**Package leaflet: Information for the user**

**Zaptafar 5 mg and 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.

**What is in this leaflet**


## 1. What Zaptafar 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 an antimigraine medicine and your doctor has prescribed it to treat the headache phase of your migraine attack. Do not use it to prevent an attack.

Zaptafar is indicated in adults 18 years and older.

Rizatriptan reduces swelling of the 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 Zaptafar

**Do not take Zaptafar:**
- if you are allergic to rizatriptan benzoate or any of the other ingredients of this medicine (listed in section 6, Contents of the pack and other information).
- if you have moderately severe or severe high blood pressure or mild high blood pressure that is not controlled by medication.
- if you have or have ever had heart problems including heart attack or pain on the chest (angina) or you have experienced signs related to heart disease.
- if you have severe liver or severe kidney problems.

- if you have had a stroke (cerebrovascular accident, CVA) or mini stroke (transient ischaemic attack, TIA).
- if you have blockage problems with your arteries (peripheral vascular disease).
- if you are taking monoamine oxidase (MAO) inhibitors such as moclobemide, phenelzine, tranylcypromine or pargyline (medicines for depression), or linezolid (an antibiotic), or if you have taken them in the last two weeks.
- if you are currently taking ergotamine-type medicines, such as ergotamine or dihydro-ergotamine to treat your migraine or methysergide to prevent a migraine attack.
- if you are taking any similar medicines, sometimes referred to as "triptans", such as sumatriptan, naratriptan, or zolmitriptan to treat your migraine (see "Other medicines and Zaptafar" below).

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

**Take special care with Zaptafar**
Before you take rizatriptan tell your doctor or pharmacist:

- if you have any of the following risk factors for heart disease: high blood pressure, diabetes, if 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 post-menopausal woman.
- if you have kidney or liver problems.
- if you have a particular problem with the way your heart beats (bundle branch block).
- if you have or have had any allergies.
- if your headache is associated with dizziness, difficulty in walking, lack of co-ordination or weakness in the leg or arm.
- if you use any herbal preparation containing St. John's wort.
- if you have had an allergic reaction like swelling of the face, lips, tongue and/or throat which may cause difficulty breathing and/or swallowing (angioedema).
- if 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.
- if 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 Zaptafar.

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

**Other medicines and Zaptafar**
Do not take Zaptafar if you are taking:
- a 5-$HT_{1B/1D}$ agonist (sometimes referred to as 'triptans') such as sumatriptan, naratriptan or zolmitriptan.

- a monoamine oxidase (MAO) inhibitor such as moclobemide, phenelzine, tranylcypromine, linezolid, or pargyline or if you have taken them in the last two weeks.
- medicines for treating migraine which contain ergotamine or ergotamine derivatives e.g. ergotamine tartrate.
- methysergide to prevent a migraine attack.

The above listed medicines when taken with Zaptafar may increase the risk of side-effects.

You should wait at least 6 hours after taking Zaptafar 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 medicines before taking Zaptafar.

Ask your doctor for instructions and the risks about taking Zaptafar
- if you are taking propranolol (see section 3, How to take Zaptafar).
- 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. This is because Zaptafar can affect the way some medicines work and other medicines can affect the way Zaptafar works.

**Zaptafar with food and drink**
Rizatriptan can take longer to work if it is taken after food. Although it is better to take your tablets on an empty stomach, you can still take them if you have eaten.

**Pregnancy, breast-feeding and fertility**
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.

It is not known whether rizatriptan is harmful to an unborn baby when taken by a pregnant woman.

Breast-feeding should be avoided for 24 hours after treatment.

**Driving and using machines**
These tablets may make you feel drowsy or dizzy. If this happens you should not drive or use any tools or machines.

**Zaptafar contains sorbitol (E420)**
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

## 3. How to take Zaptafar

Zaptafar is used to **treat** migraine attacks. Take Zaptafar 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.

Zaptafar tablets should be taken by mouth and swallowed whole with liquid.

**Adults, 18 years and older**
The usual dose is 10 mg.

If you are currently taking propranolol or have kidney or liver problems you should use a 5 mg dose of rizatriptan, as prescribed by your doctor. You should leave at least 2 hours between taking propranolol and rizatriptan. Do not take more than 2 doses of Zaptafar in a 24-hour period.

Rizatriptan is also available as orodispersible tablets that dissolve in the mouth. The orodispersible tablets 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 your migraine symptoms disappear after treatment but return 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 you still have a migraine 2 hours after treatment**
If you do not respond to the first dose of Zaptafar during an attack, you should **not** take a second dose of Zaptafar 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 Zaptafar in a 24-hour period. You should always wait at least 2 hours between doses.**

If your condition worsens, seek medical attention.

**Use in children and adolescents**
The use of Zaptafar 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 Zaptafar is amongst patients older than 65 years.

**If you take more Zaptafar than you should**
If you take more Zaptafar than you should, talk to your doctor or pharmacist straight away. Remember to take the medicine pack and any remaining tablets 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.

**Tell your doctor right away if you have symptoms of the following uncommon side effects:**
**- allergic reaction:** swelling of the face, lips, tongue and/or throat which may cause difficulty breathing and/or swallowing (angioedema and anaphylactoid reactions).

**And also if you have symptoms of the following rare side effects:**
- severe shedding of the skin, with or without fever (toxic epidermal necrolysis).
**- 'serotonin syndrome':** symptoms may include coma, unstable blood pressure, extremely high body temperature, lack of muscle co-ordination, agitation and hallucinations.
**- heart attack or stroke.** 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, post-menopausal women, particular problem with the way your heart beats [bundle branch block]).

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

The following side effects have also been reported:

***Common (affects 1 to 10 users in 100)***
- tingling (paraesthesia), headache, decreased sensitivity of skin (hypaesthesia), decreased mental sharpness, tremor
- fast or irregular heart beat (palpitation), very fast heartbeat (tachycardia)
- flushing (redness of the face lasting a short time), hot flushes, sweating
- throat discomfort, difficulty breathing (dyspnoea)
- feeling sick (nausea), dry mouth, vomiting, diarrhoea
- feeling of heaviness in parts of the body
- pain in abdomen or chest
- rash

***Uncommon (affects 1 to 10 users in 1000)***
- allergic reaction (hypersensitivity)
- unsteadiness when walking (ataxia), dizziness (vertigo), blurred vision
- confusion, insomnia, nervousness
- high blood pressure (hypertension); thirst, indigestion (dyspepsia)
- itching and lumpy rash (hives)
- neck pain, feeling of tightness in parts of the body, stiffness, muscle weakness

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

- bad taste in your mouth
- fainting (syncope)
- facial pain, wheezing

***Not known (frequency cannot be estimated from the available data)***
- 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,
- muscle pain,
- changes in the rhythm or rate of the heartbeat (arrhythmia), slow heartbeat (bradycardia), abnormalities of the electrocardiogram (a test that records the electrical activity of your heart).

**If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.**

## 5. How to store Zaptafar

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household 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

### What Zaptafar contains

The active substance is rizatriptan.
Each 5 mg tablet contains 5 mg of rizatriptan (as benzoate).
Each 10 mg tablet contains 10 mg of rizatriptan (as benzoate).

The other ingredients are mannitol, sorbitol (E420), iron oxide red (E172), crospovidone, colloidal anhydrous silica and magnesium stearate.

### What Zaptafar looks like and contents of the pack

The 5 mg tablets are pale pink, convex capsule shaped tablets with ‘RZ5’ on one side and ‘>’ logo on the other side and dimensions of approximately 9.5 x 4.0 mm.

The 10 mg tablets are pale pink, convex capsule shaped tablets with ‘RZ10’ on one side and ‘>’ logo on the other side and dimensions of approximately 12.0 x 4.8 mm.

The 5 mg tablets are packed in blister packs of 3, 6 or 12 tablets.
The 10 mg tablets are packed in blister packs of 2, 3, 6, 12 or 18 tablets.

Not all pack sizes may be marketed.

**Marketing Authorization Holder**
Vaia S.A., 1, 28 Octovriou str., Agia Varvara, 123 51, Athens, Greece

**Manufacturer**
Arrow Pharm (Malta) Limited, 62 Hal Far Industrial Estate, Birzebuggia, BBG 3000, Malta

Or

Specifar S.A., 1, 28 Octovriou str., Agia Varvara, 123 51, Athens, Greece

**This medicinal product is authorised in the Member States of the EEA under the following names:**

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|---|---|
| Germany: | Zaptafar 5 mg, 10 mg Tabletten |
| Sweden: | Zaptafar 5 mg, 10 mg tabletter |

**This leaflet was last revised in**: 8 November 2012