PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

ZYVENTI 24 mg tablets

Betahistine dihydrochloride

Contains sugar alcohol

(Each tablet contains 22,5 mg mannitol.)

Read all of this leaflet carefully before you start taking ZYVENTI.

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

What is in this leaflet

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

1. What ZYVENTI is and what it is used for

ZYVENTI contains the active ingredient betahistine dihydrochloride, which is a histamine analogue. ZYVENTI is used for the treatment of the symptoms of Ménière's syndrome, which is a disease affecting the inner ear characterised by ringing in the ears, nausea (feeling sick), dizziness and

progressive hearing loss.

2. What you need to know before you take ZYVENTI

Do not take ZYVENTI

- If you are hypersensitive (allergic) to betahistine dihydrochloride or any of the other ingredients of ZYVENTI listed in section 6 of this leaflet.
- If you suffer from a tumour of the adrenal gland (pheochromocytoma).

Warnings and precautions

Tell your doctor before taking ZYVENTI:

- If you have ulcers of the stomach or intestine or have had them in the past.
- If you suffer from asthma.
- If you suffer from hives, skin rashes, or allergic rhinitis (runny or blocked nose caused by allergies), as your symptoms may get worse.
- If you have low blood pressure.
- If you suffer from porphyria (an inherited disorder of blood pigment metabolism).
- If you are taking other medicines used to treat allergies or colds (antihistamines).

Children and adolescents

Safety and efficacy of ZYVENTI have not been established in children and adolescents under the age of 18 years and should therefore not be given to these patients.

Other medicines and ZYVENTI

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

Tell your doctor or pharmacist before you take ZYVENTI if you are taking:

- Antihistamines (medicines for the treatment of allergies) or cold medicines containing antihistamines. If ZYVENTI and these medicines are used at the same time, the effects of both

medicines may be reduced.

- A monoamine oxidase inhibitor (MAOI) (used to treat depression or Parkinson's disease).

Pregnancy and breastfeeding

The safety of ZYVENTI during pregnancy and whilst breastfeeding has not been established.
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 ZYVENTI.

Driving and using machines

ZYVENTI may cause side effects, such as drowsiness. Do not drive a vehicle or operate machinery until you know how ZYVENTI affects you.

3. How to take ZYVENTI

Do not share medicines prescribed for you with any other person.
Always take ZYVENTI exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Adults

The usual dose is 24 mg to 48 mg (one to two tablets) daily, divided into two equal doses.
Your doctor will adjust your dose according to your response.

Swallow the tablets with water.
Take the tablet with or after a meal. Taking ZYVENTI with food can help reduce stomach problems.

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

If you take more ZYVENTI than you should

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

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre.

If you forget to take ZYVENTI

If you forget to take a dose, take it as soon as you remember unless it is nearly time to take your next dose. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

ZYVENTI can have side effects.

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

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

- swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ZYVENTI. 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:

- changes in the way your heart beats (beating faster or slower) or chest pain.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache;
- nausea (feeling sick), indigestion.

Less frequent side effects:

- head pressure;
- worsening of existing asthma;
- vomiting (being sick), stomach pain or swelling, feeling bloated, gagging.

The following side effects have been reported with an unknown frequency:

- feeling drowsy;
- skin rashed 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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8

By reporting side effects, you can help provide more information on the safety of ZYVENTI.

5. How to store ZYVENTI

- Store at or below 25 °C.
- Keep the blister strips in the outer carton until required for use.

- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton or blister strips.
- 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 ZYVENTI contains

The active substance in ZYVENTI is betahistine dihydrochloride. Each tablet contains 24 mg betahistine dihydrochloride.

The other ingredients are citric acid (anhydrous), colloidal silica (anhydrous), magnesium stearate (E572), mannitol, microcrystalline cellulose (E460a) and talc (E553b).

What ZYVENTI looks like and contents of the pack

Off-white to cream white, round, flat faced, bevelled edge, uncoated tablet with median line on one side and plain on the other side.
The median line is only to facilitate identification of the tablet and not to divide ZYVENTI into equal halves.

Aluminium/PVC/OPA and aluminium foil blister strips placed in an outer carton.
Pack size: 20 tablets.

Holder of certificate of registration

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