

Package leaflet: Information for the patient

Piracetam ABR 1 200 mg powder for oral solution in sachet

Piracetam ABR 2 400 mg powder for oral solution in sachet

piracetam

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. See section 4.

What is in this leaflet

1. What Piracetam ABR is and what it is used for
2. What you need to know before you take Piracetam ABR
3. How to take Piracetam ABR
4. Possible side effects
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1. What Piracetam ABR is and what it is used for

Piracetam ABR belongs to the group of nootropic medicinal products, derivatives of gamma-butyric acid. Piracetam ABR improves and restores disturbances in cognitive processes (learning ability, memory, attention and mental performance) due to brain diseases and intoxication (poisoning). It has no calming and psycho-stimulating effect. Piracetam ABR improves the rheological properties (blood flow) of the blood.

Piracetam ABR is used in:

Adults

- To improve memory and attention disorders, as well as loss of motivation due to brain diseases and impairments (so-called psycho-organic syndrome);
- For the treatment of sudden, involuntary muscle contractions (so-called cortical (core) myoclonus), alone or in combination with other medicines;
- For the treatment of vertigo and related disturbances of balance, except for dizziness of vascular or mental origin;
- For the prevention and remission of sickle cell vaso-occlusive crisis (the so-called vascular crisis - obstruction of the small blood vessels) in sickle cell anaemia (a hereditary disease in which the structure of haemoglobin is disturbed and the shape of red blood cells is altered).

Children

- Treatment of speech disorders (dyslexia), in combination with other appropriate measures such as speech therapy;
- For the prevention and remission of sickle cell vaso-occlusive crisis.

2. What you need to know before you take Piracetam ABR

Do not take Piracetam ABR if:

- if you are allergic to piracetam or any of the other ingredients of this medicine (listed in section 6);
- if you have cerebral haemorrhage;
- if you suffer from end-stage renal failure;
- if you suffer from so-called Huntington's chorea.

Warnings and precautions

Talk to your doctor or pharmacist before taking Piracetam ABR if:

- if you have severe bleeding or if you are at an increased risk of bleeding (e.g., you have gastrointestinal ulcer, bleeding disorders, have had a brain haemorrhage in the past, have undergone major surgery (including dental surgery);
- you have severe kidney disease. Your doctor may consider changing your daily dose if you have impaired renal function. Elderly patients require periodic monitoring of renal function.
- it should be borne in mind that a sudden discontinuation of the product in patients with myoclonus may lead to the recurrence of symptoms or their worsening.

Administration of a lower dose than recommended for patients with sickle cell anemia may lead to recurrent crisis.

It is recommended that elderly patients visit their physician regularly to adjust the dose as needed.

Other medicines and Piracetam ABR

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Concomitant use of piracetam and thyroid hormone (T3 + T4) was associated with confusion, irritability and sleep disturbances.

Concomitant treatment with anticoagulants and platelet antiplatelet agents (anti-clotting medicines and medicines used to thin the blood), including acetylsalicylic acid (in low doses) increases the risk of bleeding.

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.

Pregnancy

There are insufficient data on the use of piracetam in pregnant women. The use of the product during pregnancy is not recommended unless absolutely necessary at the discretion of the physician.

Breastfeeding

Piracetam is excreted in human milk, and therefore it is not recommended to use it during breast-feeding. Breast-feeding should be discontinued if treatment with the product is necessary.

Driving and using machines

Some of the side effects (drowsiness, depression) associated with taking the product may adversely affect the ability to drive and use machines, which should be considered.

Piracetam ABR contains mannitol and aspartame

The content of mannitol in one sachet of Piracetam ABR 1200 mg is 1385.5 mg. The content of mannitol in one sachet of Piracetam ABR 2400 mg is 2771 mg. Mannitol may have a slight laxative effect if daily doses of 8.7 g piracetam or more are taken.

Aspartame contains a source of phenylalanine. May be harmful to people with phenylketonuria.

3. How to take Piracetam ABR

Always use this medicine as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Adults

Treatment of myoclonus (sudden involuntary muscle contractions) of cortical origin

The starting daily dose is 7.2 g, which is increased by 4.8 g every 3-4 days until a maximum daily dose of 24 g is divided into 2 or 3 doses. Treatment with other anti-myoclonic medicinal products should be maintained at the same dose. Depending on the clinical outcome, the dose of other such medicinal products should be reduced if possible.

Once started, treatment with piracetam should continue for as long as the primary brain disease continues. Attempts to lower the dose or discontinue treatment should be made every 6 months.

Caution - patients with kidney problems should take lower doses (see Warnings and precautions). The duration of treatment depends on the nature of your illness and the response to your complaints. If you think the effect of the medicine is too strong or too weak, talk to your doctor or pharmacist.

Symptomatic treatment of psycho-organic syndrome (impaired mental activity)

The recommended daily dose ranges from 2.4 to 4.8 g, divided into 2 or 3 doses.

Treatment of vertigo (dizziness and tinnitus)

The recommended daily dose ranges from 2.4 to 4.8 g, divided into 2 or 3 doses.

Prevention and remission of sickle cell vaso-occlusive crisis

The recommended daily dose for prophylaxis is 160 mg/kg taken orally.

The recommended daily dose for remission is 300 mg/kg given in a vein.

A daily dose lower than 160 mg/kg or irregular intake may lead to a recurrent crisis.

Use in children and adolescents

Dyslexia treatment (difficulty reading and understanding what is being read) in combination with speech therapy

For children 8 years of age and adolescents, the recommended daily dose is 3.2 g divided in 2 doses.

For the prevention and remission of sickle cell vaso-occlusive crisis

The recommended daily dose for prophylaxis is 160 mg/kg taken orally.

The recommended daily dose for remission is 300 mg/kg given in a vein.

A daily dose lower than 160 mg/kg or irregular intake may lead to a recurrent crisis.

Piracetam can be given to children over 3 years suffering from sickle cell anemia at the recommended daily doses (in mg/kg). Piracetam has been administered to a limited number of children aged 1 to 3 years.

Method of administration

The contents of the sachet are dissolved in water before ingestion. The daily dose is divided into 2-4 equal doses. This medicine is taken regardless of the meal time.

Duration of treatment

You should take Piracetam ABR for as long as your doctor has told you. In the treatment of chronic diseases, an optimal effect is usually achieved after 6 to 12 weeks.

If you take more Piracetam ABR than you should

If you accidentally or intentionally use more than the prescribed dose, contact your doctor immediately or visit your nearest hospital. Do not use the medicine more often or for longer than prescribed to avoid overdose.

If you forget to take Piracetam ABR

Do not take a double dose to make up for a forgotten dose. Take the usual dose as soon as possible after you remember and continue treatment as usual.

If you stop taking Piracetam ABR

In order to avoid any recurrence of complaints, discontinuation of Piracetam ABR treatment should be gradual - the dose is reduced by 1.2 g every 2 days.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If any of the following effects occur and you are concerned, tell your doctor.

The following side effects are possible with piracetam treatment:

Common (may affect up to 1 in 10 patients):

- nervousness;
- increased motor activity (hyperkinesia);
- weight gain.

Uncommon (may affect up to 1 in 100 patients):

- depression;
- drowsiness;
- weakness (asthenia).

Not known frequency (frequency cannot be estimated from available data):

- blood clotting disorders, bleeding (hemorrhagic disorders);
- severe allergic reaction that causes difficulty breathing or dizziness, hypersensitivity;
- agitation, anxiety, confusion, hallucinations;
- difficult coordination of movements, impaired balance, worsening of epilepsy, headache, insomnia;
- dizziness (vertigo);
- abdominal pain, upper abdominal pain, diarrhoea, nausea, vomiting;
- severe allergic reaction that causes swelling of the face or throat (angioneurotic oedema), dermatitis (inflamed and irritated skin), itching, urticaria.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

Bulgarian Drug Agency
8 Damyan Gruev Street
1303 Sofia
Tel. +359 28903417
Website: www.bda.bg

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Piracetam ABR

Keep this medicine out of the sight and reach of children.
Store below 25°C.

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

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 Piracetam ABR contains

- The active substance is piracetam. Piracetam ABR 1200 mg powder for oral solution in sachet contains 1200 mg piracetam. Piracetam ABR 2400 mg powder for oral solution in sachet contains 2400 mg piracetam.
- The other ingredient is mannitol (E421), aspartame (E951), wild berry flavour.

What Piracetam ABR looks like and contents of the pack

Piracetam ABR is an off-white to light beige powder.

The product is packed into paper aluminium/polyethylene sachets, in carton boxes containing 10, 20, 30, 50, 60 and 100 sachets.

Marketing Authorisation Holder

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Manufacturer

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For additional information about this medicinal product, please contact the local representative of the Marketing Authorization Holder:

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