

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Rizatriptan Rizatriptan Inovamed Orodispersible 10 mg Inovamed 10 mg

Tablets	Orodispersible Tablets
Each tablet contains: Rizatriptan 10 mg (as benzoate)	Each orodispersible tablet contains: Rizatriptan 10 mg (as benzoate)

For a list of inactive and allergenic ingredients in the preparation, see section 2 "Important information about some of the ingredients in this medicine" and section 6 "Further Information".

Unless otherwise stated, the information in this patient package insert applies to both **Rizatriptan Inovamed 10 mg** tablets and **Rizatriptan Orodispersible Inovamed 10 mg** orodispersible tablets.

Read this leaflet carefully in its entirety before using the medicine.

- This leaflet contains concise information about the medicine. If you have further questions, refer to your doctor or pharmacist.
- This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.
- This medicine is intended for adults above the age of 18.

1. WHAT IS THE MEDICINE INTENDED FOR?

Rizatriptan is used for the acute treatment of migraine attacks in adults, with or without aura.

Rizatriptan is not to be used to prevent migraine attacks.

Rizatriptan is not for the treatment of hemiplegic or basilar migraines.

It is not known if Rizatriptan is safe and effective for the treatment of cluster headaches.

Therapeutic group: A class of medicines called selective 5-HT_{1B/1D} receptor agonists or triptans.

2. BEFORE USING THE MEDICINE

<p>Do not use Rizatriptan if:</p> <ul style="list-style-type: none">- you are sensitive (allergic) to the active ingredient or any of the additional ingredients contained in the medicine, which are listed in section 2 and section 6.- you have or have had heart problems.- you are having or have had a stroke or a transient ischemic attack (TIA).- you have or have had blood vessel problems, including ischemic bowel disease.- you have uncontrolled high blood pressure.- you are concurrently taking antidepressant medicines from the monoamine oxidase (MAO) inhibitors group or have taken a MAO inhibitor within the last two weeks.- you have taken any other medicine in the same class (triptans), such as sumatriptan, naratriptan, zolmitriptan or eletriptan, to treat your migraine in the last 24 hours.- you have taken ergotamine-containing medicines such as ergotamine, dihydroergotamine or methysergide in the last 24 hours.- you have hemiplegic or basilar migraines.

Talk to your doctor before taking Rizatriptan if you have any of the conditions listed above or if you are not sure if you are taking any of the medicines listed above.

Special warnings regarding use of this medicine Before beginning treatment with Rizatriptan, tell your doctor if:

- you have or have had heart problems (such as heart attack, decreased blood flow to the heart, or changes in the rhythm or rate of the heartbeat), high blood pressure, chest pain or shortness of breath.
 - you have any risk factors for heart disease or blood vessel disease such as high blood pressure, diabetes, high cholesterol, obesity, smoking, family history of heart problems, you are a post-menopausal woman, you are a male over 40.
 - you have or have had any allergies.
 - you have phenylketonuria (PKU). Rizatriptan Orodispersible Inovamed 10 mg orodispersible tablets contain phenylalanine (see section 2 "Important information about some of the ingredients in this medicine").
 - you are pregnant or plan to become pregnant, or you are breastfeeding or plan to breastfeed.
 - you are taking or plan to take any medicines, including those obtained without a prescription, and those you normally take for a migraine, because an exacerbation of headache (MOH – medication overuse headache) can develop due to overuse of medicines for the treatment of migraine (such as: ergotamine, triptans, opioids or using a combination of these medicines for more than 10 days a month).
 - you are suffering or have suffered in the past from kidney or liver problems.
- If you take Rizatriptan too often, this may result in you getting chronic headaches. In such cases, you should contact your doctor, as you may have to stop taking Rizatriptan.
- you have any other medical conditions.
- Tell the doctor about your symptoms. Your doctor will decide if you have migraines. 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 neurological conditions.

Drug interactions

If you are taking, or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Medicines that should not be taken concomitantly with Rizatriptan

- Do not take Rizatriptan with any other medicine in the same class (triptans) within 24 hours, such as sumatriptan, naratriptan, zolmitriptan or eletriptan.
- Do not take Rizatriptan within 24 hours of taking ergotamine-containing medicines, such as ergotamine, dihydroergotamine or methysergide to treat your migraine.
- Do not take Rizatriptan when you are taking antidepressant medicines from the monoamine oxidase (MAO) inhibitors group, such as moclobemide, isocarboxazid, phenelzine or tranlycypromine and pargyline, or if it has been less than two weeks since you stopped taking a MAO inhibitor.

In particular, inform the doctor or pharmacist if you are taking:

- propranolol-containing medicines.
- medicines used to treat mood disorders, including medicines from the group of selective serotonin re-uptake inhibitors (SSRIs), such as fluoxetine, fluvoxamine, paroxetine, escitalopram oxalate and sertraline, or serotonin norepinephrine reuptake inhibitors (SNRIs), such as venlafaxine and duloxetine for depression.

Use of the medicine and food

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 breastfeeding

It is not known whether Rizatriptan is harmful to an unborn baby when taken by a pregnant woman. Tell the doctor before taking this medicine if you are pregnant or planning to become pregnant.

It is not known if Rizatriptan passes into breast milk. If you are breastfeeding or plan to breastfeed, consult your doctor. Breastfeeding should be avoided for 24 hours after treatment.

Consult your doctor or pharmacist before using medicines.

Driving and using machinery

Rizatriptan may cause dizziness, sleepiness, tiredness, weakness or fainting. If you have these symptoms, do not drive a car, operate dangerous machinery or engage in any other activity which requires alertness.

Important information about some of the ingredients in this medicine

Rizatriptan Inovamed 10 mg: The tablet of Rizatriptan Inovamed 10 mg contains lactose monohydrate, which is a type of sugar. If you have been told by the doctor that you have an intolerance to lactose or you are unable to digest certain sugars, consult with the doctor before taking this medicine.

Rizatriptan Orodispersible Inovamed 10 mg:

- This medicine contains 3.741 mg aspartame in each orodispersible tablet of Rizatriptan Orodispersible Inovamed 10 mg. 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.
- This medicine contains less than 23 mg sodium per orodispersible tablet, and is therefore considered to be sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation. The dosage and treatment regimen will be determined by the doctor only.

Do not exceed the recommended dosage.

The maximum dosage is 30 mg Rizatriptan in any 24-hour period. Do not take more than 30 mg of Rizatriptan in a 24-hour period (for example, do not take more than three 10 mg tablets or orodispersible tablets in a 24-hour period).

Some patients should receive a lower dose of Rizatriptan, in particular the following patient groups:

- Patients taking propranolol
- Moderate to severe hepatic impairment
- Renal impairment
- Elderly patients

If a lower dose is not optional, the doctor should consider alternative therapies for these patients, for example, other 5-HT_{1B/1D} agonists.

This medicine is not intended for administration to children and adolescents below the age of 18 years.

Most migraine attacks are relieved with Rizatriptan. However, 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 you do not respond to Rizatriptan during an attack, it is recommended that you do not take Rizatriptan for treatment of the same attack. You may, however, still respond to Rizatriptan during the next attack.

Directions for use

Rizatriptan Inovamed 10 mg: The tablet should be swallowed whole with liquid. There is no information regarding crushing/halving/chewing the tablets.

Rizatriptan Orodispersible Inovamed 10 mg: Leave the orodispersible tablet in its package until the moment you are ready to take it.

Open the blister pack with dry hands and place the orodispersible tablet on your tongue, where it will dissolve rapidly and be swallowed with your saliva. Administration with liquid is not necessary. The orodispersible tablet can be taken without regard to meals.

If you accidentally take a higher dose than you should:

If you took more Rizatriptan than you should, refer immediately to your doctor or proceed immediately to the nearest hospital emergency room.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Rizatriptan may cause side effects in some users.

Do not be alarmed by the list of side effects. You may not suffer from any of them.

Contact the doctor or proceed to the nearest hospital emergency room immediately if you develop any of the serious side effects of Rizatriptan, including:

- **heart attack.** Symptoms of a heart attack may include:
 - discomfort in the center of your chest that lasts for more than a few minutes or that goes away and comes back
 - chest discomfort that feels like uncomfortable pressure, squeezing, fullness or pain
 - pain or discomfort in your arms, back, neck, jaw or stomach
 - shortness of breath with or without chest discomfort
 - cold sweat
 - nausea or vomiting
 - feeling dizzy
- **stroke.** Symptoms of a stroke may include the following sudden symptoms:
 - numbness or weakness in your face, arms or legs, especially on one side of your body
 - confusion, problems speaking or understanding
 - problems seeing in one or both of your eyes
 - problems walking, dizziness, loss of balance or coordination
 - severe headache with no known cause
- **blood vessel problems.** Symptoms of blood vessel problems may include:
 - abdominal pain
 - bloody diarrhea
 - vision problems
 - coldness and numbness of hands and feet
- **serotonin syndrome.** A condition called serotonin syndrome can happen when triptan medicines such as Rizatriptan are taken with certain other medicines. Symptoms of serotonin syndrome may include:
 - agitation
 - hallucinations
 - coma
 - fast heartbeat
 - fast changes in your blood pressure
 - increased body temperature
 - muscle spasms
 - loss of coordination
 - nausea, vomiting or diarrhea
- **increased blood pressure.**
- **Allergic reactions** including swelling of face, lips, tongue and/or throat which may cause difficulty in breathing and/or swallowing, wheezing, hives, rash and severe sloughing of the skin.

In addition, tell your doctor if you experience any symptoms that suggest an allergic reaction (such as a rash or itching) after taking Rizatriptan.

Additional side effects:

The most common side effects of Rizatriptan include:

- feeling sleepy or tired
- pain or a sensation of pressure in your chest or throat
- dizziness

Other side effects (common: 1-10 in 100 patients; uncommon: 1-10 in 1,000 patients; rare: 1-10 in 10,000 patients) and side effects of unknown frequency:

Immune system disorders: *rare:* allergic reaction (hypersensitivity), sudden life-threatening allergic reaction (anaphylaxis).

Gastrointestinal disorders: *common:* nausea, vomiting, diarrhea, dry mouth; *uncommon:* thirst, indigestion (dyspepsia).

Respiratory, tracheal and thoracic disorders: *common:* throat discomfort/pain, difficulty breathing (dyspnea); *rare:* wheezing.

Musculoskeletal and connective tissue disorders: *common:* feelings of heaviness in parts of the body, neck pain; *uncommon:* feeling of tightness in certain parts of the body, muscle weakness, stiffness, muscle pain and facial pain.

Skin and subcutaneous tissue disorders: *common:* flushing (redness of the face lasting a short time); *uncommon:* sweating, itching, lumpy rash (hives), rash, angioedema (swelling of the face, lips, tongue and/or throat which may cause difficulty breathing and/or swallowing).

Cardiac disorders: *common:* fast or irregular heartbeat (palpitation); *uncommon:* very fast heartbeat (tachycardia), changes in the rhythm or rate of the heartbeat (arrhythmia), slow heartbeat (bradycardia), abnormalities of the ECG (a test that records the electrical activity of your heart); *rare:* stroke (this generally occurs in patients with risk factors for cardiovascular disease (high blood pressure, diabetes, smoking, use of nicotine replacement, family history of heart disease or stroke, males over 40 years of age, postmenopausal women, particular problem with the way your heart beats (bundle branch block)).

Vascular disorders: *uncommon:* hypertension; *rare:* hot flushes; *unknown frequency:* peripheral vascular ischemia.

Nervous system disorders: *common:* dizziness, sleepiness, tingling sensation in the skin (paresthesia), headache, decreased sensitivity of skin (hypoesthesia), decreased mental sharpness, tremor; *uncommon:* bad taste in your mouth, unsteadiness when walking (ataxia), vertigo; *rare:* fainting.

Psychiatric disorders: *uncommon:* confusion/disorientation, insomnia.

Eye disorders: *uncommon:* blurred vision.

General disorders and administration site conditions: *common:* pain in abdomen or chest, tiredness.

Reported side effects with unknown frequency (effects whose frequency has not been determined):

- heart attack, spasm of the blood vessels of the heart (these generally occur in patients with risk factors for cardiovascular disease (hypertension, diabetes, smoking, use of nicotine replacement, family history of heart disease or stroke, males over 40 years of age, postmenopausal women, particular problem with the way your heart beats (bundle branch block)).
- severe shedding of the skin with or without fever (toxic epidermal necrolysis).
- seizures (convulsions/epileptic fits).
- a syndrome called "serotonin syndrome" that may cause side effects, e.g.; coma, unstable blood pressure, extremely high body temperature, lack of muscle coordination, agitation and hallucinations.
- spasm of blood vessels of the extremities including coldness and numbness of the hands or feet.
- spasm of the blood vessels of the large bowel, which can cause abdominal pain.
- visual disorders such as flickering, reduced vision, double vision, loss of vision and in some cases even permanent defects of vision (however, these may also occur due to the migraine attack itself).

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects may be reported to the Ministry of Health by clicking the link "Report side effects of drug treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the following link:

<https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- **Avoid poisoning!** This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store at a temperature below 25°C.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose medicines no longer in use. These measures will help to protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, **Rizatriptan Inovamed 10 mg** also contains:

Microcrystalline cellulose (PH-101), lactose monohydrate, maize starch, pregelatinized starch, magnesium stearate, ferric oxide red.

In addition to the active ingredient, **Rizatriptan Orodispersible Inovamed 10 mg** also contains: Microcrystalline cellulose (PH-101), mannitol, pregelatinized starch, crospovidone (type A), aspartame, peppermint flavor (maltodextrin, natural flavors, modified corn starch), sodium stearyl fumarate.

What the medicine looks like and the contents of the package:

Rizatriptan Inovamed 10 mg: Pale, pink, circular, flat, uncoated tablets debossed with "X" on one side and "14" on other side.

Rizatriptan Orodispersible Inovamed 10 mg: White to off-white, circular, biconvex tablets debossed with "F25" on one side and plain on other side, with a peppermint flavor.

Pack sizes:

Rizatriptan Inovamed 10 mg: packs with 1, 2, 3, 6, 12 or 18 tablets.

Rizatriptan Orodispersible Inovamed 10 mg: packs with 2, 3, 6, 10, 12 or 18 orodispersible tablets. Not all pack sizes may be marketed.

Manufacturer and address: Aurobindo Pharma Ltd., Plot #2, Maitrivihar, Ameerpet, Hyderabad, 500 038, India.

Registration holder and importer and its address: Inovamed Ltd., P.O.B. 62, Even Yehuda 40500.

Revised in March 2022 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Rizatriptan Inovamed 10 mg: 155.08.34133

Rizatriptan Orodispersible Inovamed 10 mg: 155.09.34154