

1.5.5.4 FINAL PATIENT INFORMATION LEAFLET

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ZOMIG 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.

SCHEDULING STATUS: S 4**PROPRIETARY NAME (and Dosage Form):****Zomig® 2,5; Zomig® 5; Zomig Rapimelt® (Tablet)**

The active substance is zolmitriptan.

1. WHAT ZOMIG CONTAINS:

Each ZOMIG tablet contain either 2,5 mg or 5 mg zolmitriptan.

The other ingredients are:

Hypromellose, iron oxide (yellow – 2,5 mg tablet, red – 5 mg tablet), lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium starch glycollate and titanium dioxide.

Each ZOMIG RAPIMELT tablet contains 2,5 mg zolmitriptan.

The other ingredients are:

Aspartame, anhydrous citric acid, anhydrous colloidal silica, crospovidone, magnesium stearate, mannitol, microcrystalline cellulose, orange flavour and sodium hydrogen carbonate.

2. WHAT ZOMIG IS USED FOR:

ZOMIG belongs to a group of medicines called 5HT₁ agonists which are used to treat migraines. ZOMIG is used to treat migraine when it happens. It should not be used to prevent migraine attacks from happening.

3. BEFORE YOU TAKE ZOMIG:

Do not take ZOMIG

- If you are allergic to zolmitriptan or any of the other ingredients of ZOMIG.
- If you have high blood pressure that is difficult to treat.
- If you have ischaemic or coronary heart disease (poor blood flow in the arteries of the heart), or if you suffer from a particular type of chest pain known as Prinzmetal's angina, or if you have ever been told that you may have an increased risk of heart disease.
- If you have been told that you have Wolff-Parkinson-White Syndrome.
- If you have problems with your liver.
- In pregnancy and breastfeeding.
- If you are younger than 18 years.
- If you are older than 65 years.

Take special care with ZOMIG

- If you have a history of problems with your heart, including angina, heart attack or a history of cerebral bleeding, stroke or high blood pressure.
- If you have phenylketonuria (ZOMIG RAPIMELT tablets contain aspartame, which is a source of phenylalanine).
- If you are taking any other medicine for your migraine or for treatment of depression, such as fluoxetine and other SSRIs (selective serotonin reuptake inhibitors) and SNRIs (serotonin norepinephrine reuptake inhibitors).

Pregnancy and breastfeeding

Before taking ZOMIG tell your doctor if you are pregnant, trying to become pregnant or if you are breastfeeding.

If you are pregnant or breastfeeding your baby while taking ZOMIG, please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machinery

ZOMIG is unlikely to affect your ability to drive or to operate machinery but it could cause you to become sleepy. You should wait to see how a ZOMIG tablet affects you before you try these activities.

Important information about some of the ingredients of ZOMIG

ZOMIG RAPIMELT tablets contain phenylalanine, which may cause a problem in a small number of patients who have phenylketonuria.

ZOMIG Tablets contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Taking other medicines with ZOMIG

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of ZOMIG with these medicines may cause undesirable interactions.

Please consult your doctor, pharmacist or other health care professional for advice.

If you are taking any of the following medicines tell your doctor, pharmacist or other health care professional:

- Medicines of the same type as ZOMIG (5HT₁ agonists/serotonin agonists/triptans).
- Medicines containing ergotamine or ergot-type medicines (like dihydroergotamine or methysergide). You should allow 24 hours after taking these medicines and taking ZOMIG and allow 6 hours after taking ZOMIG before taking ergotamine or ergot-type medicines.

Medicines for treatment of depression:

- Medicines called MAO-A inhibitors such as moclobemide.
- Medicines called SSRIs (selective serotonin reuptake inhibitors) such as fluoxetine, paroxetine, sertraline, fluvoxamine.

- Medicines called SNRIs (serotonin norepinephrine reuptake inhibitors) such as venlafaxine and duloxetine.

Other medicines:

- Cimetidine (for treatment of indigestion or stomach ulcers).
- Quinolone antibiotics such as ciprofloxacin.

4. HOW TO TAKE ZOMIG:

Always take ZOMIG exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

If you have the impression that the effect of ZOMIG is too strong or too weak, talk to your doctor or pharmacist.

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

ZOMIG can be taken at any stage of a migraine attack but should ideally be taken at the first signs of the migraine attack.

The usual dose is one ZOMIG 2,5 tablet as soon as you feel your migraine start.

ZOMIG 2,5 or 5 tablets should be swallowed whole with water.

After 2 hours if your migraine is still present, or if it returns within 24 hours, take another tablet.

If these tablets did not give you enough help with your migraine, tell your doctor, who may wish to change your treatment.

If ZOMIG works well for you, you should expect to see relief from your migraine within two hours. You should not use more than 10 mg of ZOMIG in a day (that is not more than 4 ZOMIG 2,5 or 2 ZOMIG 5 tablets).

ZOMIG RAPIMELT can be taken if you suffer from nausea or if you are unable to drink liquid during a migraine attack. The tablet should be placed on the tongue where it dissolves.

The blister pack in which the ZOMIG RAPIMELT is stored should be peeled open as shown on the foil and the tablet should not be pushed through the foil.

If you take more ZOMIG than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre. Try to remember to take your tablets with you.

5. POSSIBLE SIDE-EFFECTS:

ZOMIG can have side-effects.

Not all side-effects reported for ZOMIG are included in this leaflet. Should your general health worsen while taking ZOMIG, please consult your doctor, pharmacist or other health care professional for advice.

Frequent side-effects are:

Stomach pain

Feeling sick

Vomiting

Dizziness

Headache

Sleepiness

Feeling warm

Feeling weak

Dry mouth

Feelings of heaviness, tightness, pain or pressure in the throat, neck, chest, arms or legs

Muscle aches and pains

Tingling in the fingers and toes

Increased sensation of touch to the skin

Difficulty in swallowing

Palpitations (irregular heart beat)

Less frequent side-effects are:

Tachycardia (fast heart rate)

A temporary increase in blood pressure

Increase in production of urine or in the frequency of urination

Allergic (hypersensitivity) reactions, including urticaria (hives/welts) and angioedema (swelling of the mouth, tongue or neck) or severe allergic reactions (anaphylaxis).

Angina (severe pain in the chest)

Spasm of the blood vessels of the heart

Myocardial infarction (heart attack)

Bloody diarrhoea

Spasm of the blood vessels of the gastro-intestinal tract and spleen with possible serious restriction of blood flow.

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

6. STORING AND DISPOSING OF ZOMIG:

Keep all medicines out of the reach and sight of children.

Store at or below 30 °C.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF ZOMIG:

ZOMIG 2,5 mg and 5 mg tablets are available in blister packs containing 6 or 18 tablets.

ZOMIG RAPIMELT tablets are available in blister packs containing 6 tablets.

8. IDENTIFICATION OF ZOMIG:

ZOMIG 2,5:

Round, biconvex, yellow film-coated tablets. The tablets are plain on one side and intagliated with a 'Z' on the other side.

ZOMIG 5:

Round, biconvex, pink film-coated tablets. The tablets are plain on one side and intagliated with a 'Z' on the other side.

ZOMIG RAPIMELT:

White, flat faced, round, bevelled edge tablets, intagliated with the letter "Z" on the one side.

9. REGISTRATION NUMBERS:

ZOMIG 2,5: 32/7.3/0478

ZOMIG 5: 32/7.3/0479

ZOMIG Rapimelt: 34/7.3/0107

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE:


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11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

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