PACKAGE LEAFLET: INFORMATION FOR THE USER

MAXALT® MELT 10 mg ORAL LYOPHILISATE

(rizatriptan benzoate)

Your medicine is known as Maxalt Melt 10mg Oral Lyophilisate but will be referred to as Maxalt Melt throughout the following leaflet.

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 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 MAXALT MELT IS AND WHAT IT IS USED FOR

Maxalt Melt belongs to a class of medicines called selective serotonin 5-$HT_{1B/1D}$ receptor agonists.

Maxalt Melt is used to treat the headache phase of the migraine attack in adults.

Treatment with Maxalt Melt:

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

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MAXALT MELT

Do not take Maxalt Melt if:

- you are allergic (hypersensitive) 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
- you are now taking ergotamine-type medications, such as ergotamine or dihydro-ergotamine 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 migraine (see **Other medicines and Maxalt Melt** below).

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Maxalt Melt, 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 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 allergies
- your headache is associated with dizziness, difficulty in walking, lack of coordination 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 Maxalt Melt 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 Maxalt Melt.

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

Tell your doctor or pharmacist if you are taking, have recently taken or might 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 Maxalt Melt can affect the way some medicines work. Also, other medicines can affect Maxalt Melt.

Other medicines and Maxalt Melt

Do not take Maxalt Melt:

- if you are already taking a 5-$HT_{1B/1D}$ 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 dihydro-ergotamine to treat your migraine
- if you use methysergide to prevent a migraine attack.

The above listed medicines when taken with Maxalt Melt may increase the risk of side effects.

You should wait at least 6 hours after taking Maxalt Melt before you take ergotamine-type medications such as ergotamine or dihydro-ergotamine or methysergide.

You should wait at least 24 hours after taking ergotamine-type medications before taking Maxalt Melt.

Ask your doctor for instructions and the risks about taking Maxalt Melt

- if you are taking propranolol (see section 3: **How to take Maxalt Melt**)
- 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.

Maxalt Melt with food and drink

Maxalt Melt 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.

Available data on the safety of rizatriptan when used during the first 3 months of pregnancy do not suggest an increased risk of birth defects. It is not known whether MAXALT MELT is harmful to an unborn baby when taken by a pregnant woman after the first 3 months of pregnancy.

If you are breastfeeding, you may postpone breastfeeding for 12 hours after treatment to avoid exposure in your baby.

Children and adolescents

The use of Maxalt Melt oral lyophilisates 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 Maxalt Melt is amongst patients older than 65 years.

Driving or using machines

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

Maxalt Melt contains aspartame

This medicine contains 3.75 mg aspartame in each 10 mg oral lyophilisate which is equivalent to 2.1 mg phenylalanine.

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 MAXALT MELT

Maxalt Melt is used to treat migraine attacks. Take Maxalt Melt 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 has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is 10 mg.

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

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 Maxalt Melt. 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 Maxalt Melt during an attack, you should not take a second dose of Maxalt Melt for treatment of the same attack. It is still likely, however, that you will respond to Maxalt Melt during the next attack.

Do not take more than 2 doses of Maxalt Melt in a 24-hour period, (for example, do not take more than two 10 mg oral lyophilisates or more than two 10 mg 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.

How to administer Maxalt Melt oral lyophilisates

- Maxalt Melt (rizatriptan benzoate) is available as a 5 or 10 mg oral lyophilisate that dissolves in the mouth.
- Open the Maxalt Melt oral lyophilisate blister pack with dry hands.
- The oral lyophilisate should be placed on your tongue, where it dissolves and can be swallowed with the saliva.
- The oral lyophilisate 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.

Maxalt Melt is also available as a tablet to be taken with liquids.

If you take more Maxalt Melt than you should:

If you take more Maxalt Melt 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 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. The following side effects may happen with this medicine.

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

Common (affects 1 to 10 users in 100)

- tingling (paraesthesia), headache, decreased sensitivity of skin (hypoaesthesia), decreased mental sharpness, insomnia
- fast or irregular heart beat (palpitation)
- flushing (redness of the face lasting a short time)
- throat discomfort
- feeling sick (nausea), dry mouth, vomiting, diarrhoea, indigestion (dyspepsia)
- feeling of heaviness in parts of the body, neck pain, stiffness
- pain in abdomen or chest.

Uncommon (affects 1 to 10 users in 1000)

- bad taste in your mouth
- unsteadiness when walking (ataxia), dizziness (vertigo), blurred vision, tremor, fainting (syncope)
- confusion, nervousness
- 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 (angioedema), difficulty breathing (dyspnoea)
- feeling of tightness in parts of the body, muscle weakness.
- changes in the rhythm or rate of the heartbeat (arrhythmia); abnormalities of the electrocardiogram (a test that records the electrical activity of your heart), very fast heartbeat (tachycardia)
- facial pain; muscle pain.

Rare (affects 1 to 10 users in 10,000)

- 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, postmenopausal women, particular problem with the way your heart beats (bundle branch block))
- slow heartbeat (bradycardia).

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 Maxalt Melt.

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 or search for MHRA Yellow Card in the **Google Play** or **Apple App Store.** By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE MAXALT MELT

- **KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.**
- Do not store above 30°C.
- Do not remove the wafer blister or the aluminium sachet until you are ready to take the medicine inside.
- Always keep the aluminium sachets in the carrying case.
- Store in the original package in order to protect from moisture.
- Do not use Maxalt Melt after the expiry date which is stated on the container after EXP. The expiry date refers to the last day of the month.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Maxalt Melt contains

- The active substance is rizatriptan.

  Each oral lyophilisate contains 14.53mg rizatriptan benzoate equivalent to 10mg rizatriptan.
- Maxalt Melt also contains the following inactive ingredients: gelatin, mannitol (E421), glycine, aspartame (E951) and peppermint flavour (composed of peppermint oil, maltodextrin and dextrin).

What Maxalt Melt looks like and contents of the pack

Maxalt Melt Oral Lyophilisates are white to off-white, round with a modified square on one side, with a peppermint flavour.

Maxalt Melt is available in packs with 2, 3, 6 or 12 oral lyophilisates.

Product Licence holder

Procured from within the EU and repackaged for the PL Holder: Abacus Medicine Ltd., Abbey House, 282 Farnborough Road, Farnborough, GU14 7NA, United Kingdom.

Manufacturer

This product is manufactured by Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, The Netherlands.

POM PL: 45763/1673

Leaflet revision date: 07 April 2025

Blind or partially sighted? Is this leaflet hard to see or read? Call 02036301310 or write to info@abacusmedicine.com to obtain the leaflet in a format suitable for you.

Maxalt® is a registered trade mark of Merck Sharp & Dohme Corp., USA.

Further information about migraine is available from the following organisations:

Migraine Action Association

4th Floor, 27 East Street

Leicester

LE1 6NB

Tel: 08456 011 033

Email: info@migraine.org.uk

and

The Migraine Trust

4th Floor

Mitre House

44-46 Fleet Street

London

EC4Y 1BN

Tel: 0203 9510 150

(Migraine Action Association and The Migraine Trust are independent organisations and are not associated with Merck Sharp & Dohme Limited.)

A1673 LEAFLET Maxalt 20250407

PACKAGE LEAFLET: INFORMATION FOR THE USER

RIZATRIPTAN 10 mg ORAL LYOPHILISATE

(rizatriptan benzoate)

Your medicine is known as Rizatriptan 10mg Oral Lyophilisate but will be referred to as Rizatriptan throughout the following leaflet.

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 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

Rizatriptan belongs to a class of medicines called selective serotonin 5-$HT_{1B/1D}$ 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.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RIZATRIPTAN

Do not take Rizatriptan if:

- you are allergic (hypersensitive) 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
- you are now taking ergotamine-type medications, such as ergotamine or dihydro-ergotamine 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 migraine (see **Other medicines and Rizatriptan** below).

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 before taking Rizatriptan, 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 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 allergies
- your headache is associated with dizziness, difficulty in walking, lack of coordination 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.

Tell your doctor or 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.

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

Do not take Rizatriptan:

- if you are already taking a 5-$HT_{1B/1D}$ 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 dihydro-ergotamine 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 dihydro-ergotamine or methysergide.

You should wait at least 24 hours after taking ergotamine-type 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 and drink

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 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.

Available data on the safety of rizatriptan when used during the first 3 months of pregnancy do not suggest an increased risk of birth defects. It is not known whether MAXALT MELT is harmful to an unborn baby when taken by a pregnant woman after the first 3 months of pregnancy.

If you are breastfeeding, you may postpone breastfeeding for 12 hours after treatment to avoid exposure in your baby.

Children and adolescents

The use of Rizatriptan oral lyophilisates 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 is amongst patients older than 65 years.

Driving or using machines

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

Rizatriptan contains aspartame

This medicine contains 3.75 mg aspartame in each 10 mg oral lyophilisate which is equivalent to 2.1 mg phenylalanine.

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 RIZATRIPTAN

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.

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

The usual dose is 10 mg.

If you are currently taking propranolol or have kidney or liver problems you should use the 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.

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. 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 oral lyophilisates or more than two 10 mg 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.

How to administer Rizatriptan oral lyophilisates

- Rizatriptan (rizatriptan benzoate) is available as a 5 or 10 mg oral lyophilisate that dissolves in the mouth.
- Open the Rizatriptan oral lyophilisate blister pack with dry hands.
- The oral lyophilisate should be placed on your tongue, where it dissolves and can be swallowed with the saliva.
- The oral lyophilisate 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.

Rizatriptan is also available as a tablet to be taken with liquids.

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

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. The following side effects may happen with this medicine.

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

Common (affects 1 to 10 users in 100)

- tingling (paraesthesia), headache, decreased sensitivity of skin (hypoaesthesia), decreased mental sharpness, insomnia
- fast or irregular heart beat (palpitation)
- flushing (redness of the face lasting a short time)
- throat discomfort
- feeling sick (nausea), dry mouth, vomiting, diarrhoea, indigestion (dyspepsia)
- feeling of heaviness in parts of the body, neck pain, stiffness
- pain in abdomen or chest.

Uncommon (affects 1 to 10 users in 1000)

- bad taste in your mouth
- unsteadiness when walking (ataxia), dizziness (vertigo), blurred vision, tremor, fainting (syncope)
- confusion, nervousness
- 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 (angioedema), difficulty breathing (dyspnoea)
- feeling of tightness in parts of the body, muscle weakness.
- changes in the rhythm or rate of the heartbeat (arrhythmia); abnormalities of the electrocardiogram (a test that records the electrical activity of your heart), very fast heartbeat (tachycardia)
- facial pain; muscle pain.

Rare (affects 1 to 10 users in 10,000)

- 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, postmenopausal women, particular problem with the way your heart beats (bundle branch block))
- slow heartbeat (bradycardia).

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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store.** By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE RIZATRIPTAN

- **KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.**
- Do not store above 30°C.
- Do not remove the wafer blister or the aluminium sachet until you are ready to take the medicine inside.
- Always keep the aluminium sachets in the carrying case.
- Store in the original package in order to protect from moisture.
- Do not use Rizatriptan after the expiry date which is stated on the container after EXP. The expiry date refers to the last day of the month.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Rizatriptan contains

- The active substance is rizatriptan.

  Each oral lyophilisate contains 14.53mg rizatriptan benzoate equivalent to 10mg rizatriptan.
- Rizatriptan also contains the following inactive ingredients: gelatin, mannitol (E421), glycine, aspartame (E951) and peppermint flavour (composed of peppermint oil, maltodextrin and dextrin).

What Rizatriptan looks like and contents of the pack

Rizatriptan Oral Lyophilisates are white to off-white, round with a modified square on one side, with a peppermint flavour.

Rizatriptan is available in packs with 2, 3, 6 or 12 oral lyophilisates.

Product Licence holder

Procured from within the EU and repackaged for the PL Holder: Abacus Medicine Ltd., Abbey House, 282 Farnborough Road, Farnborough, GU14 7NA, United Kingdom.

Manufacturer

This product is manufactured by Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, The Netherlands.

POM PL: 45763/1673

Leaflet revision date: 07 April 2025

Blind or partially sighted? Is this leaflet hard to see or read? Call 02036301310 or write to info@abacusmedicine.com to obtain the leaflet in a format suitable for you.

Further information about migraine is available from the following organisations:

Migraine Action Association

4th Floor, 27 East Street

Leicester

LE1 6NB

Tel: 08456 011 033

Email: info@migraine.org.uk

and

The Migraine Trust

4th Floor

Mitre House

44-46 Fleet Street

London

EC4Y 1BN

Tel: 0203 9510 150

(Migraine Action Association and The Migraine Trust are independent organisations and are not associated with Merck Sharp & Dohme Limited.)

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