

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **Rizatriptan 5 mg Tablets** **Rizatriptan 10 mg Tablets** (Rizatriptan)

**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 Rizatriptan Tablets are and what they are used for**
- 2. What you need to know before you take Rizatriptan Tablets**
- 3. How to take Rizatriptan Tablets**
- 4. Possible side effects**
- 5. How to store Rizatriptan Tablets**
- 6. Contents of the pack and other information**

#### **1. What Rizatriptan Tablets are and what they are used for**

Rizatriptan belongs to a class of medicines called serotonin 5-HT<sub>1B/1D</sub> receptor agonists. Rizatriptan Tablets is used to treat the headache phase of the migraine attack in adults.

Treatment with Rizatriptan Tablets:

Reduces swelling of blood vessels surrounding the brain. This swelling results in the headache pain of a migraine attack.

Rizatriptan Tablets can be used to treat migraine attacks which may or may not be associated with visual disturbances (an aura). They are not used to prevent migraine attacks.

Please tell your doctor or pharmacist about your symptoms. Your doctor will decide if you suffer from migraines. You should take Rizatriptan Tablets **only for a migraine** attack. This medicine should not be used to treat headaches that might be caused by other, more serious conditions.

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

##### **Do not take Rizatriptan Tablets**

- you are allergic to rizatriptan or any of the other ingredients of this medicine (listed in section 6)
- you have moderately severe or severe high blood pressure or mild high blood pressure that is not controlled by medication
- you have or have ever had heart problems including heart attack or pain on the chest (angina) or you have experienced heart disease related signs

- you have had a stroke (cerebrovascular accident CVA) or mini stroke (transient ischaemic attack TIA)
- you have blockage problems with your arteries (peripheral vascular disease)
- have severe liver or severe kidney problems
- you are taking monoamine oxidase (MAO) inhibitors such as moclobemide, phenelzine, tranylcypromine or pargyline (drugs against depression) or linezolid (an antibiotic), or if it has been less than 2 weeks since you stopped taking MAO inhibitors
- you are taking any other drug in the same class, such as sumatriptan, naratriptan or zolmitriptan to treat your migraine (see **other medicines below**).
- you are now taking ergotamine-type medicines, such as ergotamine or dihydro-ergotamine to treat your migraine or methysergide to prevent a migraine attack.

You should wait at least 6 hours after taking Rizatriptan Tablets before you take ergotamine-type medicines such as ergotamine or dihydro-ergotamine or methysergide. You should wait at least 24 hours after taking ergotamine-type medicines before taking Rizatriptan Tablets.

If you are not sure if any of the above apply to you talk to your doctor or pharmacist before taking Rizatriptan Tablets.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Rizatriptan Tablets if:

- you have any of the following risk factors for heart disease: high blood pressure, diabetes, you smoke or you are using nicotine substitution, your family has a history of heart disease, you are a man over 40 years of age or you are a post-menopausal woman
- you have kidney or liver problems
- you have a particular problem with the way your heart beats (bundle branch block)
- you have or have had any allergies
- your headache is associated with dizziness, difficulty walking, lack of co-ordination or weakness in your leg and/or arm
- you use herbal preparation containing St John's Wort
- you have had an allergic reaction like swelling of the face, lips, tongue and/or throat which may cause difficulty breathing and/or swallowing (angioedema)
- you are taking selective serotonin reuptake inhibitors (SSRIs) such as sertraline, escitalopram oxalate and fluoxetine, or serotonin norepinephrine reuptake inhibitors (SNRIs) such as venlafaxine and duloxetine, for depression.
- you have had short-lived symptoms including chest pain and tightness

If you take this medicine too often this may result in you getting a chronic headache. In such cases you should contact your doctor as you may have to stop taking Rizatriptan Tablets.

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

### **Other medicines and Rizatriptan Tablets**

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

Do not take Rizatriptan Tablets

- if you are already taking a 5-HT<sub>1B/1D</sub> agonist (sometimes referred to as ‘triptans’), such as sumatriptan, naratriptan or zolmitriptan.
- if you are taking a monoamine oxidase (MAO) inhibitor such as moclobemide, phenelzine, tranylcypromine, linezolid, or pargyline or if it has been less than two weeks since you stopped taking an MAO inhibitor.
- if you use ergotamine-type medications such as ergotamine or dihydro-ergotamine to treat your migraine.
- if you use methysergide to prevent a migraine attack.

The above listed medicines when taken with Rizatriptan Tablets may increase the risk of side effects.

Ask your doctor for instructions and the risks about taking Rizatriptan Tablets

- if you are taking propranolol (see section 3: **How to take Rizatriptan Tablets**)
- if you are taking SSRIs such as sertraline, escitalopram oxalate and fluoxetine, or SNRIs such as venlafaxine, and duloxetine, for depression.

### **Taking Rizatriptan Tablets with food and drink**

Rizatriptan Tablets can take longer to work if it is taken after food. Although it is better to take it on an empty stomach, you can still take it if you have eaten.

### **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 whether Rizatriptan Tablets is harmful to an unborn baby when taken by a pregnant woman. Breast-feeding should be avoided for 24 hours after treatment.

### **Children and adolescents**

The use of Rizatriptan Tablets in children under 18 years of age is not recommended.

### **Use in patients older than 65 years**

There have been no full studies to look at how safe and effective Rizatriptan Tablets is amongst patients older than 65 years.

### **Driving and using machines**

You may feel sleepy or dizzy while taking Rizatriptan Tablets. If this happens, do not drive or use any tools or machines.

### **Rizatriptan Tablets contain lactose**

Rizatriptan Tablets **contain** lactose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

## **3. How to take Rizatriptan Tablets**

**Rizatriptan Tablets is used to treat migraine attacks. Take Rizatriptan Tablets as soon as possible after your migraine headache has started. Do not use it to prevent an attack.**

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

The recommended dose is **10 mg**.

If you are currently taking propranolol or have liver or kidney problems, you should use the 5 mg tablets of Rizatriptan Tablets. You should leave at least 2 hours between taking propranolol and Rizatriptan Tablets up to a maximum of 2 doses in a 24-hour period.

Rizatriptan Tablets should be taken by mouth and swallowed whole with liquid.

**If migraine returns within 24 hours**

In some patients, migraine symptoms can return within a 24-hour period. If your migraine does return you can take an additional dose of Rizatriptan Tablets. You should always wait at least two hours between doses.

**If after 2 hours you still have a migraine**

If you do not respond to the first dose of Rizatriptan Tablets during an attack, you should not take a second dose of Rizatriptan Tablets for treatment of the same attack. It is still likely, however, that you will respond to Rizatriptan Tablets during the next attack.

**Do not take more than two doses of Rizatriptan Tablets in a 24-hour period, (for example, do not take more than two 10 mg tablets or 5 mg tablets in a 24-hour period). You should always wait at least 2 hours between doses.**

If your condition worsens, seek medical attention.

**If you take more Rizatriptan Tablets than you should**

If you take more Rizatriptan Tablets than you should, talk to your doctor or pharmacist straight away. Take the medicine pack with you.

Signs of overdosage can include dizziness, drowsiness, vomiting, fainting and slow heart rate.

**If you forget to take Rizatriptan Tablets**

If you forgot or were unable to take Rizatriptan Tablets at the start of your migraine attack, you can take it at anytime during the attack.

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 you get any of the following rare allergic symptoms after taking these tablets, stop taking Rizatriptan and go the hospital immediately:**

- **signs of an allergic reaction** such as rashes, itching, sudden wheezing, difficulty breathing, swelling of the eyelids, face, lips, tongue or throat
- **peeling and blistering** of the skin, mouth, eyes and genitals
- **rash** affecting your whole body.
- **toxic epidermal necrolysis**, symptoms of which include a fever, sore throat and generally not feeling very well, accompanied by intense skin rash and lesions which may occur on the face, upper body, arms, legs and soles of the feet. Large blisters can progress to extensive peeling of layers of the skin.

**Tell your doctor or pharmacist if you notice any of the following side effects, they get worse or if you notice any effects not listed.**

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

- dizziness, sleepiness, tiredness
- headache, dry mouth
- stomach pains
- chest pains, throat discomfort
- heaviness, pain or pressure in the throat, neck, limbs or chest
- palpitations (irregular heart beat), fast racing heart beat
- decreased sensitivity of skin
- feeling or being sick, diarrhoea
- sweating, flushing (redness of the face which lasts a short time), hot flushes
- shaking (tremor) usually of the hands
- tingling in the fingers and toes
- difficulty thinking
- difficulty breathing

**Uncommon** (may affect up to 1 in 100 people)

- neck pain
- difficulty sleeping, increased thirst
- increased blood pressure
- indigestion, blurred vision
- unsteadiness when walking
- ECG abnormalities
- bad taste in your mouth
- dizziness
- muscle weakness, stiffness and tightness of muscles
- rash, itching and lumpy skin rash
- confusion, nervousness
- muscle pain
- facial pain
- arrhythmia (changes in the rhythm or rate of the heartbeat)
- swelling of face, lips, tongue and/or throat which may cause difficulty breathing and/or swallowing

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

- fainting, especially on standing
- wheezing
- allergic reaction (hypersensitivity), sudden life-threatening allergic reaction (anaphylaxis)
- stroke (this generally occurs in patients with risk factors for heart and blood vessel disease high blood pressure, diabetes, smoking, use of nicotine substitution, family history of heart disease or stroke, man over 40 years of age, post-menopausal woman, particular problem with the way your heart beats [bundle branch block]).
- Slow heartbeat (bradycardia)

**Not known (frequency cannot be estimated from the available data)**

- seizure (convulsions/fits)
- ischemic colitis
- a syndrome called “serotonin syndrome” that may cause side effects like coma, unstable blood pressure, extremely high body temperature, lack of muscle coordination, agitation and hallucinations.
- heart attack, spasm of blood vessels of the heart, – these generally occur
- spasm of blood vessels of the extremities including coldness and numbness of the hands or feet

- in patients with risk factors for heart and blood vessel disease (high blood pressure, diabetes, smoking, use of nicotine substitution, family history of heart disease or stroke, man over 40 years of age, post-menopausal woman, particular problem with the way your heart beats (bundle branch block)).
- severe shedding of the skin with or without fever (toxic epidermal necrolysis)

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Rizatriptan Tablets**

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

Do not use Rizatriptan Tablets after the expiry date which is stated on the pack as “EXP”. The expiry date refers to the last day of that month.

Do not store above 30°C.

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 Rizatriptan Tablets contain**

The active substance is Rizatriptan.

Each Rizatriptan 5 mg Tablet contains 5 mg of rizatriptan (as rizatriptan benzoate).

Each Rizatriptan 10 mg Tablet contains 10 mg of rizatriptan (as rizatriptan benzoate).

The other ingredients are lactose monohydrate, microcrystalline cellulose, pregelatinised maize starch, iron oxide red (E 172) and magnesium stearate.

### **What Rizatriptan Tablets look like and contents of the pack**

Rizatriptan 5 mg Tablets are light pink to pink coloured capsule shaped biconvex tablets with R on one side and 5 on the other.

Rizatriptan 10 mg Tablets are light pink to pink coloured capsule shaped biconvex tablets with R on one side and 10 on the other.

**Rizatriptan Tablets** are available in pack sizes of 1, 2, 3, 6, 12 or 18 tablets. Not all pack sizes may be marketed.

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

Lupin (Europe) Limited  
Victoria Court  
Bexton Road  
Knutsford  
Cheshire, WA16 0PF  
United Kingdom

**This medicinal product is authorised in the Member States of the EEA under the following names:**

**Germany – Rizatriptan-Hormosan 5 mg Tabletten**  
**Germany – Rizatriptan-Hormosan 10 mg Tabletten**

**UK – Rizatriptan 5 mg Tablets**  
**UK – Rizatriptan 10 mg Tablets**

**This leaflet was last approved in March 2014**