Package leaflet: Information for the patient Nootropil® 33% Oral Solution Piracetam

Read all of this 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 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 Solution is and what it is used for
- 2. What you need to know before you take Nootropil Solution
- 3. How to take Nootropil Solution
- 4. Possible side effects
- 5. How to store Nootropil Solution
- 6. Contents of the pack and other information.

1. What Nootropil Solution is and what it is used for

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

Nootropil Solution 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 Solution is 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 Solution

Do not take Nootropil Solution

- 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 Solution and talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Nootropil Solution

- 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 Solution

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 medicines, 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 Solution and you think you may be pregnant, consult your doctor immediately.

Driving and using machines

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

Warnings about some of the ingredients in Nootropil Solution

Nootropil Solution contains parahydroxybenzoate which may cause allergic reactions (possibly delayed). This medicine contains less than 1 mmol sodium (23 mg) per 22.6 g, that is to say essentially 'sodium-free'. When the dose is greater than 22.6 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 (24 g) this medicine contains-24.3 mg of sodium. This is equivalent to 1.2% of the recommended maximum daily dietary intake of sodium for an adult.

Also contains glycerol which may cause headache, stomach upset and diarrhoea.

3. How to take Nootropil Solution

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 which is approximately 4 teaspoons of solution per day (using a 5ml measuring teaspoon). This will be approximately 20ml.
- It is best to split the dose so that the solution is taken on two or three separate occasions during the day (e.g. Two spoons in the morning and two spoons in the evening or one spoon in the morning, one at midday and two spoons 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 undiluted solution
- Do not mix the solution with any other liquid
- As the medicine has a very bitter taste you may drink a glass of water or a soft drink afterwards.

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 Solution 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 Solution

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 Solution

Do not stop taking Nootropil Solution 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 Solution

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

Do not use Nootropil Solution 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 Solution contains

The active substance is piracetam. Each 5 ml of solution contains 1.666 g piracetam.

The other ingredients are glycerol, methyl parahydroxybenzoate (E 218), propyl parahydroxybenzoate (E 216), sodium acetate, acetic acid and purified water.

Nootropil Solution is a clear, colourless solution. It comes in bottle which contains 125ml or 300 ml of the solution.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Manufacturer

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This leaflet was last revised May 2025.

If this leaflet is difficult to see or read or you would like it in a different format, please contact: Mercury Pharmaceuticals Limited Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom