

PACKAGE LEAFLET: INFORMATION FOR THE USER
Nootropil[®] 800mg TABLETS / PIRACETAM 800mg TABLETS
(piracetam)

This product is available using any of the above names but will be referred to as Nootropil Tablets throughout the remainder of this leaflet.

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What Nootropil Tablets are for
2. Before you take Nootropil Tablets
3. How to take Nootropil Tablets
4. Possible side effects
5. How to store Nootropil Tablets
6. Further information.

1. WHAT NOOTROPIL TABLETS ARE 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. BEFORE YOU TAKE NOOTROPIL TABLETS

Do not take Nootropil Tablets if:

- You are allergic to the active ingredient piracetam
- You are allergic to any of the other ingredients of Nootropil (these are listed in Section 6)
- You have ever had serious kidney problems
- You suffer from Huntington's Disease (also known as Huntington's Chorea)
- You have ever experienced a brain haemorrhage

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

Check with your doctor 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.)
- You have ever had any kind of bleeding problem.

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

- Thyroid extract or thyroxine
- Anticoagulants such as warfarin or aceno-coumarol
- Low dose aspirin
- Any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

If you are pregnant, trying to become pregnant or breast-feeding ask your doctor or pharmacist for advice before taking Nootropil Tablets. 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 46 mg sodium per dose.

To be taken into consideration by patients on a controlled sodium diet.

This medicine contains the colouring agent sunset yellow (E110) which may cause allergic reactions.

3. HOW TO TAKE NOOTROPIL TABLETS

Always take Nootropil Tablets exactly as your doctor has told you.

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 normal starting dose is 7.2 g each day (nine tablets).
- It is best to split the dose so that the tablets are taken on two or three separate occasions during the day (3 tablets in the morning, 3 at midday and 3 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 missed dose. Simply take the next dose as planned.

Stopping 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 about the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines Nootropil Tablets 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly on the Yellow Card Scheme website: 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 out of the sight and reach of children.
- Do not use after the expiry date shown on the end panel of the carton. The expiry date refers to the last day of that month.
- If the tablets becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION**What Nootropil Tablets contain**

Each pack of Nootropil Tablets contains 60 orange capsule shaped tablets marked N breakline N on one side and breakline on the reverse.

The tablets have the letters N breakline N on one side and breakline on the reverse marked on them to allow them to be easily identified.

Each tablet contains 800mg of piracetam as the active ingredient. Each tablet also contains macrogol 6000, macrogol 400, colloidal anhydrous silica, magnesium stearate, hypromellose, titanium dioxide (E171), sunset yellow (E110), talc.

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