

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND DOSAGE FORM

DAHIDE 8 mg TABLETS

DAHIDE 16 mg TABLETS

DAHIDE 24 mg TABLETS

Betahistine dihydrochloride

Read all of this leaflet carefully before you start taking DAHIDE TABLETS.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **DAHIDE TABLETS** have been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT DAHIDE TABLETS CONTAIN

The active substance is betahistine dihydrochloride.

DAHIDE 8 mg TABLETS:

Each uncoated tablet contains betahistine dihydrochloride 8 mg.

DAHIDE 16 mg TABLETS:

Each uncoated tablet contains betahistine dihydrochloride 16 mg.

DAHIDE 24 mg TABLETS:

Each uncoated tablet contains betahistine dihydrochloride 24 mg.

The other ingredients of **DAHIDE TABLETS** are cellulose microcrystalline, citric acid, crospovidone, mannitol, povidone, silica colloidal anhydrous, stearic acid and talc.

2. WHAT DAHIDE TABLETS ARE USED FOR

DAHIDE TABLETS are used to treat vertigo (dizziness) associated with Ménière's syndrome.

Vertigo is a condition that causes sufferers to have a sensation of rotation or movement of themselves or their surroundings. **DAHIDE TABLETS** work by improving blood flow in the inner ear. This lowers the build up of pressure.

BEFORE YOU TAKE DAHIDE TABLETS

Do not take DAHIDE TABLETS:

- If you are hypersensitive (allergic) to betahistine dihydrochloride, or any of the other ingredients of **DAHIDE TABLETS**.
- If you have a stomach ulcer.
- If you suffer from phaeochromocytoma (a tumour on the adrenal gland).

Take special care with DAHIDE TABLETS:

- If you have asthma.
- If you have ever had a stomach ulcer.

Taking DAHIDE TABLETS with food:

- **DAHIDE TABLETS** are preferably taken with meals.

Pregnancy and Breast-feeding:

- The safe use of **DAHIDE TABLETS** during pregnancy and breast-feeding has not been determined.

If you are pregnant or breast-feeding your baby, please consult your doctor, pharmacist or other health care professional for advice.

Effects on the ability to drive and use machinery

DAHIDE TABLETS do not appear to make one sleepy or drowsy, so you can drive or operate machinery, if necessary. Please consult your doctor or pharmacist for advice.

Taking other medicines with DAHIDE TABLETS:

- Do not take **DAHIDE TABLETS** together with antihistamine medicines i.e. medicines used for the treatment of allergy.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **DAHIDE TABLETS** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

HOW TO TAKE DAHIDE TABLETS

Always take **DAHIDE TABLETS** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **DAHIDE TABLETS** is too strong or too weak, talk to your doctor or pharmacist. Do not share medicines prescribed for you with any other person.

- **Adults (including the elderly):**
 - **DAHIDE TABLETS** are preferably taken with meals.
 - Dosage is determined according to the individual patient's response. Depending on the severity of your complaints, your doctor will determine the necessary dose for the treatment of your disease.
 - The usual starting dose is 16 mg three times a day.
 - Thereafter, the usual recommended dose is 24 – 48 mg daily, taken in divided doses.
- **Children:**

- **DAHIDE TABLETS** should not be used in children.

If you take more DAHIDE TABLETS than you should:

- The symptoms of overdose include nausea, vomiting and headache. Low blood pressure may occur.
- Treatment may include emptying the stomach.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take DAHIDE TABLETS:

- Do not take a double dose to make up for forgotten individual doses.

5.POSSIBLE SIDE-EFFECTS

DAHIDE TABLETS can have side-effects.

Get emergency medical help immediately if you have any of these **signs of an allergic reaction**:

- Difficulty breathing; swelling of your face, lips, tongue, or throat.
- A red skin rash, inflamed itchy skin; hives

Other side-effects include: Headache, itching, rash, hives, mild gastric complaints such as vomiting, stomach pain and bloating. Taking **DAHIDE TABLETS** during meals or lowering the dose can help reduce any stomach problems.

Tell your doctor as soon as possible if any of the above side-effects are severe, bothersome, do not go away or about any concerns you have while taking **DAHIDE TABLETS**.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **DAHIDE TABLETS**, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF DAHIDE TABLETS

Store at or below 25 °C (room temperature).

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

Keep the containers tightly closed.

Store all medicines out of the reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF DAHIDE TABLETS

DAHIDE 8 mg TABLETS:

Blister Pack:

Tablets are packed in blister packs (composed of OPA / aluminum foil /PVC film and printed aluminium foil). Each blister contains 10 tablets.

Pack size: 30's – Each carton contains 3 blisters of 10 tablets each.

HDPE Container Pack:

Tablets are packed in 40 ml HDPE containers with polypropylene closures with induction sealing wad, containing cotton coil. Each container contains 30 tablets.

Pack size: 30's - One HDPE container contains 30 tablets.

DAHIDE 16 mg TABLETS:

Blister Pack:

Tablets are packed in blister packs (composed of OPA / aluminum foil / PVC film and printed aluminium foil). Each blister contains 10 tablets.

Pack size: 30's – Each carton contains 3 blisters of 10 tablets each.

HDPE Container Pack:

Tablets are packed in 40 ml HDPE containers with polypropylene closures with induction sealing wad, containing cotton coil. Each container contains 30 tablets.

Pack size: 30's - One HDPE container contains 30 tablets.

DAHIDE 24 mg TABLETS:

Blister Pack:

Tablets are packed in blister packs (composed of OPA / aluminum foil / PVC film and printed aluminium foil). Each blister contains 10 tablets.

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

HDPE Container Pack:

Tablets are packed in 40 ml HDPE containers with polypropylene closures with induction sealing wad, containing cotton coil. Each container contains 30 tablets.

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

8. IDENTIFICATION OF DAHIDE TABLETS

DAHIDE 8 mg TABLETS:

White to off-white round, flat, uncoated tablets debossed with 'X' on one side and '87' on the other side.

DAHIDE 16 mg TABLETS:

White to off-white round, uncoated tablets, debossed with 'X' and a break line on one side and '88' on the other side.

DAHIDE 24 mg TABLETS:

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

REGISTRATION NUMBER

DAHIDE 8 mg TABLETS: 45/5.6/0574

DAHIDE 16 mg TABLETS: 45/5.6/0575

DAHIDE 24 mg TABLETS: 45/5.6/0576

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Aurogen South Africa (Pty) Ltd

Woodhill Office Park, Building 1,

Applicant: Aurogen South Africa (Pty) LTD
Product Name: DAHIDE 8mg,16mg and 24mg .

Dosage form and strength: Each uncoated tablet contains betahistine dihydrochloride
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