

Package leaflet: information for the user

Zolmitriptan Sanofi 2.5 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 Zolmitriptan Sanofi is and what it is used for
2. What you need to know before you take Zolmitriptan Sanofi
3. How to take Zolmitriptan Sanofi
4. Possible side effects
5. How to store Zolmitriptan Sanofi
6. Contents of the pack and other information

1. What Zolmitriptan Sanofi is and what it is used for

Zolmitriptan Sanofi contains active substance zolmitriptan and belongs to a group of medicines called triptans.

Zolmitriptan Sanofi is used to **treat migraine attacks** (headache and nausea).

Migraine symptoms may be caused by swollen blood vessels in the head. Zolmitriptan Sanofi reduces 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.

Zolmitriptan Sanofi 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 Zolmitriptan Sanofi

Do not take Zolmitriptan Sanofi if you

- are allergic to zolmitriptan or any of the other ingredients of this medicine (listed in section 6).
- have high blood pressure.
- 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.
- have circulatory problem (restricted blood flow in your legs or arms).
- have had a stroke or short-lasting symptoms similar to stroke (transient ischaemic attack or TIA).

- have severe kidney problem.
- 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 (see section below: 'Other medicines and Zolmitriptan Sanofi ').

Do not take Zolmitriptan Sanofi if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Zolmitriptan Sanofi .

Warnings and precautions

- Talk to your doctor or pharmacist before taking Zolmitriptan Sanofi 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.
- have ever had liver problems.
- have headaches which are not like your usual migraine headache.
- have been told that you have Wolff-Parkinson-White Syndrome (a type of abnormal heart beat).
- are taking any medicine for treatment of depression or herbal remedy called St. John's wort (see section below: 'Other medicines and Zolmitriptan Sanofi ').

Zolmitriptan Sanofi is not recommended for patients under 18 years or over 65.

As with other migraine treatments, using too much Zolmitriptan Sanofi 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 Zolmitriptan Sanofi to correct the problem.

Other medicines and Zolmitriptan Sanofi

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

➤ ***Medicines for migraine***

- If you take a triptan other than Zolmitriptan Sanofi (such as sumatriptan or naratriptan) leave 24 hours before taking Zolmitriptan Sanofi .
- After taking Zolmitriptan Sanofi leave 24 hours before taking another triptan.
- If you take medicines containing ergotamine or ergot-type medicines (such as dihydroergotamine or methysergide), leave 24 hours before taking Zolmitriptan Sanofi .
- After taking Zolmitriptan Sanofi leave 6 hours before taking ergotamine or ergot-type medicines.

➤ ***Medicines for depression***

- Mono-Amine Oxidase Inhibitors, also known as MAOIs (such as moclobemide).
- SSRIs (selective serotonin reuptake inhibitors) such as fluoxetine, paroxetine, fluvoxamine or sertraline.
- SNRIs (serotonin norepinephrine reuptake inhibitors) such as venlafaxine or duloxetine.

➤ ***Other medicines***

- ***Cimetidine*** (for indigestion or stomach ulcers).
- A ***quinolone antibiotic*** (such as ciprofloxacin).
- You should not take the herbal remedy ***St. John's wort (Hypericum perforatum)*** at the same time as this medicine because side effects of Zolmitriptan Sanofi may be more likely to happen. If you already take a St. John's wort preparation, stop taking it and mention this to your doctor at your next visit.

Zolmitriptan Sanofi with food and drink

You can take Zolmitriptan Sanofi with or without food. It does not affect the way that Zolmitriptan Sanofi 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 for advice before taking this medicine.

It is not known if taking Zolmitriptan Sanofi during pregnancy is harmful.

Therefore it should be used during the pregnancy only if the potential benefit to the mother outweighs the potential risk to the unborn child and no other appropriate treatment option is available.

No data exist on the excretion of zolmitriptan into breast milk. Therefore, as a precautionary measure, breast-feeding should be avoided for 24 hours after treatment.

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.

Zolmitriptan Sanofi is unlikely to affect driving or using tools or machines. However, it may make you feel sleepy. Wait to see how Zolmitriptan Sanofi affects you before you try these activities.

Zolmitriptan Sanofi contains aspartame

Aspartame (951) contains a source of phenylalanine. May be harmful for people with phenylketonuria.

3. How to take Zolmitriptan Sanofi

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

Zolmitriptan Sanofi is used to treat migraine attacks. Take Zolmitriptan Sanofi as soon as possible after your migraine headache has started. You can also take it once an attack is underway. Do not use it to prevent an attack.

How much to take

Do not use more than the dose prescribed for you.

Adults (aged over 18 years and under 65 years)

The usual starting dose is 2.5 mg zolmitriptan.

If 2.5 mg zolmitriptan did not give you enough help with your migraine, tell your doctor. Your doctor may change your treatment and recommend you 5 mg zolmitriptan for next attack.

Occurrence of side effects is more likely with higher doses.

The maximum daily dose is 10 mg zolmitriptan.

Special patient groups

Patients aged over 65 years

Zolmitriptan Sanofi should not be given to patients over 65 years.

Patients with liver problems

If you have liver problems, the recommended maximum daily dose is lowered to 5 mg.

Patients with kidney problems

Your dosage can be the same as in adults.

Children and adolescents under 18 years of age

Zolmitriptan Sanofi should not be given to children or adolescents under 18 years of age.

Taking this medicine

- Oral use.
- Place the tablet on your tongue, where it will dissolve and be swallowed with the saliva. You do not have to take a drink of water in order to swallow your tablet.
- You can take Zolmitriptan Sanofi with or without food. It does not affect the way that Zolmitriptan Sanofi works.

If after 2 hours after taking Zolmitriptan Sanofi you still have migraine or migraine returns within 24 hours

You can take another dose if the migraine is still present after two hours or if it returns within 24 hours.

Do not take more than 2 doses of Zolmitriptan Sanofi in a 24-hour period.

Always wait at least 2 hours between doses.

If Zolmitriptan Sanofi did not give you enough help with your migraine, tell your doctor.

Your doctor may change your treatment.

If your condition worsens, seek medical attention.

If you take more Zolmitriptan Sanofi than you should

If you take more than you should or someone accidentally swallows some, contact your doctor or go to the nearest hospital straight away. Take the medicine pack and any remaining tablets with you so that the doctor knows what has been taken.

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.

If you experience any of the side effects listed below stop taking the medication and seek the doctor immediately

- Rare: may affect up to 1 in 1,000 people
 - Allergic reactions including itchy rash (urticaria) and swelling of the face, lips, mouth, tongue and throat.
- 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. The signs include chest pain and shortness of breath.

- Spasm of the blood vessels of the gut, which can cause damage to your gut. The signs include stomach pain or bloody diarrhoea.
- Bleeding in the brain (cerebral bleeding) or stroke.

In the course of the treatment with active substance of the product Zolmitriptan Sanofi following adverse effects have also been observed

➤ Common: may affect up to 1 in 10 people

These side effects are usually mild and go away after a short time.

- Abnormal sensations such as tingling in your fingers and toes or skin that is sensitive to touch.
- Feeling sleepy, dizzy or warm.
- Headache.
- Uneven heartbeat.
- Feeling sick (nausea) or being sick (vomiting).
- Stomach pain.
- Dry mouth.
- Muscle weakness or muscle pain.
- Feeling weak.
- Heaviness, tightness, pain or pressure in the throat, neck, arms and legs, or chest.
- Difficulty in swallowing (dysphagia).

➤ Uncommon: may affect up to 1 in 100 people

- Very fast heartbeat.
- 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 any side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie E-mail: medsafety@hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Zolmitriptan Sanofi

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 package. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions.

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 Zolmitriptan Sanofi contains

The active substance is zolmitriptan.

Each orodispersible tablet contains 2.5 mg zolmitriptan.

The other ingredients are mannitol (E421), cellulose microcrystalline, aspartame (E951), croscarmellose sodium, silica colloidal anhydrous, magnesium stearate (E470b), orange flavor (containing nature-identical flavouring substance(s), flavouring preparation, natural flavouring substance(s), maltodextrin, acacia gum (E414), ascorbic acid (E300), butylated hydroxyanisole (E320)).

What Zolmitriptan Sanofi looks like and contents of the pack

Zolmitriptan Sanofi is a white to off-white, round, flat faced beveled edge uncoated tablet of 6.4 ± 0.3 mm diameter and with '2.5' debossed on one side and plain on other side.

Size of packing: 2 and 6 orodispersible tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Sanofi-aventis Ireland Limited T/A SANOFI
Citywest Business Campus
Dublin 24
Tel: 00353 (0)1 4035600
Fax: 00353 (0)1 4035687
email: IEmedinfo@sanofi.com

Manufacturer

S.C. Zentiva S.A
Theodor Pallady Nr 50,
032266Bucharest,
Romania

This medicinal product is authorised in the Member States of the EEA under the following name

Germany	Zolmizen 2,5 mg Schmelztabletten
Austria	Zolmitriptan sanofi-aventis 2,5 mg Schmelztabletten
Spain	Zolmitab Flas 2,5 mg comprimidos bucodispersables
Finland	Zolmitriptan sanofi-aventis 2,5 mg suussa hajoava tabletti
Ireland	Zolmitriptan Sanofi 2.5mg orodispersable tablets
Norway	Zolmitriptan sanofi-aventis 2,5 mg smeltetabletter
Latvia	Zolmitriptan Zentiva 2,5 mg mutē disperģējamās tabletes
Portugal	Zolmitriptano Sanofi
Slovenia	Zolmitriptan sanofi-aventis 2,5 mg orodisperzibilne tablete

This leaflet was last revised in November 2014