PACKAGE LEAFLET

Package leaflet: Information for the patient

Betahistine Sandoz® 8 mg, tabletten
Betahistine Sandoz® 16 mg, tabletten
Betahistine Sandoz® 24 mg, tabletten

betahistinedihydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet
1. What {[nationally completed name]} is and what it is used for
2. What you need to know before you take {[nationally completed name]}
3. How to take {[nationally completed name]}
4. Possible side effects
5. How to store {[nationally completed name]}
6. Contents of the pack and other information

1. What {Nationally completed name} is and what it is used for
{Nationally completed name} contains the active substance betahistine that is similar to histamine, a substance which occurs naturally in the human body.

{Nationally completed name} is used to treat **Ménière's syndrome**, a disorder characterised by symptoms which may include:
- dizziness - often associated with feeling sick and/or vomiting
- ringing in the ears
- hearing loss

2. What you need to know before you take {Nationally completed name}

Do not take {Nationally completed name}
- if you are allergic to betahistine dihydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from a tumour of the adrenal gland (phaeochromocytoma)

Warnings and precautions
Talk to your doctor or pharmacist before taking {Nationally completed name}
- if you have or have ever had a stomach ulcer (peptic ulcer). Treatment with {Nationally completed name} can cause dyspepsia.
- if you suffer from a chronic disease of the respiratory tract (bronchial asthma)
- if you suffer from hives, skin rashes or allergic rhinitis – your symptoms may worsen when taking {Nationally completed name}
- if you have very low blood pressure
- if you are concomitantly taking other medicines used to treat allergies or colds – so called antihistamines (see also section‘Other medicines and {nationally completd name}).

Children and adolescents
{Nationally completed name} is **not recommended** for children and adolescents under 18 years, because of insufficient data on safety and efficacy.

Other medicines and {Nationally completed name}
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:
- Monoamine-oxidase inhibitors (MAOIs) - used to treat depression or Parkinson’s disease. These may increase the exposure of {[Nationally completed name]}.
- Anti-histamines - used to treat allergies or colds
  These may in theory lower the effect of {Nationally completed name} and vice versa.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Do not take {Nationally completed name} if you are pregnant unless your doctor has decided that it is necessary. It is not known if {Nationally completed name} passes into breast milk. Therefore, do not breast-feed while using {Nationally completed name} unless instructed by your doctor.

Driving and using machines
Ménière’s syndrome can negatively affect the ability to drive and use machines. In clinical studies specifically designed to investigate the ability to drive and use machines, betahistine had no or negligible effects. However, {Nationally completed name} may cause drowsiness which can affect the ability to drive and use machines.

3. How to take {Nationally completed name}
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for adults is
Your doctor will individually adapt your dose according to your response.

{Nationally completed name} 8 mg tablets
1 to 2 tablets, 3 times daily

{Nationally completed name} 16 mg tablets
½ to 1 tablet, 3 times daily
The tablet can be divided into equal doses

{Nationally completed name} 24 mg tablets
The initial daily dose is 24 mg. Lower strengths of this medicine are available to achieve this.
The maintenance dose is 1 to 2 tablets daily. If the maximum dose is required, take 1 tablet in the morning and 1 tablet in the evening.
The tablet can be divided into equal doses.

Use in children and adolescents
{Nationally completed name} is not recommended for those under 18 years old.

Method of use
{Nationally completed name}.is for oral use. Take the tablets with one glass of water during or directly after meals.

Duration of use
Your doctor will tell you how long to take {Nationally completed name}. Usually it is a long-term treatment. Improvement can sometimes only be observed after a couple of weeks. Best results are sometimes obtained after a few months.

If you take more {Nationally completed name} than you should
If you have taken too many tablets (an overdose), you may have a dry mouth, feel sick (nauseous), vomit, have digestion problems, coordination problems, feel sleepy or have stomach pain. You may even experience fits in case you took a high amount of tablets. Talk to a doctor or go to a hospital immediately. Take the {[Nationally completed name]} pack with you.

If you forget to take {Nationally completed name}
If you forget to take a dose, take it as soon as you remember. If it is almost time to take the next dose, wait until then and carry on as normal. Do not take a double dose to make up for a forgotten tablet.

If you stop taking {Nationally completed name}
Do not stop taking {Nationally completed name} before your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking {Nationally completed name} immediately and contact your doctor at once or go to the nearest hospital if you experience any of the following symptoms of a serious side effect called angioneurotic oedema (not known: frequency cannot be estimated from the available data):

- Swelling of your face, lips, tongue or neck
- Red or lumpy skin rash or inflamed itchy skin
- Drop in your blood pressure
- Loss of consciousness
- Difficulty breathing

You may experience any of the other reported side effects listed below according to the frequencies:
Common: may affect up to 1 in 10 people

- Headaches
- Nausea
- Indigestion

Rare: may affect up to 1 in 1,000 people

- Rapid heart beat or tightness of the chest
- An existing bronchial asthma could be worsened
- Retching, heartburn, gastric discomfort and pain, flatulence

Not known: frequency cannot be estimated from the available data

- Drowsiness
- Vomiting
- Allergic reactions
- Cutaneous and subcutaneous hypersensitivity reactions, such as rash, pruritus and urticaria

Special notice:
Please ask your doctor for appropriate measures if you notice any of the above side effects.
Stomach disorders can be avoided by taking {Nationally completed name} during or after meals or by reducing the dose.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist**.** This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store {[Nationally completed name]}

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the (bottle) label, blister and carton after EXP. The expiry date refers to the last day of that month.

After first opening of the bottle: 70 days

This medicine does not require any special storage conditions

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What {[Nationally completed name]} contains

Betahistine Sandoz 8 mg, tabletten
- The active substance is betahistine dihydrochloride.
Each tablet contains 8 mg betahistine dihydrochloride.
- The other ingredients are citric acid anhydrous, microcrystalline cellulose (PH-102), mannitol, colloidal anhydrous silica and talc.

Betahistine Sandoz 16 mg, tabletten
- The active substance is betahistine dihydrochloride.
Each tablet contains 16 mg betahistine dihydrochloride.
- The other ingredients are citric acid anhydrous, microcrystalline cellulose (PH-102), mannitol, colloidal anhydrous silica and talc.

Betahistine Sandoz 24 mg, tabletten
- The active substance is betahistine dihydrochloride.
Each tablet contains 24 mg betahistine dihydrochloride.
- The other ingredients are citric acid anhydrous, microcrystalline cellulose (PH-102), mannitol, colloidal anhydrous silica and talc.

What {[Nationally completed name]} looks like and contents of the pack
Betahistine Sandoz 8 mg, tabletten
White colour, round and flat uncoated tablet plain on both sides.
Diameter: approximately 7 mm

Betahistine Sandoz 16 mg, tabletten
White colour, round and biconvex uncoated tablet scored on one side with embossing “I” on the either sides of the score and plain in the other side.
Diameter: approximately 8.7 mm

Betahistine Sandoz 24 mg, tabletten
White colour, round and biconvex uncoated tablet scored on one side with the embossing "II" on either sides of the score and plain on the other side.

Diameter: approximately 10 mm

{[Nationally completed name]} is packed in PVC/PVDC/Al foil blisters or in HDPE bottle with a PP screw closure with an induction seal liner.

[NL/H/3700]
Pack size
Blister packs: 10, 20, 30, 40, 50, 60, 80, 90, 100, 120 tablets
Bottle packs: 100, 120 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Houder van de vergunning voor het in de handel brengen
Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Nederland

Fabrikant
Santa, Str. Carpaţilor nr. 60, obiectiv nr. 47, 48, 58, 133, 156,
Braşov, Jud.
Braşov, cod 500269,
Romania

In het register ingeschreven onder:
Betahistine Sandoz 8 mg, tabletten is geregistreerd onder RVG 118840
Betahistine Sandoz 16 mg, tabletten is geregistreerd onder RVG 118842
Betahistine Sandoz 24 mg, tabletten is geregistreerd onder RVG 118843

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Nederland:	Betahistine Sandoz 8 mg, tabletten
	Betahistine Sandoz 16 mg, tabletten
	Betahistine Sandoz 24 mg, tabletten
België:	Betados 8 mg tabletten
	Betados 16mg tabletten
	Betahistine Sandoz 24 mg tabletten
Bulgarije:	ВЕРТОТРИТ 16 mg таблетки
	ВЕРТОТРИТ 24 mg таблетки
Tsjechië:	Betahistin Sandoz 8 mg
	Betahistin Sandoz 16 mg
	Betahistin Sandoz 24 mg
Duitsland:	Betahistin HEXAL 8 mg Tabletten
	Betahistin HEXAL 16 mg Tabletten
	Betahistin HEXAL 24 mg Tabletten
Estland:	Betahistidine Sandoz

Frankrijk:	Bétahistine GNR 8 mg, comprimé
	Bétahistine GNR 24 mg, comprimé
Litouwen:	Betahistine Sandoz 8 mg tabletės
	Betahistine Sandoz 16 mg tabletės
	Betahistine Sandoz 24 mg tabletės
Letland:	Betahistine Sandoz 8 mg tabletes
	Betahistine Sandoz 16 mg tabletes
	Betahistine Sandoz 24 mg tabletes
Portugal:	Beta-histina Teclave (16 mg)
	Beta-histina Sandoz (24mg)
Roemenië:	Betahistina Sandoz 8 mg comprimate
	Betahistina Sandoz 16 mg comprimate
	Betahistina Sandoz 24 mg comprimate
Slovenië:	Betahistin Sandoz 8 mg tablete
	Betahistin Sandoz 16 mg tablete
	Betahistin Sandoz 24 mg tablete
Slovakije:	Betahistin Sandoz 8 mg
	Betahistin Sandoz 16 mg
	Betahistin Sandoz 24 mg

Deze bijsluiter is voor het laatst goedgekeurd in februari 2024.