

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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

### **1. What Zolmitriptan Orodispersible Tablets is and what it is used for**

Zolmitriptan Orodispersible Tablets contains zolmitriptan and belongs to a group of medicines called triptans.

#### **Zolmitriptan Orodispersible Tablets is used to treat migraine headache.**

- Migraine symptoms may be caused by the widening of blood vessels in the head. Zolmitriptan Orodispersible Tablets 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.
- Zolmitriptan Orodispersible Tablets works only when a migraine attack has started. Do not use it to prevent a migraine attack.

### **2. What you need to know before you take Zolmitriptan Orodispersible Tablets**

#### **Do not take Zolmitriptan Orodispersible Tablets:**

- if you are allergic to zolmitriptan or 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 on 'Other medicines and Zolmitriptan Orodispersible Tablets' 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 taking Zolmitriptan Orodispersible Tablets. Let your doctor know 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 medicines for treatment of depression (see section below for 'Other medicines and Zolmitriptan Orodispersible Tablets' for further information).

If you go into hospital tell the medical staff you are taking Zolmitriptan Orodispersible Tablets.

Zolmitriptan Orodispersible Tablets is not recommended for people aged under 18 years, or over 65.

As with other migraine treatments, taking too much Zolmitriptan Orodispersible Tablets 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 Orodispersible Tablets to correct the problem.

## **Other medicines and Zolmitriptan Orodispersible Tablets**

Tell your doctor or pharmacist if you are taking, have recently taken any or might take any other medicines. This include 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 Zolmitriptan Orodispersible Tablets, leave 24 hours before taking Zolmitriptan Orodispersible Tablets.
- After taking Zolmitriptan Orodispersible Tablets, leave 24 hours before taking triptans other than Zolmitriptan Orodispersible Tablets.
- If you take medicines containing ergotamine or ergot-type medicines (such as dihydroergotamine or methysergide), leave 24 hours before taking Zolmitriptan Orodispersible Tablets.
- After taking Zolmitriptan Orodispersible Tablets, 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 Orodispersible Tablets 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 Zolmitriptan Orodispersible Tablets may be more likely to happen..

## **Zolmitriptan Orodispersible Tablets with food and drink**

You can take Zolmitriptan Orodispersible Tablets with or without food. It does not affect the way that Zolmitriptan Orodispersible Tablets works.

### **Pregnancy, breast-feeding and fertility**

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 Zolmitriptan Orodispersible Tablets during pregnancy is harmful. Before taking Zolmitriptan Orodispersible Tablets, tell your doctor if you are pregnant or trying to become pregnant.
- Do not breast-feed within 24 hours taking zolmitriptan.

### **Driving and using machines**

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

### **Zolmitriptan Orodispersible Tablets contains Aspartame (E951)**

Zolmitriptan 2.5 mg Orodispersible Tablets contains 2 mg aspartame (E951) in each orodispersible tablets. Zolmitriptan 5 mg Orodispersible Tablets contains 4 mg aspartame (E951) in each orodispersible tablets. 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.

## **3. How to take Zolmitriptan Orodispersible Tablets**

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

The recommended dose is 2.5 mg or 5 mg. Zolmitriptan Orodispersible Tablets is used to treat migraine attacks. Take Zolmitriptan Orodispersible Tablets as soon as possible after your migraine headache has started. You can also take it once an attack is underway.

If the symptoms of migraine return within 24 hours, you may take a second dose of zolmitriptan. The second dose should not be taken within 2 hours of your first dose.

If the tablets did not relieve your migraine, tell your doctor. Your doctor may raise the dose to 5 mg or change your treatment.

Do not use more than two doses in one day. The maximum daily dose is 10 mg zolmitriptan.

### Method of administration

Oral Use.

Peel the blister pack open as shown on the foil. Do not push the tablet through the foil.

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.

### **If you take more Zolmitriptan Orodispersible Tablets than you should**

If you have taken more Zolmitriptan Orodispersible Tablets than prescribed by your doctor, tell your doctor or go to the nearest hospital straight away. Take the Zolmitriptan Orodispersible Tablets medicine with you.

### **If you forget to take Zolmitriptan Orodispersible Tablets**

Do not take a double dose to make up for a forgotten tablet.

If you have any further questions on the use of this product, 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 Zolmitriptan Orodispersible Tablets 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 Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Zolmitriptan Orodispersible Tablets

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 after EXP: The expiry date refers to the last day of that month.

- This medicinal product does not require any special storage conditions.
- 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 to protect the environment.

## **6. Contents of the pack and other information**

### **What Zolmitriptan Orodispersible Tablets contains**

2.5mg

The active substance is zolmitriptan. Zolmitriptan 2.5 mg Orodispersible Tablets contain 2.5 mg of zolmitriptan.

The other ingredients are Mannitol (E421), Cellulose microcrystalline, Crospovidone Type A, Aspartame (E951), Silica colloidal anhydrous, Talc, Magnesium Stearate, Peppermint Flavour.

5mg

The active substance is zolmitriptan. Zolmitriptan Orodispersible 5 mg Tablets contain 5 mg of zolmitriptan.

The other ingredients are Mannitol (E421), Cellulose microcrystalline, Crospovidone Type A, Aspartame (E951), Silica colloidal anhydrous, Talc, Magnesium Stearate, Peppermint Flavour.

### **What Zolmitriptan Orodispersible Tablets looks like and contents of the pack**

Zolmitriptan 2.5 mg Orodispersible Tablets are supplied as:

White to off-white, round tablets debossed 'F7' on one side and plain on other side (diameter approximately: 6,5 mm).

Zolmitriptan 5 mg Orodispersible Tablets are supplied as:

White to off-white, round tablets debossed 'F11' on one side and plain on other side (diameter approximately: 8 mm).

Zolmitriptan 2.5 mg Orodispersible Tablets are available in Aluminium/Aluminium peelable blisters in cartons containing 2, 3, 4, 5, 6, 12, 18 tablets.

Zolmitriptan 5 mg Orodispersible Tablets are available in Aluminium/Aluminium peelable blisters in cartons containing 2, 3, 4, 5, 6, 12, 18 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

Glenmark Pharmaceuticals Europe Limited  
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**This leaflet was last revised in 10/2022.**