosage including nausea, dry mouth, epigastric pain and sleepiness at doses above 200 mg. A case of convulsion was reported at a dose of 728 mg. In all cases recovery was complete.

Treatment: Treatment should include standard supportive measures.

For further advice on management of overdose please contact the National Poisons Information Centre (0800 POISON or 0800 764 766).

5. Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antivertigo preparation, ATC code: N07CA01

Pharmacodynamic effects

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.

In further animal pharmacological studies, betahistine was found to have weak H₁ receptor agonistic and considerable H₃ antagonistic properties in the CNS and autonomic nervous system. Betahistine was also found to have a dose dependent inhibiting effect on spike generation of neurons in lateral and medial vestibular nuclei. The importance of this observation in the action against Ménière's syndrome or vestibular vertigo, however, remains unclear.

5.2 Pharmacokinetic properties

In man, orally administered doses of betahistine dihydrochloride are rapidly and completely absorbed from the gastrointestinal tract. The drug is rapidly metabolised to one major metabolite - 2-pyridylacetic acid - and excreted in the urine. Studies with radio-labelled betahistine have demonstrated a plasma half life of 3.4 hours and a urinary half life of 3.5 hours for the radio-label. Urinary excretion of the label was about 90% complete within 24 hours of administration.

5.3 Preclinical safety data

Not applicable.

6. Pharmaceutical Particulars

6.1 List of excipients

Vergo 16 tablet also contains:

- Cellulose microcrystalline
- Mannitol
- Talc
- Colloidal anhydrous silica
- Citric acid monohydrate

Vergo 16 is gluten and lactose free.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at or below 25°C, protect from light.

6.5 Nature and contents of container

PP bottles of 100 tablets.

PVC, PVdC blister packs of 25 tablets and 84 tablets.

Not all pack types or pack sizes may be marketed.

6.6 Special precautions for disposal

Not applicable.

7. Medicines Schedule

Prescription Medicine

8. Sponsor Details

Mylan New Zealand Ltd
PO Box 11183
Ellerslie
AUCKLAND
Telephone 0800 579 811

9. Date of First Approval

04 May 2000

10. Date of Revision of the Text

13 July 2020

Section	
4.6	Relocated fertility data from section 4.4.
6.1	Re-organized excipient list.
8	Updated sponsor contact number.