PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

ZYGOVERT 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 ZYGOVERT.

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

1. What ZYGOVERT is and what it is used for

ZYGOVERT contains the active ingredient betahistine dihydrochloride, which is a histamine analogue.

ZYGOVERT 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 ZYGOVERT

Do not take ZYGOVERT

- If you are hypersensitive (allergic) to betahistine dihydrochloride or any of the other ingredients of ZYGOVERT 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 ZYGOVERT:

- 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 ZYGOVERT 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 ZYGOVERT

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 ZYGOVERT if you are taking:

- Antihistamines (medicines for the treatment of allergies) or cold medicines containing

antihistamines. If ZYGOVERT 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 ZYGOVERT 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 ZYGOVERT.

Driving and using machines

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

3. How to take ZYGOVERT

Do not share medicines prescribed for you with any other person.
Always take ZYGOVERT 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 ZYGOVERT with food can help reduce stomach problems.

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

If you take more ZYGOVERT 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 ZYGOVERT

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

ZYGOVERT can have side effects.

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

If any of the following happens, stop taking ZYGOVERT 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 ZYGOVERT. 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 ZYGOVERT.

5. How to store ZYGOVERT

- 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 ZYGOVERT contains

The active substance in ZYGOVERT 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 ZYGOVERT 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 ZYGOVERT 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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