

**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

Tablets

Composition:

Each tablet contains:

Zolmitriptan 2.5 mg

For inactive ingredients, please see section 6 - "Further Information".

Read this leaflet carefully in its entirety before using the medicine.

Keep this leaflet; you may need it again.

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 5HT₁ agonist (5HT₁ agonists).

2. BEFORE USING THE MEDICINE

X Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine.
- you suffer from high blood pressure that is difficult to treat.
- you suffer from an ischemic heart disease or from a coronary heart disease (poor blood flow in the arteries of the heart), including myocardial infarction (heart attack), angina pectoris (chest pain caused by exercise or effort) or you have experienced heart-related symptoms such as shortness of breath or pressure over the chest.
- you suffer from a certain type of chest pain known as Prinzmetal's angina.
- you suffer from a peripheral vascular disease.
- you suffered from a stroke or from signs similar to a stroke, that passed within one or two days (transient ischemic attack), or problems with blood circulation or if you suffer from hemiplegic and basilar migraines due to a high risk of stroke.
- you suffer from an ischemic bowel disease.
- you are concomitantly using any other medicine for migraine, including other medicines that belong to the same group (5HT₁ agonists) and ergotamine or preparations from the ergot group.
- you are using medicines from the MAO inhibitors group to treat depression or other conditions (in the past two weeks).

! Special warnings regarding use of this medicine

Before beginning treatment with Zomig, tell the doctor if:

- You are pregnant, are trying to become pregnant or are breastfeeding.
- You suffered in the past from impaired function of the heart, including chest pains, myocardial infarction (heart attack) or Wolff-Parkinson-White syndrome (abnormal heart rate).
- You suffered in the past from hypertension.
- You suffered in the past from a stroke or from signs similar to a stroke, that passed within one or two days (transient ischemic attack) {see section "When should the medicine not be used"}.
- You have been told that you have an increased risk of heart disease. The risk is greater if you smoke, are at the age of menopause, if you have high blood pressure, high levels of cholesterol, diabetes, are overweight, or have a family history of heart disease or stroke.
- You suffered in the past from impaired liver function.

- You have headaches that are not similar to your regular migraines.
- You are sensitive to any food or medicine.
- As with other medicines to treat migraines, overuse of Zomig may cause daily headaches or may make your migraines worse. Ask the doctor if you think this is the case. You may need to stop using Zomig to correct the problem.
- If you are taking a medicine to treat depression (see "If you are taking other medicines").

¶ If you are taking other medicines

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:

Other medicines for treatment of migraine:

- Other medicines belonging to the same group (5HT₁ agonists).
- Wait a period of 24 hours after taking other medicines from the triptans group (sumatriptan, naratriptan) and taking Zomig 2.5 mg; similarly, wait a period of 24 hours after taking Zomig 2.5 mg and taking other medicines from the triptans group.
- Ergotamine or preparations from the ergot group (e.g., dihydroergotamine or methysergide). Wait a period of at least 24 hours between taking ergotamine or its derivatives and taking Zomig 2.5 mg and alternatively, wait a period of at least 6 hours between taking Zomig 2.5 mg and taking ergotamine preparations or its derivatives.

Medicines for depression:

- Medicines from the MAO inhibitors group to treat depression, e.g., moclobemide.
- Medicines from the SSRIs group (selective serotonin reuptake inhibitors) such as fluoxetine, fluvoxamine, paroxetine and sertraline.
- Medicines from the SNRIs group (serotonin norepinephrine reuptake inhibitors) such as venlafaxine or duloxetine.

Additional medicines:

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

Hypericum perforatum (St. John's Wort).

Use of the medicine and food

The tablet may be taken with or without food.

Pregnancy and breastfeeding

It is not known whether use of Zomig during pregnancy is harmful. Before using Zomig, tell the doctor if you are pregnant or trying to become pregnant.

Before using Zomig, tell the doctor if you are breastfeeding.

Driving and use of machinery

Use of this medicine is not supposed to impair patient ability to drive or operate machinery. However, take into account that sleepiness may occur. Wait to see how Zomig affects you before performing these activities.

During a migraine attack, your reactions may be slower than usual. Bear this in mind when you drive or use tools or machines.

Important information about some of the ingredients of the medicine

Each tablet contains 100 mg lactose.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain. The dosage and treatment regimen will be determined by the doctor only. Do not exceed the recommended dose.

Recommended dosage, unless instructed otherwise by the doctor:

One tablet (2.5 mg) as soon as the migraine starts. If the migraine does not pass after two hours, or if it returns within 24 hours, 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! Swallow the tablets with water.

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.

How can you contribute to the success of the treatment?

- It is recommended to take a tablet immediately upon occurrence of the first signs of the migraine. If you cannot do so, take as soon as you can, since the efficacy of the preparation is not impaired at any stage at which it is taken.
- 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.

Side effects that require special attention - stop taking the medicine and refer to the doctor immediately in the following cases:

If you experience chest pains, stop taking Zomig until you have consulted your doctor.

Some people can have a reaction called serotonin syndrome, which may be life-threatening when using Zomig. This may occur when concomitantly using Zomig with medicines from the SSRIs or SNRIs group. Symptoms include mental changes (hallucinations, anxiety, coma), fast heartbeat, changes in blood pressure, high body temperature or sweating, tight muscles, difficulty walking, nausea, vomiting and diarrhea. Refer to the doctor immediately if you experience any of these effects.

Rare side effects (occur in 1-10 patients in 10,000):

- hypersensitivity reactions, including urticaria (rash accompanied with itching), angioedema (swelling of the mouth, tongue and neck, with fluid in the tissues), and anaphylactic reactions (a type of serious allergic reaction). If swelling around the mouth occurs, seek immediate medical attention.
- high blood pressure.
- bleeding in the brain or strokes.

Very rare side effects (occur in less than one patient in 10,000):

As with other preparations of this type (5HT₁ agonists):

- angina (chest pains), 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 (symptoms may include bloody diarrhea or abdominal pain).
- when using medicines from the triptans group (selective serotonergic 5HT₁ agonist) to treat a migraine, transient or permanent blindness has been reported, as well as significant partial vision loss. Loss of vision may be part of the migraine attack, therefore, it is not clear if these effects are necessarily associated with use of medicines from this group.

Additional side effects:

Common side effects (between 1 and 10 patients in 100):

- nausea,
- vomiting,
- abdominal pains,
- dizziness,
- drowsiness,
- tiredness,
- feeling warm or cold,
- weakness,
- dry mouth,
- headaches,
- palpitations (abnormal heartbeat),
- feeling of heaviness, pressure or pain in the throat, neck, jaw, chest, arms or legs,
- muscle aches and pain or weakness,
- abnormal sensations such as tingling in the fingers and toes or sensitivity of the skin to touch,
- difficulty swallowing.

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

Uncommon side effects (occur in 1-10 patients in 1000):

- tachycardia (fast heart rate),
- short-term increase in blood pressure,
- increase in the frequency of urination and quantity of urine.

In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult the doctor immediately.

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 of children and/or infants in order to avoid poisoning.
- Even when packaged/stored as recommended, medicines may be kept for a limited period only. 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. In any case of doubt, consult the pharmacist who dispensed this medicine to you.
- Store below 25°C.
- Do not induce vomiting without an explicit instruction from the doctor!
- **Do not give this medicine to your relatives, neighbors or acquaintances.**
- Do not store different medicines in the same package.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Lactose anhydrous, microcrystalline cellulose, sodium starch glycollate type A, magnesium stearate, polyethylene glycol (400 and 8000), hydroxypropyl methylcellulose, titanium dioxide, yellow iron oxide.

What the medicine looks like and the contents of the package:

Zomig 2.5 mg tablets are yellow, round, biconvex and marked with the letter "Z" on one side.

License holder and address: AstraZeneca (Israel) Ltd., P.O.B. 4070 Ra'anana 4366241.

Manufacturer and address: AstraZeneca UK Limited, Macclesfield, UK.

This leaflet was checked and approved by the Ministry of Health in March 2015.

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