

Rizatriptan Inovamed 10 mg Tablets

Each tablet contains:

Rizatriptan 10mg (as benzoate)

Rizatriptan Melt Inovamed 10 mg Soluble tablets

Each tablet contains:

Rizatriptan 10mg (as benzoate)

Inactive and allergenic substances in the preparation: please see Additional Information section at the end of the leaflet.

Please read the leaflet carefully and thoroughly prior to using the medicine. This leaflet contains concise information about the medicine. If you have any additional questions, please consult your physician or pharmacist
This medicine was prescribed for you. Do not transfer it to others. It may harm them even if their medical condition appears to be similar to yours.

This medicine is not designated for children and adolescents under 18 years.

What is this medicine used for?

For treatment of acute migraine attacks in adults with or without aura.

Do not use Rizatriptan to prevent migraine attacks.

Rizatriptan is not designated for treatment of hemiplegic or basilar migraines

It is unknown whether Rizatriptan is safe and effective for treatment of cluster headaches.

Therapeutic group: triptans, selective 5HT1 serotonin receptor agonist.

BEFORE TAKING THE MEDICINE

Do not use the medicine if:

- You are sensitive to the active ingredient or any other ingredients of the medicine
- You have unbalanced hypertension
- You have cardiac disease or history of cardiac disease
- You are taking anti-depression medicines of monoamine oxidase (MAO) inhibitor group or if you have taken one of these medicines in the last two weeks (see “interactions”)
- 24 hours after the treatment with another medicine of the same group (e.g. sumatriptan, naratriptan, zolmitriptan, alatriptan) or medicines of the ergotamine group, e.g. ergotamine, dehydroergotamine or methysergide
- You have or previously had a stroke or ischemic attack (TIA)
- You have or used to have vascular problems including ischemic intestinal disease
- You have hemiplegic or basilar migraines

Speak to your physician before taking this medicine if you have one of the above listed conditions or are not sure whether you are taking one of the above medicines.

SPECIAL WARNINGS REGARDING USE OF THE MEDICINE

Before taking this medicine, let your physician know whether:

- You have or used to have cardiac problems (e.g. heart attack, decreased blood supply to the heart or changes in the rhythm or rate of your heartbeats), hypertension, chest pains or shortness of breath
- You have a risk factor for cardiac disease or cardiovascular disease including hypertension, diabetes, high cholesterol level, obesity, smoking, family history of cardiac problems – post-menstrual woman, man over 40
- You have or had any allergies
- You have phenylketonuria (PKU). Soluble Rizatriptan – soluble tablets contain phenylalanine (also see Important Information Regarding Some Components section)
- You are taking or about to take medicines of any type, including non-prescription drugs, and those you usually take for migraine (see section 2.3 “Taking Other Medicines”). This may cause your headaches to get worse (medicine overuse headache – MOH) due to excessive use of migraine medicines (e.g. ergotamine, triptans, opioids or a combination of these medicines for over 10 days per month)
- If you take Rizatriptan too often, you may suffer from chronic headaches. In this case, you must consult your physician since you may have to stop using Rizatriptan
- You suffered or are suffering from kidney or liver problems
- You have other medical problems
- Tell your physician about your symptoms and let him decide whether you have migraine. Rizatriptan should only be administered for migraine attacks. Do not use Rizatriptan for treating headaches that may be caused by other, more serious, neurological conditions

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

Medicines that should not be administered together with Rizatriptan (see section “Don't Take Rizatriptan if”):

- Do not take the drug with another medicine of the same group (triptans) for 24 hours, e.g. sumatriptan, naratriptan, zolmitriptan or alatriptan.
- Do not take the medicine 24 hours after taking medicines containing ergotamine, e.g. ergotamine, dehydroergotamine or methysergide to treat your migraine.
- Do not take if you are taking monoamine oxidase (MAO) inhibitor anti-depressants, e.g. moclobemide, isocarboxazid, phenelzine, tranylcypromine or fragiline, or if less than two weeks passed after you stopped taking the MAO inhibitor.

Inform your physician or pharmacist if you are taking:

- Medicines containing propranolol
- Medicines used to treat depression including medicines from the selective serotonin reuptake inhibitor (SSRI) group: fluoxetine, fluvoxamine, paroxetine, escitalopram and sertraline, or selective norepinephrine reuptake inhibitors (SNRI), including venlafaxine and duloxetine antidepressants.

Using the medicine with food

The medicine may take more time to work if it is taken together with food. Although it is better to take the medicine on an empty stomach, it can still be taken after a meal.

Pregnancy and lactation

It is unknown whether Rizatriptan can infiltrate into mother's milk. If you are lactating or planning to do so, please consult your physician. Do not breastfeed for the 24 hours following the medicine administration.

Driving and operating machines

Caution must be taken when driving, operating dangerous machinery and any other action that requires alertness because use of this medicine may cause dizziness, weakness or faintness, drowsiness, fatigue or exhaustion.

Important information regarding some ingredients of the medicine

- Rizatriptan Inovamed tablets contain lactose. Please inform your physician in case of lactose intolerance
- Soluble Rizatriptan Inovamed tablets contain phenylalanine, a component of Aspartame sweetener (a 10mg soluble tablet contains 10.2mg phenylalanine). Therefore, please notify your physician if you are suffering from phenylketonuria.

How to use the medicine?

Always use according to doctor's instructions. You must check with your physician or pharmacist if you have any doubts. Dosage and administration are determined by the physician alone.

Maximum dosage is 30mg per day (24 hours).

Do not exceed the recommended dosage

If you do not respond to Rizatriptan during an attack, you should not take Rizatriptan to treat the same attack. However, you may still respond to Rizatriptan in the next attack. Rizatriptan alleviates most migraine attacks. However, in some patients migraine symptoms may recur within the 24-hour time span. If the migraine returns, you may take another dose of Rizatriptan. Always wait at least two hours between doses.

USAGE

Rizatriptan Inovamed tablets: swallow the entire tablet with liquid. There is no information regarding mashing/halving/chewing the tablet.

Soluble Rizatriptan Inovamed tablets: keep the tablet in its packaging until administering. Do not remove the tray out of the external bag until close to the use of the medicine. Open the tray with dry hands and place the tablet on your tongue where it will dissolve and will be swallowed with your saliva. There is no need to drink anything. The tablet may be taken regardless of meals.

Not for chronic treatment!

If you have taken an overdose or if a child has swallowed the medicine by mistake, go immediately to a hospital emergency room and bring the drug package with you.

Do not take medicine in the dark! Check the label and dosage every time you take the drug. Use glasses if you require them.

If you have any further questions regarding the use of the medicine, consult your physician or pharmacist.

SIDE EFFECTS

Like any medicine, use of this medicine may cause side effects in some patients. Do not panic when reading the list of side effects, you may not necessarily suffer from any of them.

Stop using and immediately go to the emergency room of the nearest hospital if you develop any of the following symptoms:

Serotonin syndrome – the condition called serotonin syndrome may occur when triptan type medicines are taken with certain other substances. The symptoms of serotonin syndrome may include:

- Disquiet
- Hallucinations
- Coma
- Accelerated heart rate
- Quick fluctuations in blood pressure
- Rise in body temperature
- Muscle spasms
- Loss of coordination
- Nausea, vomiting or diarrhea

- Heart attack.** Heart attack symptoms may include:
 - Discomfort in the center of the chest for more than a few minutes or that comes and goes
 - Discomfort in the chest that feels like uneasy pressure, squeezing, sense of fullness or pain
 - Pain or discomfort in the arms, back, neck, jaw or stomach
 - Shortness of breath with or without discomfort in the chest
 - Cold sweat
 - Nausea or vomiting
 - Dizziness

- Stroke.** Stroke (CVA) symptoms may include the following sudden occurrences:
 - Lack of feeling or weakness in the face, arms or legs, particularly on one side of the body
 - Disorientation, problems with speech or comprehension
 - Impaired sight in one or both eyes
 - Problems with walking, dizziness, imbalance or lack of coordination
 - Severe headache without an apparent cause

- Vascular problems.** Vascular problems may include:
 - Stomach aches
 - Bloody diarrhea
 - Impaired eyesight
 - Coolness and lack of sensation in arms and legs

Hypertension

- Allergic reactions** including swelling of the face, lips, tongue and/or throat that may cause impaired breathing and/or swallowing, wheezing, urticaria, rash or severe peeling of the skin

- Additionally, tell your physician if you are experiencing symptoms attesting to allergic reaction (e.g. rash or itching) after taking Rizatriptan.

ADDITIONAL SIDE EFFECTS

The most common side effects of Rizatriptan include:

- Feeling of drowsiness or fatigue
- Pain or sense of pressure in the chest or throat
- Dizziness

Other side effects (common: 1-10 in 100 patients; uncommon: 1-10 in 1000 patients; rare: 1-10 in 10,000 patients) and side effects with unknown frequency:

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

Digestive system disorders: frequent: nausea, vomiting, diarrhea, dry mouth, digestion disorders (dyspepsia). Uncommon: thirst.

Respiratory system, trachea and chest disorders: common: throat discomfort/pain. Uncommon: shortness of breath. Rare: wheezing

Skeleton, muscular and connective tissue disorders: common: sense of heaviness in various body parts, hardness, neck ache. Uncommon: sense of tension in certain parts of the body, muscular weakness, muscle and face pains

Skin and subcutaneous tissue disorders: blushing (short-term facial redness). Uncommon: sweating, itching, rash characterized by elevated contusions (urticarial), rash, angioedema (swelling of the face, lips, tongue and/or throat that may case breathing and/or swallowing disorders).

Cardiac disorders: common: quick or irregular heart rate (palpitation). Uncommon: very fast heart rate (tachycardia), changes in the rhythm or rate of heartbeats (arrhythmia), unusual ECG (examination that records the heart electric activity) findings. Rare: heart attack (usually in patients with cardiovascular disease risk factors (hypertension, diabetes, smoking, use of nicotine substitutes, family history of cardiac disease or heart attacks, men over 40, post- menstrual women, certain problems with the way one's heart beats, bundle branch block, slow heart rate (bradycardia).

Vascular disorders: uncommon: heat waves, hypertension. Unknown frequency: ischemia in peripheral blood vessels.

Nervous system disorders: common: dizziness, drowsiness, tingling of the skin (paresthesia), headache, decline in skin sensitivity (hypoesthesia), decline in mental sharpness. Uncommon: fainting, trembling, bad taste in the mouth, unstable walking (ataxia), vertigo.

Psychiatric disorders: common: insomnia. Uncommon: confusion/disorientation

Eye disorders: uncommon: blurred eyesight

General disorders and conditions relating to the administration area: common: stomach or chest pain, fatigue.

Reported side effects with unknown frequency:

- Heart attack, constriction of cardiac blood vessels (usually occurs in patients with cardiovascular disease risk factors - hypertension, diabetes, smoking, use of nicotine substitutes, family history of cardiac disease or heart attacks, men over 40, post-menstrual women, certain problems with the way one's heart beats, bundle branch block)
- Severe peeling of the skin, with or without fever – toxic epidermal necrolysis)
- Spasms (convulsions/epileptic attacks)
- Serotonin syndrome that may cause side effects including drowsiness, unstable blood pressure, very high body temperature, lack of muscle coordination, disquiet and hallucinations.
- Blood vessel contractions in the limbs, including coolness and lack of sensation in hands or feet
- Blood vessel contractions in the intestine that may cause stomach ache
- Eyesight disorders including flashing, decline in vision, double vision, loss of vision and in certain cases even irreversible eyesight disorders (although they may derive from the migraine attack).

Whenever you experience side effects not listed in this leaflet or if your general feeling has changed, you must consult your physician immediately.

Side effects may be reported to the Ministry of Health by clicking the link "report side effects of medicinal treatment" on the Ministry of Health website home page (www.health.gov.il) that will refer you to the online form for reporting side effects,

Or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

STORING THE MEDICINE

Prevent poisoning! This medicine, like any other, must be stored in a closed place out of reach of children and/or babies to avoid poisoning. Do not cause vomiting without expressed instruction from a physician!

Rizatriptan Inovamed tablets: 10mg tablets – store below 25°C

Soluble Rizatriptan Inovamed tablets: 10mg dissolving tablets – store below 25°C

Do not use the medicine after the expiration date on the package. The expiration date relates to the last day of the month. Do not dispose of medicines in the sewer or home garbage. Ask the pharmacist how to dispose of drugs that are not being used. These actions will help protect the environment.

ADDITIONAL INFORMATION

In addition to the active substance, the medicine also contains:

Rizatriptan Inovamed tablets: Microcrystalline cellulose, lactose monohydrate, pregelatinised starch, maize starch, magnesium stearate and ferric oxide red.

A 10mg tablet contains 60.5mg lactose

Soluble Rizatriptan Inovamed tablets: Microcrystalline cellulose, pre-gelatinised starch, mannitol, crospovidone (type A), aspartame, peppermint flavor (501500 TP0504) and sodium stearyl fumarate.

A 10mg soluble tablet contains 3.741mg aspartame

What does the medicine look like and what does the package contain:

Rizatriptan Inovamed 10mg tablets: pale pink tablets, round, flat, with an X on one side and 14 on the other side.

Soluble Rizatriptan Inovamed 10mg dissolving tablets: whitish-cream tablets, round, concave on both sides, with 25F on one side. The tablets are mint flavored.

Registration owner's name and address: Inovamed Ltd., 55 Beer Ganim St., POB 62, Even Yehuda
Manufacturer's name and address: Aurobindo Pharma Ltd. India

This leaflet was inspected and approved by the Ministry of Health in 12/2015

Medicine registration number in the Ministry of Health government medicine register

Rizatriptan Inovamed 10mg: 34133

Soluble Rizatriptan Inovamed 10mg: 34154