PATIENT INFORMATION LEAFLET FOR

BETAHISTINE 24 UNICORN

SCHEDULING STATUS

S3

BETAHISTINE 24 UNICORN tablets

Betahistine hydrochloride

Contains sugar (mannitol 61,80 mg)

Read all of this leaflet carefully before you start taking BETAHISTINE 24 UNICORN.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- BETAHISTINE 24 UNICORN has 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.

What is in this leaflet

1. What BETAHISTINE 24 UNICORN is and what it is used for.
2. What you need to know before you take BETAHISTINE 24 UNICORN.
3. How to take BETAHISTINE 24 UNICORN.
4. Possible side effects.
5. How to store BETAHISTINE 24 UNICORN.
6. Contents of the pack and other information.

1. What BETAHISTINE 24 UNICORN is and what it is used for

Betahistine, as in BETAHISTINE 24 UNICORN is similar to histamine, a substance which is found

naturally in the human body. Betahistine works by improving blood flow in the inner ear. This lowers the build-up of pressure.

BETAHISTINE 24 UNICORN is used to treat dizziness (vertigo) associated with Ménière's disease

2. What you need to know before you take BETAHISTINE 24 UNICORN

Do not take BETAHISTINE 24 UNICORN

- If you are hypersensitive (allergic) to betahistine dihydrochloride or any of the other ingredients of BETAHISTINE 24 UNICORN (listed in section 6).
- If you have a tumour (phaeochromocytoma). This may cause high blood pressure.

Warnings and precautions

Take special care with BETAHISTINE 24 UNICORN:

- If you have a stomach ulcer,
- If you have asthma,
- If you have an allergic reaction causing skin rashes and/or swelling of the skin.
- If you have severe low blood pressure.
- If you have been diagnosed with porphyria (an inherited disorder of blood pigment metabolism).
- If you are taking other medicines used to treat allergies or colds called antihistamines. If BETAHISTINE 24 UNICORN and these medications are used at the same time, the effects of both medicines may be reduced. If you are currently taking an antihistamine, your doctor will slowly reduce the dose over about 6 days before you can start using BETAHISTINE 24 UNICORN.

Children and Adolescents: BETAHISTINE 24 UNICORN should not be used by children and adolescents below the age of 18 years.

Other medicines and BETAHISTINE 24 UNICORN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

- Monoamine-oxidase inhibitors (MAOIs) (medicines used to treat depression or Parkinson's disease).
- Antihistamines (medicines used for allergies or colds).

Taking BETAHISTINE 24 UNICORN with food and drink

BETAHISTINE 24 UNICORN may cause mild stomach disorders such as vomiting, stomach pain and discomfort and bloating. These side effects can be avoided by taking BETAHISTINE 24 UNICORN after a meal.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Do not take BETAHISTINE 24 UNICORN if you are pregnant.

It is not known if BETAHISTINE 24 UNICORN passes into breast milk, therefore you should not take BETAHISTINE 24 UNICORN if you are breastfeeding your baby.

Driving and using machines

BETAHISTINE 24 UNICORN may cause drowsiness.

It is not always possible to predict to what extent BETAHISTINE 24 UNICORN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which BETAHISTINE 24 UNICORN affects them.

3. How to take BETAHISTINE 24 UNICORN

Do not share medicines prescribed for you with any other person.

Always take BETAHISTINE 24 UNICORN exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is 24 mg to 48 mg (one to two tablets) of BETAHISTINE 24 UNICORN daily in divided doses.

Your doctor will adjust your dose according to your response.

Your doctor will tell you how long your treatment with BETAHISTINE 24 UNICORN will last. If you have the impression that the effect of BETAHISTINE 24 UNICORN is too strong or too weak, tell your doctor or pharmacist.

If you take more BETAHISTINE 24 UNICORN than you should

If you use more tablets than you should, the following symptoms may occur due to overdose: headache, redness of the face, dizziness, faster heartbeat, low blood pressure, breathing difficulties due to constriction of the lungs (bronchial asthma), and swelling, especially of the surface of the upper airways due to water retention.

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

Take this leaflet and the rest of the remaining BETAHISTINE 24 UNICORN with you so the doctor will know what you have taken.

If you forget to take BETAHISTINE 24 UNICORN

If you forget to take a dose of BETAHISTINE 24 UNICORN, take the next dose at the usual time. Do not take a double dose to make up for forgotten individual doses.

If you stop taking BETAHISTINE 24 UNICORN

You should not stop taking BETAHISTINE 24 UNICORN before discussing it with your doctor.

4. Possible side effects

BESTHISTINE 24 UNICORN can have side effects. Not all side effects reported for BETAHISTINE 24 UNICORN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BETAHISTINE 24 UNICORN, please consult your health care provider for advice.

If any of the following happens, stop taking BETAHISTINE 24 UNICORN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- An allergic reaction, such as breathing difficulty; swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- An inflamed itchy skin rash with swelling.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BETAHISTINE 24 UNICORN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- fast heartbeat, tightness of the chest;
- worsening of your existing bronchial asthma.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

<u>Frequent side effects:</u>

- headache;
- nausea, indigestion

<u>Less frequent side effects</u>:

- A feeling of pressure in your head;
- retching (make the sound and movement of vomiting), heartburn, stomach discomfort and pain, flatulence.

Side effects with an unknown frequency:

- Occasional drowsiness;
- Skin rashes and itching.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.

Side effects can also be reported Unicorn Pharmaceuticals (Pty) Ltd at vigilance@unicornpharma.co.za.

By reporting side effects, you can help provide more information on safety BETAHISTINE 24 UNICORN

5. How to store BETAHISTINE 24 UNICORN

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Keep the blister strips in the outer carton until required for use.
- Do not use after the expiry date printed on the blister or carton.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What BETAHISTINE 24 UNICORN contains

BETAHISTINE 24 UNICORN: Each tablet contains 24 mg betahistine dihydrochloride.

The other ingredients are citric acid, mannitol, microcrystaline cellulose, colloidal anhydrous silica and talc.

What BETAHISTINE 24 UNICORN looks like and contents of the pack

BETAHISTINE 24 UNICORN: White colour, round & biconvex uncoated tablet scored on one side with the embossing "II" on either sides of the score and plain on the other side.

Pack size: 20 tablets

Blister pack

The tablets are packed in PVC/PVDC/Al foil blisters, which is standard pharmaceutical packaging. The blister pack comprises 25 µm hard temper lidding foil and 250 µm clear PVC film with 120gsm clear PVdC coating.

HDPE pack

Round white opaque high density polyethylene bottle with a polypropylene screw closure with an induction seal liner containing tablets.

Holder of certificate of registration

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8001

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