Package leaflet: Information for the patient

Zolmitriptan Sandoz tablet 2,5 mg, filmomhulde tabletten
Zolmitriptan Sandoz tablet 5 mg, filmomhulde tabletten

zolmitriptan

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [Nationally completed name] is and what it is used for

[Nationally completed name] contains zolmitriptan and belongs to a group of medicines called triptans.

[Nationally completed name] is used to treat migraine headache in adults aged 18 years and older.

- Migraine symptoms may be caused by the widening of blood vessels in the head. [Nationally completed name] is thought to reduce the widening of these blood vessels. This helps to take away the headache and other symptoms of a migraine attack, such as feeling or being sick (nausea or vomiting) and being sensitive to light and sound.

- [Nationally completed name] works only when a migraine attack has started. It will not stop you from getting an attack.

2. What you need to know before you take [Nationally completed name]

Do not take [Nationally completed name] if you:
- are allergic to zolmitriptan or any of the other ingredients of this medicine (listed in section 6)
- have severely impaired kidney function
- have had a stroke (cerebrovascular accident or CVA) or short-lasting symptoms similar to stroke (transient ischaemic attack or TIA)
- have moderate or severe high blood pressure, or mild high blood pressure that is NOT controlled by medication
- have ever suffered from heart disease, including heart attack, angina (chest pain caused by exercise or effort) or a particular type of chest pain known as Prinzmetal's angina, or have experienced heart related symptoms such as shortness of breath or pressure over the chest
- have had problems with the blood supply to your legs (peripheral vascular disease)
- are taking any other medicine for your migraine such as ergotamine, ergotamine-type medicines (dihydroergotamine, methysergide), or other medicine in the same class as zolmitriptan (i.e. 5-$HT_{1B/1D}$ receptor agonists or triptans, such as sumatriptan, naratriptan or rizatriptan) (see section 'Other medicines and [Nationally completed name]')

Warnings and precautions
Talk to your doctor or pharmacist before taking [Nationally completed name], if you have:
- any of the following risk factors for ischaemic heart disease (poor blood flow in the arteries of the heart):
  - high blood pressure or diabetes
  - high blood levels of cholesterol
  - you smoke
  - a family history of ischaemic heart disease
  - you are a man over 40 years, or a postmenopausal woman
- a particular problem with the way your heart beats (Wolff-Parkinson-White Syndrome) or certain other types of heart rhythm disorders
- kidney or liver problems
- a headache associated with dizziness, difficulty in walking, lack of coordination or weakness in the leg and arm

Please tell your doctor if you are taking any medicine for treatment of depression or the herbal remedy St. John's wort (*Hypericum perforatum*) (see section 'Other medicines and [Nationally completed name]' for further information).

[Nationally completed name] can lead to an increase in blood pressure. If your blood pressure rises too high, you may experience symptoms such as headache, dizziness or ringing in the ears. If this applies to you, you should contact your doctor.

If you take [Nationally completed name] too often, you may get a chronic headache. If this happens, you should contact your doctor as you may have to stop taking these tablets.

Please tell your doctor or pharmacist about your symptoms. Your doctor will decide if you have migraine. **You should only take [Nationally completed name] for a migraine attack. [Nationally completed name]** should not be used to treat headaches that might be caused by other, more serious conditions.

[Nationally completed name] is not recommended for people aged over 65 years. If you are older than 65 years, your doctor will advise whether you can take these tablets.

Children and adolescents
[Nationally completed name] is not recommended for people aged under 18 years.

Other medicines and [Nationally completed name]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do NOT take [Nationally completed name] with certain other migraine medicines i.e.
- other medicines in the same class as zolmitriptan (i.e. 5-$HT_{1B/1D}$ receptor agonists or triptans, for example sumatriptan, naratriptan or rizatriptan).
  If you take triptans other than [Nationally completed name], leave 24 hours before taking [Nationally completed name].
  After taking [Nationally completed name] leave 24 hours before taking triptans other than [Nationally completed name].
- ergotamine-type medicines such as ergotamine, dihydroergotamine or methysergide. You should wait at least 6 hours before taking these medicines after taking [Nationally completed name] and you should allow at least 24 hours between stopping ergotamine-type medicines and starting [Nationally completed name].

Ask your doctor for instructions and the risks about taking these tablets if you are also taking
- medicines for depression:
  - monoamine oxidase (MAO) A inhibitors, such as moclobemide
  - medicines called selective serotonin reuptake inhibitors (SSRIs), such as sertraline, escitalopram, fluoxetine and fluvoxamine
  - medicines called serotonin norepinephrine reuptake inhibitors (SNRIs) such as venlafaxine and duloxetine

Serotonin syndrome is a rare, life-threatening condition that has been reported in some patients who took [Nationally completed name] in combination with so called serotoninergic medicines (e.g. certain medicines for the treatment of depression). Signs of serotonin syndrome may be for example, agitation, tremor, restlessness, fever, excessive sweating, twitching, muscle rigidity uncoordinated movement of limbs or eyes and uncontrollable jerking of muscles. Your doctor may advise you on this.

- cimetidine (for indigestion or stomach ulcers)
- a quinolone antibiotic (such as ciprofloxacin)
- the herbal remedy St. John's wort (*Hypericum perforatum*). Taking this together with [Nationally completed name] may increase the likelihood of side effects. It is recommended that you do not take [Nationally completed name] and St. John's wort at the same time.

Pregnancy and breast-feeding
You must tell your doctor if you are pregnant or are planning to have a baby. If you are pregnant you may take [Nationally completed name] only if your doctor decides it is clearly needed.

If you are breast-feeding, ask your doctor for advice before taking this medicine. You should avoid breast-feeding within 24 hours of taking [Nationally completed name].

Driving and using machines
Migraine itself or treatment with [Nationally completed name] may cause sleepiness in some patients. Dizziness has also been reported in some patients receiving this medicine. If you experience these effects you should check your ability to drive or to operate machinery.

[Nationally completed name] contains lactose

[2.5 mg]
This medicine contains 83 mg of lactose in each film-coated tablet. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

[5 mg]
This medicine contains 167 mg of lactose in each film-coated tablet. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take [Nationally completed name]

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You can take [Nationally completed name] as soon as a migraine headache starts. You can also take it once an attack is underway.

The recommended dose is one 2.5 mg tablet.
Your doctor will have decided which dose is appropriate for you and it is important you take your medicine as your doctor has instructed.

Most migraine attacks are relieved with one dose (one tablet) of [Nationally completed name], but if your migraine is not relieved after a single tablet, DO NOT take a second tablet to treat the same migraine attack, as it is unlikely to be of benefit.

Speak to your doctor if the tablets do not provide sufficient effect against migraine. Your doctor may raise the dose to 5 mg or change your treatment.

If you have ANOTHER migraine attack within 24 hours of the first attack, you can take one further tablet of [Nationally completed name], but do not take more than two tablets in a 24 hour period.
If you have been prescribed the 2.5 mg tablet, the maximum daily dose is 5 mg.
If you have been prescribed the 5 mg tablet, the maximum daily dose is 10 mg.
Always leave at least 2 hours between doses.

Method of use
Swallow your tablet whole with a drink of water.
You can take [Nationally completed name] with or without food. It does not affect the way that [Nationally completed name] works.

If you take more [Nationally completed name] than you should
If you have taken more [Nationally completed name] than prescribed by your doctor, tell your doctor or go to the nearest hospital straight away. Take this medicine with you.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If any of the following happen, stop taking this medicine and contact your doctor immediately.

These are rare serious side effects (may affect up to 1 in 1,000 people):
- allergic reactions sometimes very severe, including swelling of the face, lips, mouth, tongue and throat which may cause difficulty in breathing, speaking or swallowing

These are very rare serious side effects (may affect up to 1 in 10,000 people):
- chest pain, tightness in the chest or throat, shortness of breath or other symptoms consistent with heart attack
- spasm of the blood vessels of the gut, which can cause damage to your gut. You may notice stomach pain or bloody diarrhea.

Other possible side effects

Common: may affect up to 1 in 10 people
- headache
- sensations of pins and needles, increased skin sensitivity
- feeling sleepy, dizzy or warm
- sensations of irregular or rapid heartbeat
- nausea (feeling sick), vomiting, stomach pain
- dry mouth
- muscle weakness or muscle pain
- feeling weak
- heaviness, tightness, pain or pressure in throat, neck, arms and legs or chest
- difficulty in swallowing

Uncommon: may affect up to 1 in 100 people
- rapid heart beat
- slightly higher blood pressure or short-lasting high blood pressure
- increase in the amount of water you pass (urine) or in how often you need to pass water

Rare: may affect up to 1 in 1,000 people
- itchy rash (urticaria)

Very rare: may affect up to 1 in 10,000 people
- sudden, compelling urge to urinate

As with other medicines in this class, there have been very rare reports of heart attack and stroke and most of these events have occurred in patients with risk factors for heart and blood vessel disease (high blood pressure, diabetes, smoking, family history of heart disease or stroke).

Reporting of side effects
If you get any 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 directly via [the national reporting system listed in Appendix V of the QRD template; to be completed nationally]. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Nationally completed name]

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after "EXP". The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [Nationally completed name] contains

- The active substance is zolmitriptan.
  [2.5 mg]
  Each film-coated tablet contains 2.5 mg zolmitriptan.

  [5 mg]
  Each film-coated tablet contains 5 mg zolmitriptan.

- The other ingredients are:
  - *Tablet core:* Anhydrous lactose – *see end of section 2 for further information*, colloidal anhydrous silica, microcrystalline cellulose, crospovidone and magnesium stearate.
  - *Tablet coating:* Hypromellose, hydroxypropylcellulose, macrogol, iron oxide yellow (E 172), iron oxide red (E 172) (5 mg film-coated tablet only), titanium dioxide (E 171) and talc.

What [Nationally completed name] looks like and contents of the pack
[2.5 mg]
Yellow, round, biconvex, film-coated tablets with 'ZMT 2.5' debossed on one side.

[5 mg]
Pink, round, biconvex, film-coated tablets with 'ZMT 5' debossed on one side.

The film-coated tablets are packed in Alu/Alu blisters and inserted in a carton.

NL/H/1907/001+003
Pack sizes: 2, 3, 4, 6, 12 or 18 film-coated tablets.

[NL/H/1908/001+003]
[2.5 mg]:
Pack sizes: 2, 3, 6, 12 or 18 film-coated tablets.
[5 mg]:
Pack sizes: 3, 6, 12 or 18 film-coated tablets.

[NL/H/1909/001+003]
[2.5 mg]:
Pack sizes: 2, 3, 6, 12 or 18 film-coated tablets.
[5 mg]:

Pack sizes: 3, 6, 12 or 18 film-coated tablets.

Marketing Authorisation Holder and Manufacturer
The marketing authorization holder is:
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In het register ingeschreven onder
RVG 106561
RVG 106562

This medicine is authorised in the Member States of the EEA under the following names:
[To be completed nationally]

Deze bijsluiter is voor het laatst goedgekeurd in februari 2024