

## PACKAGE LEAFLET: INFORMATION FOR THE USER

Zolmitriptan 2.5 mg Film-coated Tablets  
Zolmitriptan 5 mg Film-coated 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet:**

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

### **1. What Zolmitriptan Film-coated tablets is and what it is used for**

Zolmitriptan Film-coated Tablets contains zolmitriptan and belongs to a group of medicines called triptans.

Zolmitriptan Film-coated Tablets is used to treat migraine headache.

- Migraine symptoms may be caused by swollen blood vessels in the head. Zolmitriptan Film-coated 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 Film-coated Tablets works only when a migraine attack has started. It will not stop you from getting a migraine attack.

### **2. What you need to know before you take Zolmitriptan Film-coated tablets**

#### **Do not take Zolmitriptan Film-coated Tablets**

- If you are allergic to zolmitriptan or any of the other ingredients of this medicine s (listed in section 6).
- If you have high blood pressure.
- If you have, or previously had heart problems, including a heart attack, angina (chest pain caused by exercise or effort), Prinzmetal's angina (a chest pain which occurs at rest) or have experienced heart related symptoms such as shortness of breath or pressure in the chest.
- If you have or previously had a stroke or short-lasting symptoms similar to a stroke (transient ischaemic attack or TIA).
- If you are at the same time taking some other medicines for your 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 Film-coated Tablets' for further information.

Do not take Zolmitriptan Film-coated Tablets if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Zolmitriptan Film-coated Tablets.

## **Warnings and precautions**

Talk to your doctor or pharmacist before taking Zolmitriptan Film-coated 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 or previously had liver problems.
- you have headaches which are not like your usual migraine headache.
- you are taking other medicines for the treatment of depression (see section below for 'Other medicines and Zolmitriptan Film-coated Tablets' for further information).
- you are at the same time taking herbal medicines which contain St John's Wort (this is used for treating depression).
- you go into hospital, please ensure you tell the medical staff that you are taking Zolmitriptan Film-coated Tablets.

Zolmitriptan Film-coated Tablets is not recommended for individuals aged less than 18 years, or over the age of 65 years.

As with other migraine treatments, taking too much Zolmitriptan Film-coated Tablets can cause daily headaches or can make your migraine headaches worse. Let your doctor know if you think this applies to you, as you may need to stop taking Zolmitriptan Film-coated Tablets to correct the problem.

## **Other medicines and Zolmitriptan Film-coated Tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those medicines obtained without a prescription or if you use any herbal medicines.

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

### *Medicines used for migraine*

- If you take another type of triptan (such as sumatriptan or naratriptan) which is different from this medicine leave 24 hours before taking Zolmitriptan Film-coated Tablets.
- After taking Zolmitriptan Film-coated Tablets, leave 24 hours before taking another type of triptan.
- If you take medicines that contain ergotamine or ergot-type medicines (such as dihydroergotamine or methysergide), leave 24 hours before taking Zolmitriptan Film-coated Tablets.
- After taking Zolmitriptan Film-coated Tablets, leave 6 hours before taking ergotamine or ergot-type medicines.

### *Medicines used for depression*

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

### *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*) at the same time as this medicine, potential side effects of Zolmitriptan Film-coated Tablets may occur. Stop taking this medicine and let your doctor know.

## **Zolmitriptan Film-coated Tablets with food and drink**

You can take Zolmitriptan Film-coated Tablets with or without food. It does not affect the way that Zolmitriptan Film-coated 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.

### *Pregnancy*

It is not known if taking zolmitriptan tablets during pregnancy is harmful. Before taking zolmitriptan tablets, tell your doctor if you are pregnant or trying to become pregnant.

### *Breast feeding*

The active substance in your medicine may pass into your breast milk. To minimise the risk of exposing your baby to your medicine you should not breast-feed for 24 hours after taking zolmitriptan.

### **Driving and using machines**

- During a migraine attack your reactions may be slower than usual. Take precaution when driving or using any tools or machines that requires concentration.
- Zolmitriptan Film-coated Tablets is unlikely to affect your ability to drive or use tools or machines. However, it may make you feel sleepy. Wait to see how Zolmitriptan Film-coated Tablets affects you before you perform these activities.

### **Zolmitriptan Film-coated Tablets contains Lactose**

Zolmitriptan 2.5 mg/5 mg Film-coated Tablets contain lactose which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

## **3. How to take Zolmitriptan Film-coated Tablets**

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 Zolmitriptan Film-coated Tablets as soon as a migraine headache starts. You can also take it once an attack is underway.

- The recommended dose is one tablet, 2.5 mg or 5 mg.
- Oral use, tablet to be swallowed with a drink of water.
- You can take a second tablet if the migraine is still present after two hours or if it returns within 24 hours.

If the tablet did not relieve your migraine, tell your doctor. Your doctor may change your treatment.

Do not use more than the dose prescribed for you.

- Do not use more than two doses in one day unless prescribed to you by your doctor.
- The maximum daily dose is 10 mg.

### **Use in elderly adults**

Zolmitriptan is not recommended for older adults over the age of 65 years.

### **Use in children and adolescents**

Zolmitriptan is not recommended for use in children and adolescents aged under 18 years.

### **If you take more Zolmitriptan Film-coated Tablets than you should**

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

### **If you forget to take Zolmitriptan Film-coated 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 Film-coated Tablets and contact your doctor straight away if you notice any of the following:**

**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

Other possible side effects:

**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 heart beat
- 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
- Problems 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.

**Very rare (may affect 1 in 10,000 people)**

- Sudden urgent need to pass water (urine)

**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 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 Film-coated 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 Film-coated Tablets contains**

2.5 mg

The active substance is zolmitriptan.

Zolmitriptan 2.5 mg Film-coated Tablets contain 2.5 mg of zolmitriptan.

The other ingredients are:

Tablet core: Lactose anhydrous, Cellulose microcrystalline, Sodium Starch Glycolate type A, Magnesium Stearate

Tablet coat: Hypromellose, Titanium dioxide (E 171), Macrogol 400, Macrogol 8000, Iron Oxide Yellow (E 172)

5 mg

The active substance is zolmitriptan

Zolmitriptan 5 mg Film-coated Tablets contain 5 mg of zolmitriptan.

The other ingredients are:

Tablet core: Lactose anhydrous, Cellulose microcrystalline, Sodium starch Glycolate type A, Magnesium stearate.

Tablet coat: Hypromellose, Titanium dioxide (E171), Macrogol 400, Macrogol 8000, Iron oxide Red (E172)

### **What Zolmitriptan Film-coated Tablets looks like and contents of the pack**

Zolmitriptan 2.5 mg Film-coated Tablets:

Yellow coloured, round, biconvex Film-coated tablets debossed with 497 on one side and deep break line on other side (diameter approximately: 7 mm). The tablet can be divided into equal halves.

Zolmitriptan 5 mg Film-coated Tablets:

Pink coloured, round, biconvex Film-coated tablets debossed with 498 on one side and plain on other side (diameter approximately: 8.5 mm).

Zolmitriptan 2.5 mg Film-coated Tablets are available in blisters of 3, 6, 12 tablets.

Zolmitriptan 5 mg Film-coated Tablets are available in blisters of 3, 6, 12 tablets.

Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder**

Glenmark Pharmaceuticals Europe Limited  
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### **Manufacturer**

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