APPROVED PROFESSIONAL INFORMATION

SCHEDULING STATUS

S3

PROPRIETARY NAME (and dosage form)

DAHIDE 8 mg TABLETS

DAHIDE 16 mg TABLETS

DAHIDE 24 mg TABLETS

COMPOSITION

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 inactive pharmaceutical ingredients of the formulation are cellulose microcrystalline, mannitol, povidone, crospovidone, anhydrous citric acid, colloidal anhydrous silica, talc, and stearic acid.

PHARMACOLOGICAL ACTION

Pharmacodynamics:

The mechanism of action 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.

Betahistine was found to have weak H_1 receptor agonistic and considerable H_3 antagonistic properties in the autonomic nervous system and CNS in pharmacological studies. Betahistine was also found to have a dose dependent inhibiting effect on spike generation of neurons in lateral and

medial vestibular nuclei. However, the importance of this observation in the action against Ménière's syndrome or vestibular vertigo remains unclear.

Pharmacokinetics:

After oral administration, betahistine is completely absorbed. Only one metabolite, 2-pyridyl-acetic acid which is excreted in the urine, is known.

INDICATIONS

DAHIDE TABLETS are indicated for the symptomatic treatment of the vertigo associated with Ménière's syndrome

CONTRA-INDICATIONS

Hypersensitivity to any of the ingredients.

Patients with active peptic ulcer.

Patients with phaeochromocytoma.

WARNINGS AND SPECIAL PRECAUTIONS:

Warnings

DAHIDE TABLETS should be administered with caution to patients with bronchial asthma as clinical intolerance has been shown in relatively few patients. Caution is advised in patients with a history of peptic ulcers.

Special precautions:

Caution should be taken in the treatment of asthmatic patients and patients with a history of peptic ulcer.

Concomitant use with anti-histamines should be avoided (see "**INTERACTIONS**").

Effects on the ability to drive and use machines

On the basis of the pharmacodynamics profile and reported adverse reactions (see "**SIDE EFFECTS**"), **DAHIDE TABLETS** have no or negligible effects on the ability to drive and use machines

INTERACTIONS

Concomitant use with antihistamines should be avoided (See **"Special Precautions"**).

PREGNANCY AND LACTATION

There is insufficient data on the use of this medicine during pregnancy and lactation.

Therefore **DAHIDE TABLETS** should not be used during pregnancy and lactation.

DOSAGE AND DIRECTIONS FOR USE

Adults (including the elderly): Initially 16 mg three times daily taken preferably with meals. Maintenance doses are generally in the range of 24 to 48 mg daily, in divided doses.

DAHIDE 8 mg TABLETS	**DAHIDE 16 mg TABLETS**	**DAHIDE 24 mg TABLETS**
1 – 2 tablets 3 times/day	$^1/_2$ – 1 tablet 3 times/day	1 tablet 2 times/day

The dosage should be individually adapted according to the response.

Children: No dosage recommendations are made for children

SIDE-EFFECTS

DAHIDE TABLETS may cause the following side effects:

Immune System Disorders:

Less frequent: Hypersensitivity reactions e.g. anaphylaxis

Nervous system disorders:

Less frequent: Headache.

Gastrointestinal disorders:

Frequent: Gastro-intestinal disturbances. These can normally be dealt with by lowering the dose or by taking the dose during meals.

Skin and subcutaneous tissue disorders:

Less frequent: Cutaneous hypersensitivity reactions have been reported, in particular rash, pruritis and urticaria.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

See **SIDE EFFECTS** and **WARNINGS AND SPECIAL PRECAUTIONS**. The most common symptoms are nausea, vomiting and headache. Hypotension may occur. There is no specific antidote. Treatment may include stomach emptying by inducing emesis or by lavage. Further treatment is symptomatic and supportive.

IDENTIFICATION

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.

PRESENTATION

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.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Do not remove the blisters from the carton until required. Keep the containers tightly closed.

KEEP OUT OF REACH OF CHILDREN.

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

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

Aurogen South Africa (Pty) Ltd

Woodhill Office Park, Building 1,

53 Phillip Engelbrecht Avenue

Meyersdal, Ext. 12, 1448

Johannesburg

South Africa

DATE OF PUBLICATION OF THE PACKAGE INSERT

Date of registration:

6 March 2014

Date of revision:

13 March 2023