

Phescetam 400 mg/25 mg capsules, hard

(piracetam/cinnarizine)



Read the leaflet carefully before you start using 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 personally. Do not pass it on to others. It may harm them, even though the symptoms of their 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 point 4.

What is in this leaflet?

1. What **Phescetam** is and what it is used for
2. What you need to know before taking **Phescetam**
3. How to take **Phescetam**
4. Possible adverse drug reactions
5. How to store **Phescetam**
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1. What **Phescetam** is and what it is used for

Phescetam is combined medicinal product containing the active substances piracetam and cinnarizine. The combined product has a pronounced antihypoxic effect. The two active substances are mutually potentiated in relation to the reduction of cerebrovascular resistance. The combination increases cerebral blood flow.

Piracetam belongs to the group of so-called nootropic pharmaceuticals improving and restoring cognitive processes and mental capacity.

Cinnarizine is a selective blocker, suppressing calcium ion transport processes through cell membranes and leads to dilation of the blood vessels, reduces the excitability of the vestibular center, increases the resistance of the cells to oxygen insufficiency.

Phescetam is used in:

- Chronic and latent (concealed) cerebrovascular insufficiency in atherosclerosis and hypertension (high blood pressure); post-stroke conditions;
- Posttraumatic cerebrasthenia (post-concussion or mild brain injury);
- Encephalopathy (brain damage) of different origin;
- Psycho-organic syndrome with leading memory impairment and other cognitive functions;
- Labyrinthopathies and Meniere's syndrome (inner ear damage) - vertigo, tinnitus, nausea, vomiting, nystagmus (involuntary eye movements);
- Prophylaxis of kinetosis (motion sickness).

2. What you need to know before taking **Phescetam**

Do not take **Phescetam**:

- if you are allergic to piracetam, cinnarizine or any of the other ingredients in this medicine (listed in section 6);
- in severe kidney failure;
- in case of hemorrhagic stroke (cerebral hemorrhage)
- Huntington's chorea

Warnings and precautions

Talk to your doctor or pharmacist before taking **Phescetam**. If you have any of the following conditions, he will assess whether **Phescetam** is suitable for you:

- mild and moderate renal insufficiency, this usually requires a reduction in the therapeutic dose or a prolongation of the intervals between doses;
- hepatic failure; in such cases monitoring of liver enzymes is necessary;
- increased intraocular pressure
- Parkinson's disease
- low blood pressure

Other medicines and **Phescetam**

Inform your doctor or pharmacist if you are taking, have recently taken or might take other medicines, including those obtained without a prescription.

Your doctor or pharmacist should be informed if you are taking (or planning to take) any of the following medicines: central nervous system depressants, tricyclic antidepressants (to treat depression), alcohol, nootropic, antihypertensives (for treatment of high blood pressure) and vasodilators, thyroid hormones and oral anticoagulants (medicines that reduce blood clotting).

Phescetam with food and beverages

Alcohol should be avoided during treatment with this product.

Pregnancy and breastfeeding

If you are pregnant or you breastfeed, think you may be pregnant or plan to become pregnant, consult your doctor or pharmacist before taking this medicine.

Pregnancy

Phescetam is not recommended during pregnancy (especially in the first three months).

Breastfeeding

Piracetam passes into breast milk and therefore it is not recommended to use **Phescetam** during breastfeeding.

Driving and operating machines

No data are available to influence the ability to drive or operate machines.

Phescetam contains lactose

This medicinal product contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact him before you start taking **Phescetam**.

3. How to take **Phescetam**

Always take this medicine exactly as your doctor has told you. If you are not sure, ask your doctor or pharmacist.

Adults

1-2 capsules three times a day for 1 to 3 months, depending on the severity of the disease.

Use in children over 5 years of age - 1-2 capsules 1-2 times a day.

Elderly patients (over 65 years)

Prolonged treatment in elderly patients requires regular

control of creatinine clearance in order to adjust the dose as needed.

The product should not be used for more than 3 months without interruption.

If you have taken more than the recommended dose of Phescetam

If you take a higher dose than prescribed, contact your doctor immediately.

Phescetam is well tolerated and no serious adverse events requiring discontinuation of treatment have been observed in case of overdose.

In case of overdose, abdominal pain may occur. Excitatory effects might be observed in children - insomnia, restlessness, euphoria, irritability, tremor, rarely nightmares, hallucinations, convulsions.

Overdosage treatment is symptomatic.

If you have forgotten to take Phescetam

If you miss a single dose, take the product at the time of the next regular intake. Do not take a double dose to make up for the missed capsule.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible adverse drug reactions

Like all medicines, this product can cause adverse reactions, although not everyone experiences those.

Adverse reactions reported in clinical trials and post-marketing experience are listed in the following table by system organ class and by frequency. Frequency is defined as follows: very common ($\geq 1/10$), common ($\geq 1/100$, $< 1/10$), uncommon ($\geq 1/1000$, $< 1/100$), rare ($\geq 1/10,000$, $< 1/1000$), very rare ($< 1/10,000$), not known (frequency cannot be estimated from the available data).

Trials	
Rare	Increase in body weight
Nervous system disorders	
Common	Drowsiness, hyperkinesia
Uncommon	Somnolence
Rare	Headache
Not known	Extrapyramidal symptomatology*, Gastrointestinal disorders, ataxia, equilibrium disturbances, epilepsy aggravation, insomnia
Gastrointestinal disorders	
Uncommon	Dryness in mouth
Not known	Abdominal pain, upper abdominal pain, diarrhea, nausea, vomiting
Skin and subcutaneous tissue disorders	
Rare	Allergic skin reactions
Very rare	Lupus-like skin reactions
Not known	Angioneurotic edema, dermatitis, pruritus, urticaria
General disorders and administration site conditions	
Uncommon	Asthenia

Rare	Sweating
Blood and lymphatic system disorders	
Very rare	Cholestatic jaundice
Not known	Hemorrhagic disorders
Psychiatric disorders	
Common	Nervousness
Uncommon	Depression
Not known	Agitation, anxiety, confusion, hallucinations
Immune system disorders	
Not known	Anaphylactoid reaction, hypersensitivity
Ear and labyrinth disorders	
Not known	Vertigo

Extrapyramidal symptomatology* (Occasionally with depressive symptoms) is predominantly found in a person of advanced age under prolonged treatment. In these cases, discontinuation of treatment is required.

Reporting adverse drug reactions

If you experience any side effects, contact your doctor. This includes all possible adverse reactions not listed in this leaflet. As you report side effects, you can contribute to obtaining more information on the safety of this medicine.

5. How to store Phescetam

Store below 30°C.

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the pack. The expiry date refers to the last day of the month stamped.

Do not dispose of medicines in the sewage system or in the household waste container. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Package contents and additional information

What Phescetam contains

- The active substances: piracetam 400 mg and cinnarizine 25 mg.
- Excipients: lactose monohydrate, maize starch, silica, colloidal anhydrous, magnesium stearate.
- Hard gelatin capsule composition: Titanium dioxide (E171), gelatin.

What Phescetam looks like and package contents

White hard gelatin capsules, size 0, containing white to off-white powder.

Pack: 15 hard capsules in a PVC / Al blister of 4 blisters in a box.

Marketing Authorization Holder and Manufacturer:

Adipharm EAD
130 Simeonovsko shose Blvd.,
1700 Sofia, Bulgaria

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