

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### PHEZAM

400 mg + 25 mg capsule, hard

PIRACETAM, CINARIZIN

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •*

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#### What is in this leaflet?

1. What Phezam is and what it is used for
2. Before you take Phezam
3. How to take Phezam
4. Possible side effects
5. How to store Phezam
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#### *1. WHAT PHEZAM IS AND WHAT IT IS USED*

##### ***Phezam contains the active substances piracetam and cinarizin.***

Piracetam belongs to a group of medicines called nootropics, it improves and restores cognitive processes and mental abilities.

Cinarizin prevents the transport of calcium ions through the cell membrane and expands blood vessels, increases the resistance of cells to the lack of oxygen.

Combined preparation has expressed anti-hypoxic effect (neutralizes the negative effects of decreased oxygenation). Effects of active substances complement each other, thereby improving blood flow through the brain.

Phezam applies to:

- Chronic and latent (hidden) cerebrovascular insufficiency caused by atherosclerosis and arterial hypertension; angiodystonic ischemic stroke and condition after stroke,
- Posttraumatic cerebrosthenia (State after concussion or mild brain injury);
- Encephalopathy (brain damage) of different origin,
- Psycho organic syndrome that leads to disorders of memory and other cognitive functions;

- Pathology of labyrinth – dizziness, tinnitus (ringing in the ears), nausea, vomiting, and nystagmus,
- Meniere's syndrome (damage to the vestibular system),
- Prophylaxis of motion sickness (kinetosis).

## 2. BEFORE YOU TAKE PHEZAM

Do not take Phezam:

- If you are hypersensitive to piracetam, or cinarizin, or any of the other ingredients,
- If you have severely impaired kidney function,
- If you have had a hemorrhagic stroke.

### **Warnings and precautions:**

Talk to your doctor if you have any of the following symptoms or diseases:

- slightly or moderately impaired renal function- recommended therapeutic dose reduction or extension of the interval between doses;
- impaired liver function- liver enzyme values should be monitored;
- increased intraocular pressure;
- Parkinson's disease.

### **Taking other medicines**

If you are taking or have recently taken any other medicines, including medicines obtained without a prescription, please inform your doctors or pharmacists.

### **Tell your doctor if you are taking (or plan to take) any of the following medicines:**

- depressors of the central nervous system (hypnotics and sedatives),
- tricyclic antidepressants,
- alcohol,
- medicines for lowering blood pressure
- preparations for the expansion of the blood vessels (vasodilators),
- hormones of the thyroid glands
- oral anticoagulants (medicines which prevent blood clotting).

### **Taking Phezam with food and drink**

During treatment avoid use of alcohol.

### **Pregnancy and breastfeeding**

Before taking any medicine, seek the advice of your doctor or pharmacist.

The use of Phezam during pregnancy is not recommended.

Piracetam is excreted into breast milk and medicine should not be taken during the period of breastfeeding.

### **Driving and using machines**

We recommend caution in managing motor vehicles and handling machines during therapy with Phezam.

### **Important information about some of Phezam's ingredients**

Phezam medicine contains lactose. If you have intolerance to some sugars, before taking this medicine, consult your doctor.

The medicine is not suitable for people with lactase deficiency, galactosemia or syndrome of bad absorption of glucose/galactose.

### 3. HOW TO TAKE PHEZAM

Always take Phezam exactly as recommended by a doctor. Check with your doctor or pharmacist if you are unsure.

Adults: 1- 2 capsules three times a day during 1 to 3 months, depending on the severity of the disease.  
Children (over 5 years of age): 1-2 capsules, 1- 2 times a day.

Use in children under 5 years of age is not recommended.

This product should not be taken for longer than 3 months.

#### ***If you take more medicine than you should***

If you take the dosage that is higher than prescribed, you should immediately seek medical help.

Phezam is very well tolerated and, in the case of an overdose no serious side effects which require the interruption of therapy were spotted.

In case of overdose you may experience abdominal pain.

In children, there were noticed symptoms of irritability (excitation) – insomnia, restlessness, euphoria (elevated levels of mood), irritability, tremor, and rarely — nightmares, hallucinations and convulsions (seizures).

Treatment of overdose is symptomatic.

#### ***If you forget to take Phezam***

If you miss a dose, take it as soon as you remember, but do not take if you are closer to the time of taking the next dose.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Phezam can cause side effects.

Side effects may occur according to the following frequency: Very common ( $\geq 10\%$ ), common ( $\geq 1\%$  and  $<10\%$ ); Uncommon ( $\geq 0,1\%$  to  $<1\%$ ); rare ( $\geq 0.01\%$  to  $\geq 01\%$ ), very rare ( $<0.01\%$ ), unknown frequency.

Disorder of skin and subcutaneous tissue:

Very rare: hypersensitivity — skin reactions, photosensitivity.

Gastrointestinal disorders:

Unknown frequency: increased secretion of saliva, nausea, vomiting.

Disorder of the nervous system

Rare: in older patients, continued use can lead to extra pyramidal side effects.

If you notice any side effects that are not mentioned in this leaflet, please tell your doctor or pharmacist.

### 5. HOW TO STORE PHEZAM

Keep the medicine out of reach and sight of children.

Store below 25 ° c.

Shelf life is 3 years from the date of manufacture.  
Do not use Phezam after expiration date specified on the box.

Unused medicine will be destroyed in accordance with the applicable regulations.

## 6. FURTHER INFORMATION

### ***What's Phezam contains?***

Active substance in each hard capsule is Piracetam 400 mg and Cinarizin 25 mg.  
Auxiliary substances are: lactose monohydrate, Silicon colloidal anhydrous, magnesium stearate.

### ***What it looks like and contents of the pack?***

Phezam 400 mg/25 mg – hard capsules are available in blister packaging in PVC/ALU foil of 10 hard capsules, with six blister packs per box.

### ***Regime of dispensing***

The medicine is issued on doctor's prescription

### ***Manufacturer***

Actavis Group PTC ehf  
Reykjavikurvegur 76• 78, 220 Hafnarfjordur,  
Island

### ***Manufacturer of the medicinal product***

Balkanpharma- Dupnitsa AD,  
3, Samokovsko chaussee Str., 2600 Dupnica,  
Bulgaria