LEAFLET: INFORMATION FOR THE USER
Rizatriptan disp 10 mg Teva, orodispersible tablets
rizatriptan

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm others, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet

1. WHAT IS RIZATRIPTAN DISP TEVA AND WHAT IS IT USED FOR?
This medicine belongs to a class of medicines called selective serotonin 5-HT1B/1D receptor agonists.
This medicine is used for the treatment of the headache phase of a migraine attack in adults.

Treatment with this medicine:
reduces swelling of the blood vessels around the brain. The headache of a migraine attack is caused by this swelling.

2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR BE EXTRA CAUTIOUS?
When should you not use this medicine?
- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6 of this leaflet.
- You have moderately severe or severe high blood pressure or mild high blood pressure that cannot be controlled with medication.
- You have a heart condition or have ever had one, such as a heart attack or chest pain (angina pectoris) or you have had symptoms related to a heart condition.
- You have severe liver or kidney problems.
- You have had a stroke (cerebrovascular accident or CVA) or a mini-stroke (transient ischemic attack or TIA).
- You have problems with blockages in your arteries (peripheral vascular disease).
- You are currently using monoamine oxidase (MAO) inhibitors such as moclobemide, phenelzine, tranylcypromine, or pargyline (medications for depression) or linezolid (an antibiotic) or if it has been less than two weeks since you stopped using an MAO inhibitor.

- You are currently using ergotamine-like medication, such as ergotamine or dihydro-ergotamine for the treatment of your migraine or methysergide to prevent a migraine attack.
- You are using other medications from the same class, such as sumatriptan, naratriptan, or zolmitriptan to treat your migraine (see 'Are you taking any other medicines?' below).
- If you are not sure whether the above applies to you, consult your doctor or pharmacist before using this medicine.
- When should you be extra cautious with this medicine?
- Contact your doctor or pharmacist before using this medicine if:
- you have any of the following risk factors for a heart condition: high blood pressure or diabetes, you smoke or use nicotine substitutes, heart conditions run in your family, you are a man over 40 years old or a woman post-menopause
- you have kidney or liver problems
- you have a heart rhythm disorder (bundle branch block)
- you have or have had allergies
- your headache is accompanied by dizziness, difficulty walking, lack of coordination, or weakness in arm and leg
- you are using herbal preparations containing St. John's wort
- you have had allergic reactions, such as swelling of the face, lips, tongue, and/or throat, which may cause breathing difficulties and/or swallowing problems (angioedema)
- you are using 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-term symptoms, including chest pain and tightness.

If you take this medicine too often, you may get chronic headaches. If this happens, you should consult your doctor, as you may need to stop taking this medicine.
Tell your doctor or pharmacist about your symptoms. Your doctor will determine if you have migraines. You should only use this medicine for a migraine attack. This medicine should not be used for the

treatment of headaches that may be caused by other, possibly more serious conditions.

Children and adolescents under 18 years
The use of this medicine in children and adolescents under 18 years is not recommended.

Use in patients over 65 years
No comprehensive studies have been conducted to establish the safety and efficacy of this medicine in patients over 65 years.

Are you using any other medicines?
Are you using any other medicines besides Rizatriptan disp Teva, have you done so recently, or are you planning to do so soon? If so, tell your doctor or pharmacist. This also applies to medicines available without a prescription. This includes herbal medicines and medicines you normally use for migraines. The reason for this is that this medicine can affect the action of some other medicines. Other medicines can also affect the action of this medicine.

Do not use this medicine if:
- you are already using a 5-HT1B/1D agonist (sometimes referred to as 'triptans'), such as sumatriptan, naratriptan, or zolmitriptan
- you are using 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 using an MAO inhibitor
- you are using ergotamine-like medication such as ergotamine or dihydroergotamine for the treatment of your migraine
- you are using methysergide to prevent a migraine attack.

When the above medicines are taken in combination with this medicine, there is a greater chance of side effects.

Wait at least 6 hours after using this medication before using ergotamine-like medication, such as ergotamine, dihydroergotamine, or methysergide.
Wait at least 24 hours after using ergotamine-like medication before using this medication. Ask your doctor for instructions and the risks of using this medication:
- if you are using propranolol (see section 3 'How to use this medication?')
- if you are using SSRIs such as sertraline, escitalopram oxalate, and fluoxetine, or SNRIs such as venlafaxine and duloxetine, for depression.

What should you pay attention to with food and drink?

If this medication is taken with food, it may take longer to work. Although it is better to take this medication on an empty stomach, it can also be taken if you have already eaten.

Pregnancy and breastfeeding
Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medication.
The available data on the safety of rizatriptan during the first 3 months of pregnancy do not indicate an increased risk of birth defects. It is not known if this medication is harmful to an unborn baby if used by a pregnant woman after the first 3 months of pregnancy.

If you are breastfeeding, you can delay breastfeeding for up to 12 hours after treatment to prevent your baby from ingesting the medication.

Driving and using machines
The use of this medication can sometimes cause drowsiness and dizziness. If you experience these side effects, do not drive vehicles and/or use tools or operate machines that require alertness.

Rizatriptan disp Teva contains lactose
If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before taking this medication.

Rizatriptan disp Teva contains aspartame (E951)
This medication contains 2.0 mg of aspartame in each orodispersible tablet.

Aspartame is a source of phenylalanine. It can be harmful if you have phenylketonuria (PKU), a rare hereditary disorder in which phenylalanine builds up because the body cannot properly convert it.

Rizatriptan disp Teva contains benzoate
This medication contains 4.5 mg of benzoate (as rizatriptan benzoate) in each orodispersible tablet.

Rizatriptan disp Teva contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per orodispersible tablet, which means it is essentially 'sodium-free'.

3. HOW TO USE THIS MEDICINE?

This medicine is used for the treatment of migraine attacks. Take this medicine as soon as possible after the onset of your migraine headache. Do not use it to prevent a migraine attack.

Always use this medicine exactly as your doctor or pharmacist has told you. Unsure about the correct use? Then contact your doctor or pharmacist.
The recommended dosages are not all possible with this product, however, there are products available with a lower strength than 10 mg.

The advised dosage is 10 mg.
Use the 5 mg dose of rizatriptan if you are currently using propranolol or if you have kidney or liver problems. Wait at least 2 hours after taking propranolol before taking this medicine and do not take more than 2 doses in a 24-hour period.

How do you take this medicine?
This medicine is an orodispersible tablet that dissolves in the mouth.
The orodispersible tablet can be used in situations where you do not have liquid available, or if you become nauseous or vomit from taking tablets with liquid.

Do not handle the tablets with wet hands, as the orodispersible tablets may disintegrate.

1. Hold the blister strip at the side and remove one dose from the blister strip using the perforation line by gently pulling and loosening around it.
2. Carefully peel off the back.
3. Gently push the tablet out of the strip.
4. Place the tablet on your tongue. The tablet dissolves directly in the mouth, making it easy to swallow.

If the migraine returns within 24 hours
In some patients, migraine symptoms may return within 24 hours. If your migraine returns, you can take another dose of this medicine. However, you must wait at least 2 hours between doses.
If you still have a migraine after 2 hours

If you do not respond to this medicine during a migraine attack, do not take a second dose of this medicine for the treatment of the same attack.
However, it is likely that this medication will work during the next migraine attack.

Do not take more than 2 doses of this medication in a 24-hour period (for example, do not take more than two orodispersible tablets of 5 mg or 10 mg in a 24-hour period). Always wait at least 2 hours between doses.
If your condition worsens, seek medical help.

Have you used too much of this medication?
If you have used too much of this medication, contact your doctor or pharmacist immediately. Take the medication packaging with you.

Signs of overdose may include: dizziness, drowsiness, vomiting, fainting, and a slow heartbeat.

Do you have any other questions about the use of this medication? Then contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like any medication, this medication can have side effects. Not everyone experiences them. The following side effects may occur with the use of this medication.

In studies in adults, the most reported side effects were dizziness, drowsiness, and fatigue.

- Common: occur in less than 1 in 10 users
- Tingling sensation (paresthesia), headache, reduced skin sensitivity (hypoesthesia), reduced mental sharpness, insomnia.
- Irregular or rapid heartbeat (palpitations).
- Flushing (short-term redness of the face).
- Sore throat.
- Feeling sick (nausea), dry mouth, vomiting, diarrhea, indigestion (dyspepsia).
- Heavy feeling in parts of the body, neck pain, stiffness.
- Abdominal pain or chest pain.
- Sometimes: occur in less than 1 in 100 users
- Bad taste in the mouth.
- Feeling unsteady when walking (ataxia), dizziness (vertigo), blurred vision, trembling, fainting (syncope).
- Confusion, nervousness.
- High blood pressure (hypertension), thirst, hot flashes, sweating.
- Skin rash, itching and bumpy skin rash (hives), swelling of the face, lips, tongue and/or throat which may cause difficulty breathing and/or swallowing (angioedema), difficulty breathing (dyspnea).
- Localized feeling of tightness, muscle weakness.
- Changes in the rhythm or rate of the heartbeat (arrhythmia), abnormalities of the electrocardiogram (a test that measures the electrical activity of your heart), rapid heartbeat (tachycardia).
- Facial pain, muscle pain.

Rare: occur in less than 1 in 1,000 users

- Wheezing.
- Allergic reaction (hypersensitivity), sudden life-threatening allergic reaction (anaphylaxis).
- Stroke (this occurs mainly in patients with risk factors for cardiovascular disease (high blood pressure, diabetes, smoking, use of nicotine substitutes, heart disease or stroke in the family, men over 40 years, postmenopausal women, specific heart rhythm problems [bundle branch block])).
- Slow heartbeat (bradycardia).
- Not known: cannot be determined from the available data
- Heart attack, contraction of the blood vessels of the heart (this occurs mainly in patients with risk factors for cardiovascular disease (high blood pressure, diabetes, smoking, use of nicotine substitutes, heart disease or stroke in the family, men over 40 years, postmenopausal women, specific heart rhythm problems [bundle branch block])).
- A syndrome called 'serotonin syndrome' which can cause side effects such as coma, blood pressure fluctuations, extremely high body temperature, lack of muscle coordination, agitation, and hallucinations.
- Severe skin peeling with or without fever (toxic epidermal necrolysis).
- Seizures (convulsions).
- Contraction of blood vessels in the limbs, with coldness and numbness of the hands and feet.
- Contraction of the blood vessels in the large intestine, which can cause abdominal pain.

If you experience symptoms of an allergic reaction, serotonin syndrome, a heart attack, or stroke, contact your doctor immediately.
Also, if you experience symptoms after taking this medicine that could indicate an allergic reaction (such as a rash or itching), you should contact your doctor immediately.

Reporting side effects
If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you help us obtain more information about the safety of this medicine.

5. HOW TO STORE THIS MEDICINE?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find this on the box and the blister pack after `EXP`. It includes a month and a year. The last day of that month is the expiry date.

Store in the original packaging to protect against moisture.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed correctly and do not enter the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What substances are in this medicine?
The active substance in this medicine is rizatriptan.
Each 10 mg orodispersible tablet contains 10 mg rizatriptan, equivalent to 14.53 mg rizatriptan benzoate.
The other substances (excipients) in this medicine are lactose monohydrate, corn starch, mannitol (E421), pregelatinized starch (corn), aspartame (E951), peppermint flavor, colloidal anhydrous silica, and sodium stearyl fumarate.
What does Rizatriptan disp Teva look like and what is in a pack?
The orodispersible tablets are white to off-white, round, flat tablets with beveled edges, engraved with 'IZ' on one side and '10' on the other side.
Rizatriptan disp Teva is packaged in blister packs of 2, 3, 6, 12, 18, 28, and 30 orodispersible tablets.

Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer
Marketing authorization holder

Teva Nederland B.V. Swensweg 5
2031 GA Haarlem Netherlands

Manufacturer Pharmachemie B.V. Swensweg 5
2031 GA Haarlem Netherlands
TEVA Pharmaceutical Works Pallagi ùt 13
4042 Debrecen Hungary
Teva Operations Poland Ul. Mogilska 80
31-546 Krakow Poland

Merckle GmbH
Ludwig-Merckle-Straße 3
89143 Blaubeuren Germany
Registered in the register under
RVG 104485, orodispersible tablets 10 mg

This medicine is registered in member states of the European Economic Area under the following names:
France 10 mg: Rizatriptan Teva 10 mg, comprimé orodispersible
Germany 5 mg: Rizatriptan-ratiopharm 5 mg Schmelztabletten
10 mg: Rizatriptan-ratiopharm 10 mg orally disintegrating tablets
Italy 5 mg: Rizatriptan Teva 5 mg orodispersible tablets 10 mg: Rizatriptan Teva 10 mg orodispersible tablets
Netherlands 10 mg: Rizatriptan disp 10 mg Teva, orodispersible tablets
Spain 10 mg: Rizatriptan Teva 10 mg buccodispersible tablets EFG

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