

For Relief of Vertigo and Equilibrium Disturbances

# Merislon<sup>®</sup> Tablets




(Betahistine Mesilate Preparation)

## DESCRIPTION

### 1. Composition

Each white plain tablet contains 6 mg of betahistine mesilate. It also contains hydrated silicon dioxide, microcrystalline cellulose, calcium stearate, talc, low substituted hydroxypropylcellulose and hydroxypropylcellulose as inactive ingredients.

### 2. Product description

Brand name	Dosage form and identification code	Appearance			Description
		Face	Reverse	Lateral	
MERISLON Tablets (6 mg)	Plain tablets				White
	<b>E 150</b>	Diameter (mm) 6.1	Weight (mg) 84	Thickness (mm) 2.4	

## INDICATIONS

Vertigo and dizziness associated with the following diseases:

- Meniere's disease
- Meniere's syndrome
- Peripheral vertigo

## DOSAGE AND ADMINISTRATION

The usual adult dosage for oral use is 1 - 2 tablets (6 - 12 mg of betahistine mesilate), three times daily after meals. The dosage may be adjusted depending on the patient's age and symptoms.

## PRECAUTIONS

### 1. Careful Administration (MERISLON should be administered with care in the following patients.)

- (1) Patients with a history of peptic ulcer or with an active peptic ulcer [Since MERISLON has a histamine-like action, it may enhance gastric acid secretion through the intervention of H<sub>2</sub>-receptors.]
- (2) Patients with bronchial asthma [Since MERISLON has a histamine-like action, it may cause respiratory tract contraction through the intervention of H<sub>1</sub>-receptors.]
- (3) Patients with pheochromocytoma [Since MERISLON has a histamine-like action, it may cause an increase in blood pressure due to adrenaline hypersecretion.]

### 2. Adverse Reactions

Adverse reactions were reported in 26 of 2,254 patients (1.15 %). (Post marketing clinical investigation)

	5% > ≥0.1%
Gastrointestinal	Nausea/vomiting
Hypersensitivity <sup>note</sup>	Rash

Note) In the event of such symptoms, appropriate measures including discontinuation of MERISLON should be taken.

### 3. Use in the Elderly

Since the elderly often have a physiological hypofunction, it is advisable to take measures, such as reduction in dosage under careful supervision.

### 4. Use during Pregnancy, Delivery or Lactation

MERISLON should only be used in pregnant women or women suspected of being pregnant, if the expected therapeutic benefits are evaluated to outweigh the possible risk of treatment.

[The safety of MERISLON in pregnant women has not been established.]

### 5. Pediatric Use

The safety in children has not been established (insufficient clinical experience).

### 6. Precautions concerning Use

Caution in handing over drug

For drugs that are dispensed in a press-through package (PTP), patients should be instructed to remove the drugs from the package prior to use. [Swallowing the PTP sheet by mistake has been reported to cause puncture in the esophageal mucosa due to sharp corners of the sheet, resulting in perforation and in serious complications such as mediastinitis.]

## 7. Drug Interactions

It is not known whether Merislon Tablets can cause clinically significant interactions with other drugs.

## CLINICAL STUDIES

### Clinical efficacy

In clinical trials on a total of 875 patients including double blind clinical trials it has been demonstrated that MERISLON is useful for relieving dizziness or feeling of dizziness associated with Meniere's disease, Meniere's syndrome or vertigo, etc.

## PHARMACOLOGY

### 1. Improvement of circulatory disturbances in the inner ear

In the inner ear of the guinea pig with experimentally induced microcirculatory disturbances, the blood flow increases to 148% of the control level within 30 min after the intraperitoneal injection of betahistine mesilate. This effect is specific for pathological conditions.

### 2. Increase of blood flow in the scala media of guinea pigs with endolymphatic hydrops

When betahistine mesilate was administered to guinea pigs with endolymphatic hydrops, it produced a significant increase in blood flow in the scala media. The blood flow increased significantly from 5.5 mL/min/100 g to 8.1 mL/min/100 g. It is considered that the increase in blood flow is due to relaxation of smooth muscle of the cochlear radial arteria.

### 3. Improvement of intracerebral blood flow

In the experiment in rhesus monkeys betahistine mesilate after intravenous administration increases blood flow in the cerebral and cerebellar tissues from 70.4 to 81.4 mL/100 g/min and 73.2 to 84.0 mL/100 g/min, respectively

## PHYSICOCHEMISTRY

**Nonproprietary name:** Betahistine Mesilate (JAN)

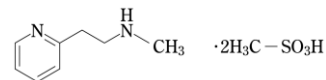
Betahistine (INN)

**Chemical name:** N-Methyl-2-pyridin-2-ylethylamine dimethanesulfonate

**Molecular formula:** C<sub>8</sub>H<sub>12</sub>N<sub>2</sub> · 2CH<sub>4</sub>O<sub>3</sub>S

**Molecular weight:** 328.41

**Structural formula:**



Description: Betahistine mesilate occurs as white crystals or crystalline powder. It is very soluble in water, freely soluble in acetic acid (100) and sparingly soluble in ethanol (99.5). It is soluble in dilute hydrochloric acid. It is hygroscopic. Melting point: 110–114°C (after desiccation)

## STORAGE AND HANDLING

1. Preserve in moisture-proof containers since Merislon Tablets are hygroscopic.
2. Merislon Tablets should be used before the expiration date stated on the package.

## Packaging

1000 Tablets (100x 10's)

## MANUFACTURER

Eisai Co., Ltd. Kawashima Plant

1, Kawashimatakehaya-machi, Kakamigahara-shi, Gifu-ken, Japan

## Date of PI revision:

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