

# BETANOR TABLET

Betahistine Dihydrochloride 16mg & 24mg

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### 1. What is BETANOR used for

BETANOR contains betahistine. It is used to treat:

- vertigo (with nausea/vomiting)
  - hearing loss (hardness of hearing)
  - tinnitus (ringing in the ear).
- Symtomatic treatment of vestibular vertigo.

### 2. How BETANOR works

Betahistine dihydrochloride is a specific histamine agonist with virtually no H<sub>2</sub>-activity. This medicine works by improving blood flow in the inner ear and thus lowering the buildup of pressure.

### 3. Before you use BETANOR

*When you must not take it*

If you are hypersensitivity to the active substance or to any of the excipients. If you have high blood pressure due to an adrenal tumour (phaeochromacytoma)

*Before you start to take it.*

Tell your doctor

- If you have a stomach ulcer
- If you have asthma
- If you are pregnant or planning to become pregnant
- If you are breast-feeding.

If any of the above applies to you, talk to your doctor before taking this medicine. Your doctor will tell you whether it is safe for you to start taking this medicine.

### *Taking other medicines*

There is no known interaction between BETANOR and other medicines. If you notice any unwanted effects tell your doctor or pharmacist.

## 4. How to take BETANOR

*How much to take it*

Adults (including the elderly):  
8 -16 mg three times daily taken preferably with meals. Maintenance doses are generally in the range 24-48 mg daily. Betahistine is not recommended for children below 18 years. No dosage adjustment is needed for the elderly, patients with renal or hepatic disorders.

*When to take it*

Take the tablet with or after a meal.

*How long to take it*

Keep taking your tablets until your doctor tells you to stop. Even when you start feeling better, your doctor may want you to carry on taking the tablets for some time to make sure that the medicine has worked completely.

*If you forget to take it*

If you miss a tablet, wait until the next dose is due. Do not try to make up for the dose you have missed.

*If you take too much (overdose)* If you take too much of BETANOR, contact your doctor or go to the nearest hospital immediately.

## 5. While you are using BETANOR

*Things you must do*

If any of the side effects become serious, or if you notice any side effects that are not listed in this leaflet, please tell your doctor or pharmacist.

*Things you must not do*

Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not stop taking Betahistine, or change the dosage, without checking with your doctor.

*Things to be careful of*

Your doctor may want to monitor your asthma while you take BETANOR.

## 6. Side effect

Allergic reaction such as swelling of your face, lips, tongues or neck. Headache, itching, rash, hives, mild gastric complaints such as vomiting, stomach pain and bloating. Taking BETANOR with food can help reduce any stomach problems. If any of the side effects that are not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumer→Reporting)

## 7. After using BETANOR

*Storage*

Store below 30°C

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## Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## Date of Revision

July 2014

## 8. Product description

### *What it looks like*

#### BETANOR 16MG TABLET:

A white to off white round shaped tablet with breaking line on one side with a diameter of 9mm.

#### BETANOR 24MG TABLET:

A white to off white round shaped tablet with breaking line on one side with a diameter of 10mm.

## Ingredients

- Active ingredient  
Betahistine dihydrochloride
- Inactive ingredients  
Citric acid monohydrate  
Mannitol  
Purified water  
Microcrystalline cellulose  
Colloidal silicone dioxide  
Talc

## Product Registration No.

BETANOR 16MG TABLET

**MAL NO:**

BETANOR 24MG TABLET

**MAL NO:**

## 9. **Manufacturer and Product registration holder**

Noripharma Sdn. Bhd  
Lot 5030, Jalan Teratai,  
5 ½ Mile Off Jalan Meru,  
41050 Klang,  
Selangor Darul Ehsan, Malaysia