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 is and what it is

- used for What you need to know before
- you take Rizatriptan
- How to take Rizatriptan
- 4. Possible side effects5. How to store Rizatriptan
- 6. Contents of the pack and other information

What Rizatriptan is and

what it is used for Rizatriptan belongs to a class of

medicines called selective serotonin 5-HT1B/1D receptor agonists. Rizatriptan is used to treat the

headache phase of the migraine attack in adults. Treatment with Rizatriptan: Reduces swelling of blood vessels

surrounding the brain. This swelling results in the headache pain of a migraine attack. What you need to know

before you take Rizatriptan Do not take Rizatriptan:

if you are allergic to rizatriptan

- benzoate 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 severe liver or severe kidney problems
- 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) 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 two weeks since you stopped taking MAO inhibitors
- as ergotamine or dihydroergotamine to treat your migraine or methysergide to prevent a migraine attack you are taking any other drug in the same class, such as sumatriptan, naratriptan or zolmitriptan to treat your

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

Talk to your doctor or pharmacist

you have any of the following

medicines below)

migraine. (See Taking with other

risk factors for heart disease: high blood pressure, diabetes, you smoke or you are using

before taking Rizatriptan if:

- nicotine substitution, your family has a history of heart disease, you are a man over 40 years of age, or you are a postmenopausal 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

your headache is associated with dizziness, difficulty in

allergies.

- walking, lack of co-ordination or weakness in the leg and arm you use herbal preparation containing St. John's wort you have had allergic reaction
- like swelling of 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 Rizatriptan 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.

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

Please tell your doctor or

are taking or have recently taken or plan to take, any other medicines including medicines obtained without a prescription. This includes herbal medicines and those you normally take for a migraine. This is because Rizatriptan can affect the way some medicines work. Also other medicines can affect Rizatriptan. Other medicines and Rizatriptan

Tell your doctor or pharmacist if you are taking, have recently

taken or might take any other medicines. Do not take Rizatriptan:

if you are already taking a 5-HT1B/1D 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 dihydroergotamine to treat your migraine if you use methysergide to prevent a migraine attack.
- The above listed medicines when taken with Rizatriptan may

increase the risk of side effects. You should wait at least 6 hours after taking Rizatriptan before you

take ergotamine-type medications such as ergotamine or dihydroergotamine or methysergide. You should wait at least 24 hours after taking ergotaminetype medications before taking Rizatriptan. Ask your doctor for instructions and the risks about taking

Rizatriptan if you are taking propranolol (see section 3: How to take Rizatriptan)

- if you are taking SSRIs such as sertraline, escitalopram oxalate, and fluoxetine or
- SNRIs such as venlafaxine, and duloxetine for depression. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines

obtained without a prescription. Rizatriptan with food, drink and alcohol Rizatriptan 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, breast-feeding and fertility It is not known whether Rizatriptan is harmful to an unborn baby when taken by a pregnant woman.

Talk to your doctor before taking

planning to get pregnant or are

breastfeeding. Breastfeeding

this medicine if you are pregnant,

should be avoided for 24 hours after treatment. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before

Use in 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

taking this medicine.

Rizatriptan is amongst patients older than 65 years. **Driving and using machines**

You may feel sleepy or dizzy while

taking Rizatriptan. If this happens,

There have been no full studies

to look at how safe and effective

do not drive or use any tools or machines. Rizatriptan contains lactose Rizatriptan contains lactose

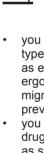
monohydrate, a type of sugar. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product. 3. How to take Rizatriptan

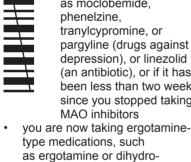
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Rizatriptan is used to treat

migraine attacks. Take Rizatriptan as soon as possible after your migraine headache has started. Do not use it to prevent an attack. The recommended dose is 10 mg.

liver problems you should use the

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





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Rizatriptan (rizatriptan benzoate) tablets should be taken by mouth and swallowed whole with liquid.

Rizatriptan is also available as a 10-mg wafer (referred to technically as an oral lyophilisate) that dissolves in the mouth. The wafer can be used in situations in which liquids are not available, or to avoid the nausea and vomiting that may accompany the ingestion of tablets with liquids.

If migraine returns within 24 hours

In some patients, migraine symptoms can return within a 24hour period. If your migraine does return you can take an additional dose of Rizatriptan. You should always wait at least 2 hours between doses.

If after 2 hours you still have a migraine If you do not respond to the first

dose of Rizatriptan during an attack, you should not take a second dose of Rizatriptan for treatment of the same attack. It is still likely, however, that you will respond to Rizatriptan during the next attack. Do not take more than 2 doses

of Rizatriptan in a 24-hour period, (for example, do not take more than two 10-mg or 5 mg tablets or orodispersible 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

than you should If you take more Rizatriptan than

you should, talk to your doctor or pharmacist straight away. Take the medicine pack with you. Signs of over-dosage can include dizziness, drowsiness, vomiting,

fainting and slow heart rate. 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. The following side effects may happen with this medicine.

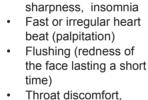
In adult studies, the most common side effects reported were dizziness, sleepiness and

tiredness. Common (may affect up to 1 in 10 people)

sensitivity of skin (hypoesthesia), decreased mental

Tingling (paraesthesia),

headache, decreased



- Feeling sick (nausea), dry mouth, vomiting, diarrhoea
- Feeling of heaviness in parts of the body, Pain in abdomen or chest. Indigestion (dyspepsia)
- Neck pain, stiffness. Uncommon (may affect up to 1 in
- Bad taste in your mouth Unsteadiness when walking (ataxia), dizziness (vertigo),

100 people)

(syncope)

high blood pressure (hypertension); thirst, hot flushes, sweating rash, itching and lumpy rash (hives); swelling of face, lips, tongue and/or throat

> which may cause difficulty breathing and/or swallowing

Confusion, nervousness.

blurred vision, tremor, fainting

- (angioedema), difficulty breathing (dyspnoea) feeling of tightness in parts of the body, muscle weakness. High blood pressure
- (hypertension); thirst, hot flushes, sweating, changes in the rhythm or rate of the heartbeat (arrhythmia); abnormalities of the electrocardiogram (a test that records the electrical activity of
- Facial pain; muscle pain. Rare (may affect up to 1 in 1,000

your heart), very fast heartbeat

people) Wheezing Allergic reaction

(tachycardia)

- (hypersensitivity) sudden lifethreatening allergic reaction (anaphylaxis). Slow heartbeat (bradycardia). 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, postmenopausal women, particular problem with the way your heart beats (bundle branch block)).

Not known (frequency cannot be estimated from the available data): Heart attack, spasm of the

- blood vessels of the heart these generally occur 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, postmenopausal women,particular problem with the way your heart beats (bundle branch block). 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. severe shedding of the skin
- with or without fever (toxic epidermal necrolysis) Seizure (convulsions/fits)
- Spasm of blood vessels of the
- extremities including coldness and numbness of the hands or feet. Spasm of the blood vessels of
- the colon (large bowel), which can cause abdominal pain. Tell your doctor right away if

you have symptoms of allergic reactions, serotonin syndrome, heart attack or stroke. In addition, tell your doctor if you experience any symptoms that

suggest an allergic reaction (such as a rash or itching) after taking Rizatriptan 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine. The United Kingdom Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or

search for MHRA Yellow Card in the Goolgle Play or Apple App

and reach of children.

Store. 5. How to store Rizatriptan Keep this medicine out of the sight

that month. This medicinal product does not require any special storage conditions.

Do not throw away any medicines

Do not use this medicine after the expiry date which is stated on the

blister and carton after EXP. The

expiry date refers to the last day of

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

via wastewater or household

What Rizatriptan contains The active substance is rizatriptan.

Each tablet contains 7.265

mg of rizatriptan benzoate equivalent to 5 mg of rizatriptan. Each tablet contains 14.530 mg of rizatriptan benzoate

equivalent to 10 mg of

rizatriptan. The other ingredients are: Cellulose, Microcrystalline, lactose monohydrate (see section 2), maize starch,

pregelatinized magnesium

ferric oxide red, starch

stearate.

be mottled.

What Rizatriptan looks like and contents of pack **Tablets** Rizatriptan 5 mg tablets: Pale pink coloured, circular, flat, beveled edge uncoated tablets debossed with 'X' on one side and '13' on other side. The tablets may

Rizatriptan 10 mg tablets:

Pale pink coloured, circular, flat, beveled edge uncoated tablets debossed with 'X' on one side and '14' on other side. The tablets may be mottled. Rizatriptan tablets are available in Polyamide/ Aluminium / PVC -

2, 3, 6, 12 and 18 tablets. Not all pack sizes may be marketed. **Marketing Authorisation Holder**

Odyssey Business Park West End Road Ruislip HA4 6QD

Manufacturer APL Swift Services (Malta) Limited HF26, Hal Far Industrial Estate, Hal Far Birzebbugia, BBG 3000

or Milpharm Limited

Ares Block

in 02/2024.

Ares Block

United Kingdom

West End Road Ruislip HA4 6QD United Kingdom This leaflet was last revised

UK_Milpharm Limited

Aluminium foil blister packs of: 1,

Malta

Odyssey Business Park