

Package leaflet: Information for the patient
Nootropil®
1200 mg film-coated Tablets
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 Nootropil Tablets are and what they are used for
2. What you need to know before you take Nootropil Tablets
3. How to take Nootropil Tablets
4. Possible side effects
5. How to store Nootropil Tablets
6. Contents of the pack and other information.

1. What Nootropil Tablets are and what they are used for

Nootropil Tablets belongs to a group of medicines known as GABA analogues.

Nootropil Tablets contains the active ingredient Piracetam. It acts on the brain and nervous system and is thought to protect it against a shortness of oxygen.

Nootropil Tablets are used in combination with other medicines to treat myoclonus. This is a condition in which the nervous system causes muscles, particularly in the arms and legs, to start to jerk or twitch uncontrollably.

2. What you need to know before you take Nootropil Tablets

Do not take Nootropil Tablets

- if you are allergic to piracetam or any of the other ingredients of this medicine (listed in section 6).
- if you have ever had serious kidney problems
- if you have ever experienced a brain haemorrhage
- if you suffer from Huntington's Disease (also known as Huntington's Chorea)

If any of the above applies to you, do not take Nootropil Tablets and talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Nootropil Tablets

- if you think your kidneys may not be working perfectly. (Your doctor may need to start you on a lower dose.)
- if you have ever had any kind of bleeding problem.

Other medicines and Nootropil Tablets

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

Tell your doctor if you are taking any of the following medicines:

- Thyroid extract or thyroxine
- Anticoagulants such as warfarin or acenocoumarol

- Low dose aspirin
- Any other medicine, including medicines obtained without a prescription.

Pregnancy and breast-feeding

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. If you are taking this medicine, use contraception to avoid becoming pregnant. If you are taking Nootropil Tablets and you think you may be pregnant, consult your doctor immediately.

Driving and using machines

Nootropil Tablets may cause drowsiness and shakiness. If this happens to you, do not drive or use machinery.

Warning about some of the ingredients in Nootropil Tablets

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'. When the used dose is greater than 10 tablets/day (12.6 g), it cannot be considered 'sodium-free' and it should be taken into consideration by patients on a controlled sodium diet. At maximum daily dose (20 tablets (24 g)) this medicine contains 43.8 mg of sodium. This is equivalent to 2.19% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Nootropil Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Important:

Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.

Adults

How much medicine to take and when to take it

- The recommended starting dose is 7.2 g each day (six tablets).
- It is best to split the dose so that the tablets are taken on two or three separate occasions during the day (e.g. 2 tablets in the morning, 2 at midday and 2 in the evening).
- When you start taking this medicine your doctor may tell you to gradually increase the dose to ensure that you receive the best dose to treat your condition.
- Follow your doctor's instructions carefully.

How to take your medicine

- Swallow the tablets whole with a glass of water.
- Do not break or chew the tablets as piracetam has a very bitter taste.
- If you find it difficult to swallow the tablets tell your doctor as soon as possible as they can prescribe piracetam in the form of a solution.

Elderly and patients with kidney problems

If you are elderly or have kidney problems your doctor may reduce your dose.

If you take more Nootropil Tablets than you should

If you accidentally take too much, immediately go to the nearest hospital casualty department or your doctor.

If you forget to take Nootropil Tablets

Do not take a double dose to make up for a forgotten dose. Simply take the next dose as planned.

If you stop taking Nootropil Tablets

Do not stop taking Nootropil Tablets without first talking to your doctor. Abruptly stopping your medicine may cause twitching and jerking.

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. You may notice the following side effects:

- An allergic reaction and experience difficulty breathing, swelling, fever
- Spontaneous bleeding caused by defects in your blood clotting mechanism
- Worse fits
- Hallucinations
- Difficulty balancing and unsteadiness when standing
- Anxiety and agitation
- Confusion
- Restlessness
- Nervousness
- Sleepiness
- Depression
- Weakness
- Vertigo
- Weight increase
- Stomach pain
- Diarrhoea
- Feeling or being sick
- Headache
- Being unable to sleep
- Swelling of the skin, particularly around the face
- Skin rash and itching.

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

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

5. How to store Nootropil Tablets

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

Do not use Nootropil Tablets after the expiry date which is stated on the carton 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 Nootropil Tablets contains

The active substance is piracetam. Each tablet contains 1200 mg piracetam.

The other ingredients are Macrogol 6000, colloidal anhydrous silica, magnesium stearate and croscarmellose sodium. The film coating contains hypromellose (E464), titanium dioxide (E171) and Macrogol 400.

What Nootropil Tablets look like and contents of the pack

Nootropil 1200 mg Tablets are white, film-coated tablets. The tablets have the letters N/N marked

on them to allow them to be easily identified. They come in a blister pack of 60 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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This leaflet was last revised May 2024.

If this leaflet is difficult to see or read or you would like it in a different format, please contact UCB Pharma Ltd., 208 Bath Road, Slough, SL1 3WE, UK.