

Package leaflet: Information for the patient

Zolmitriptan Teva 2.5 mg orodispersible tablets

Zolmitriptan Teva 5 mg orodispersible tablets

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

1. What {Product name} is and what it is used for

{Product name} contains zolmitriptan and belongs to a group of medicines called triptans.

{Product 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. {Product 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.
- {Product 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 {Product name}

Do not take {Product name}

- if you are allergic to zolmitriptan, peanut or soya or to any of the other ingredients of this medicine (listed in section 6).
 - if you have high blood pressure
 - if you have ever had heart problems, including a heart attack, angina (chest pain caused by exercise or effort), Prinzmetal's angina (chest pain which happens at rest) or have experienced heart related symptoms such as shortness of breath or pressure over the chest
 - if you have had a stroke or short-lasting symptoms similar to stroke (transient ischaemic attack or TIA)
 - if you have severe kidney problems
 - if you are at the same time taking some other medicines for migraine (e.g. ergotamine or ergot- type medicines like dihydroergotamine and methysergide) or other triptan medicines for migraine. See section below: 'Other medicines and {Product name}' for further information.

If you are not sure if any of these apply to you, talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor before using {Product name} if:

- you are at risk of getting ischaemic heart disease (poor blood flow in the arteries of the heart). Your risk is greater if you smoke, have high blood pressure, high levels of cholesterol, diabetes or if anyone in your family has ischaemic heart disease
- you have been told that you have Wolff-Parkinson-White Syndrome (a type of abnormal heart beat)
- you have ever had liver problems
- you have headaches which are not like your usual migraine headache
- you are taking any other medicine for treatment of depression (see 'Other medicines and {Product name}' later in this section).

If you go into hospital tell the medical staff you are taking {Product name}.

{Product 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.

{Product name} is not recommended for people aged under 18 years or over 65.

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

Other medicines and {Product name}

Tell your doctor or pharmacist if you are taking, have recently taken any or might take any other medicines. This includes herbal medicines and medicines you buy without prescription.

In particular, tell your doctor if you are taking any of the following medicines:

Medicines for migraine

- If you take triptans other than {Product name}, leave 24 hours before taking {Product name}.
- After taking {Product name} leave 24 hours before taking triptans other than {Product name}.
- If you take medicines containing ergotamine or ergot-type medicines (such as dihydroergotamine or methysergide), leave 24 hours before taking {Product name}.
- After taking {Product name} leave 6 hours before taking ergotamine or ergot-type medicines.

Medicines for depression

- moclobemide or fluvoxamine
- medicines called SSRIs (selective serotonin reuptake inhibitors)
- medicines called SNRIs (serotonin norepinephrine reuptake inhibitors) such as venlafaxine, duloxetine

Serotonin syndrome is a rare, life-threatening condition that has been reported in some patients who took zolmitriptan in combination with so called serotonergic 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.

Other medicines

- cimetidine (for indigestion or stomach ulcers)
- a quinolone antibiotic (such as ciprofloxacin)

If you are using herbal remedies containing St John's Wort (*Hypericum perforatum*), side effects of {Product name} may be more likely to happen.

{Product name} with food and drink

You can take {Product name} with or without food. It does not affect the way that {Product name} works.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- It is not known if taking {Product name} during pregnancy is harmful. Before taking {Product name}, tell your doctor if you are pregnant or trying to become pregnant.
- Do not breast-feed within 24 hours of taking {Product name}.

Driving and using machines

- During a migraine attack your reactions may be slower than usual. Bear this in mind when you drive or use any tools or machines.
- {Product name} is unlikely to affect driving or using tools or machines. However, it is best to wait to see how {Product name} affects you before you try these activities.

{Product name} contains lactose, sucrose and glucose (component of maltodextrin).

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

{Product name} contains aspartame (E951).

2,5 mg tablets

This medicine contains 2 mg aspartame in each orodispersable tablet.

5 mg tablets

This medicine contains 4 mg aspartame in each orodispersable tablet.

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

{Product name} contains soya lecithin.

If you are allergic to peanut or soya, do not use this medicine.

{Product name} contains sodium.

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

3. How to take {Product name}

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

You can take {Product name} as soon as a migraine headache starts. You can also take it once an attack is underway.

- The usual dose is one tablet (either 2.5 mg or 5 mg).
- You can take another tablet if the migraine is still present after two hours **or** if it returns within 24 hours.

If the tablets did not give you enough help with your migraine, tell your doctor. Your doctor may raise the dose to 5 mg or change your treatment.

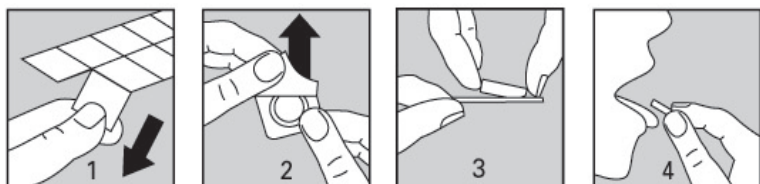
Do not use more than the dose prescribed for you.

- Do not use more than two doses in one day. 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.

You do not have to take your tablet with liquid. The tablet will dissolve directly in your mouth. Put the tablet on your tongue and once it is dissolved swallow it with saliva.

Please follow these steps to remove the tablet from the blister strip:

1. Separate one individual blister cell from the rest of the strip by gently tearing along the perforations around it
2. Peel off the backing
3. Carefully take the tablet out (do not push it out)
4. Put the tablet on your tongue, allow it to dissolve directly in your mouth and swallow it with saliva



If you have liver problems, or are taking certain other medicines your doctor may decide that you need a lower dose.

If you take more {Product name} than you should

If you have taken more {Product name} than prescribed by your doctor, tell your doctor or go to the nearest hospital straight away. Take the {Product name} 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. Some of the symptoms below could be part of the migraine attack itself.

Stop taking {Product name} and contact your doctor straight away if you experience any of the following side effects:

Rare (may affect up to 1 in 1,000 people):

- Allergic/hypersensitivity reactions including lumpy rash (hives), swelling of the face, lips, mouth, tongue or throat; difficulty swallowing or breathing difficulties.

Very rare (may affect up to 1 in 10,000 people):

- Angina (pain in the chest, often brought on by exercise), heart attack or spasm of the blood vessels of the heart. You may notice chest pain or shortness of breath.
- Spasm of the blood vessels of the gut, which can cause damage to your gut. You may notice stomach pain or bloody diarrhoea.

Other side effects that may occur:

Common (may affect up to 1 in 10 people):

- Abnormal sensations such as tingling in your fingers and toes or skin that is sensitive to touch.
- Feeling sleepy, dizzy or warm
- Headache
- Uneven heart beat
- 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):

- Very fast heart beat
- Slightly higher blood pressure
- Increase in the amount of water you pass (urine) or in how often you need to pass water

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](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store {Product 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. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not use this medicine if you notice visible signs of deterioration.

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 {Product name} contains

- The active substance is zolmitriptan.

2.5 mg tablets

- Each orodispersible tablet contains 2.5 mg of zolmitriptan

5 mg tablets

- Each orodispersible tablet contains 5 mg of zolmitriptan

- The other ingredients in the tablet are lactose monohydrate, silica colloidal anhydrous, maize starch, mannitol (E421), croscarmellose sodium, citric acid, sodium hydrogen carbonate, aspartame (E951), magnesium stearate, orange flavour (sucrose, maltodextrin (contains glucose), natural flavours, soya lecithin, silica colloidal anhydrous).

What {Product name} looks like and contents of the pack

{Product name} 2.5 mg orodispersible tablets are white to off-white, round flat-face bevel edged orodispersible tablets, engraved with '93' on one side and '8147' on the other side.

{Product name} 5 mg orodispersible tablets are white to off-white, round flat-face bevel edged orodispersible tablets, engraved with '93' on one side and '8147' on the other side.

Zolmitriptan Teva is supplied in aluminium blisters containing 2, 3, 6, 12 or 18 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area under the following names:

Belgium:	Zolmitriptan Teva Instant 2,5 mg orodispergeerbare tabletten
Germany:	Zolmitriptan-ratiopharm 2,5 mg Schmelztabletten Zolmitriptan-ratiopharm 5 mg Schmelztabletten
Netherlands:	Zolmitriptan disp 2,5 mg PCH, orodispergeerbare tabletten
Spain:	Zolmitriptán Teva 2,5 mg comprimidos bucodispersables EFG Zolmitriptán Teva 5 mg comprimidos bucodispersables EFG
Sweden:	Zolmitriptan Teva 2.5 mg, munsönderfallande tabletter Zolmitriptan Teva 5 mg, munsönderfallande tabletter

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[To be completed nationally]