PATIENT PACKAGE INSERT IN ACCORDANCE WITH
THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Zomig® 2.5 mg

Film-coated Tablets

Composition:
Each film-coated tablet contains:
Zolmitriptan 2.5 mg

For inactive ingredients, please see section 6 - "Further Information".
Please also see section 2 – "Important information about some of the ingredients of the medicine".

Read this leaflet carefully in its entirety before using the medicine.
This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

This medicine is not recommended for children and adolescents under 18 years of age and for adults over 65 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

Treatment of migraine with or without aura.

Therapeutic group:
Triptans, selective serotonergic $5HT_1$ agonist ($5HT_1$ agonists).

Migraine symptoms may be caused by swollen blood vessels in the head. Zomig is reducing the widening of these blood vessels. This helps to reduce the headache and other symptoms of a migraine attack, such as nausea or vomiting and being sensitive to light and sound.

Zomig works only when a migraine attack has started. It will not stop you from getting an attack.

2. BEFORE USING THE MEDICINE

X Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient Zolmitriptan or to any of the other ingredients contained in the medicine (please see section 6).
- you suffer from high blood pressure.
- you suffer or have suffered in the past from heart problems, including myocardial infarction (heart attack), angina pectoris (chest pain caused by exercise or effort), Prinzmetal's angina (chest pain which happens at rest) or you have experienced heart-related symptoms such as shortness of breath or pressure over the chest.
- you suffer from a peripheral vascular disease.
- you suffered from a stroke or from transient signs similar to a stroke (transient ischemic attack).
- you are concomitantly using any other medicine for migraine (such as ergotamine or ergot-type medicines such as dihydroergotamine and methysergide) or other triptan-type medicines for the treatment of migraine (please see "Drug interactions" for further information).

Do not take Zomig if any of the condition above apply to you. If you are not sure, consult the doctor or pharmacist before taking Zomig.

! Special warnings regarding use of this medicine

Before treatment with Zomig, tell the doctor if:

- You are at risk of getting ischemic heart disease (poor blood flow in the arteries of the heart). The risk is greater if you smoke, have high blood pressure, high levels of cholesterol, diabetes or have a family history of ischemic heart disease.
- You have been told that you suffer from Wolff-Parkinson-White syndrome (abnormal heart rate).
- You suffered in the past from liver problems.
- You have headaches that are not similar to your regular migraines.
- If you are taking a medicine to treat depression (please see "Drug interactions" for further information).

If you go into hospital tell the medical staff you are taking Zomig.

Zomig is not recommended for adults aged over 65.

Children and adolescents

Zomig is not recommended for use in children and adolescents under 18 years of age.

As with other migraine treatments, using too much Zomig can cause daily headaches or can make your migraine headaches worse. Ask your doctor if you think that this is the case for you. You may need to stop taking Zomig to correct the problem.

! Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

Medicines for treatment of migraine:

- If you take a triptan other than Zomig (such as sumatriptan, naratriptan), wait a period of 24 hours before taking Zomig.
- After taking Zomig, wait a period of 24 hours before taking other medicines from the triptans group.
- If you are taking ergotamine or ergot-type medicines (e.g., dihydroergotamine or methysergide), wait a period of 24 hours before taking Zomig.
- After taking Zomig, wait a period of 6 hours before taking ergotamine or its derivatives.

Medicines for depression:

- Medicines from the MAO (Mono Amine Oxidase) inhibitors group e.g., moclobemide.
- Medicines from the SSRIs group (selective serotonin reuptake inhibitors) such as fluoxetine, paroxetine, fluvoxamine or sertraline.
- Medicines from the SNRIs group (serotonin norepinephrine reuptake inhibitors) such as venlafaxine or duloxetine.
  Serotonin syndrome is a rare, life-threatening condition that has been reported in some patients who took Zomig in combination with so called serotoninergic medicines (e.g. certain medicines for the treatment of depression). Signs of serotonin syndrome may be agitation, restlessness, fever, excessive sweating, tremor, uncoordinated movement of limbs or eyes, uncontrollable jerking of muscles, twitching and muscle rigidity. Your doctor may advise you on this.

Additional medicines:

- Cimetidine (for indigestion or stomach ulcer).
- An antibiotic from the quinolones group (e.g., ciprofloxacin).

You should not take the herbal remedy *Hypericum perforatum* (St. John's Wort) at the same time you take Zomig. If you already take this herbal remedy, stop taking it and mention this to your doctor at your next visit.

! Use of the medicine and food

The tablet may be taken with or without food. It does not affect the way this medicine works.

! Pregnancy, breastfeeding and fertility

It is not known whether use of Zomig during pregnancy is harmful. If you are pregnant or breastfeeding, think you may be pregnant or planning a pregnancy, tell the doctor or pharmacist before using Zomig.

! Driving and use of machinery

During a migraine attack, your reactions may be slower than usual. Bear this in mind when you drive or use tools or machines.
Use of this medicine is not supposed to impair your ability to drive or operate machinery. However, it may make you feel sleepy. Wait to see how Zomig affects you before performing these activities.

! Important information about some of the ingredients of the medicine

Each Zomig 2.5 mg tablet contains lactose which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Zomig.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen.

You can take this medicine as soon as a migraine headache starts. You can also take it once an attack is underway.

The dosage and treatment regimen will be determined by the doctor only. The recommended dosage is usually:
One tablet (2.5 mg).
Swallow the tablet with a glass of water.

Do not exceed the recommended dose.

Duration of treatment
If the migraine does not pass after two hours, or if it returns within 24 hours, you can take another tablet.
If the tablets are not having an effect, tell the doctor, who may decide to change the treatment.
Do not chew, crush or halve the tablets!

Do not use more than the dose prescribed for you by your doctor.

- Do not take more than two tablets in one day unless prescribed to by your doctor.
- The maximum daily dose is 10 mg.

If you accidentally took a higher dosage or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forget to take the medicine
Do not take a double dose to make up for a forgotten dose.

Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Zomig may cause side effects in some users. Do not

be alarmed by the list of side effects. You may not suffer from any of them.

Stop taking the medicine and refer to the doctor immediately if you experience any of the following side effects:

Rare side effects (may occur in up to 1 in every 1,000 patients):

- Hypersensitivity (allergic) reactions, including urticaria (rash accompanied with itching), and swelling of the face, lips, mouth, tongue and neck.

Very rare side effects (may occur in up to 1 patient in every 10,000 patients):

- angina (chest pains, often brought on by exercise), myocardial infarction (heart attack), narrowing of the blood vessels of the heart. Symptoms may include chest pain and shortness of breath.
- narrowing of the blood vessels of the intestines, which can cause damage to your intestines. Signs may include bloody diarrhea or abdominal pain.
- bleeding in the brain or a stroke.

Additional side effects:

Common side effects (may occur in up to 1 in every 10 patients):

These effects are usually mild and pass after a short time.

- abnormal sensations such as tingling in the fingers and toes or sensitivity of the skin to touch.
- feeling sleepy, dizzy or warm.
- headaches.
- abnormal heartbeat.
- nausea or vomiting.
- abdominal pains.
- dry mouth.
- muscle weakness or muscle pain.
- weakness.
- feeling of heaviness, narrowing, pressure or pain in the throat, neck, arms or legs or chest.
- difficulty swallowing.

Uncommon side effects (may occur in up to 1 in every 100 patients):

- very fast heart rate.
- Slightly higher blood pressure.

- increase in the frequency of urination or quantity of urine.

Very rare side effects (may occur in up to 1 patient in every 10,000 patients):

- Sudden urgent need to pass water (urine).

If a side effect appears, if any of the side effects worsen or when you experience side effects not mentioned in this leaflet, consult the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il
In addition, side effects may be reported to the Patient Safety Unit of the license holder by sending an email message to:
drugsafety@neopharmgroup.com

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store in the original pack.
- Store below 25° C.
- Do not dispose medicines via household waste. Ask the pharmacist how to dispose medicines you no longer need.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Lactose anhydrous, microcrystalline cellulose, sodium starch glycollate type A, magnesium stearate.
Coating:

yellow color concentrate OY-22906 (Opadry) [hydroxypropyl methylcellulose, titanium dioxide, polyethylene glycol (400), yellow iron oxide], polyethylene glycol (8000)

What the medicine looks like and the contents of the package:
Zomig 2.5 mg film-coated tablets are yellow, round, and marked with the letter "Z" on one side.
The medicine is packed in blisters of 2, 3, 6 or 18 tablets .
Not all pack sizes may be marketed.

License holder and address: Neopharm (Israel) 1996 Ltd., 6 HaShiloach st., POB 7063, Petach Tikva.

Manufacturer and address:
Grünenthal GmbH, Zieglerstraße 6, 52078, Aachen, Germany.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 108-67-29181-00

Revised in January 2025.

Zomig FCT PIL vr 01A