

NOOTROPIL[®] TABLET/SOLUTION

Piracetam (800 mg, 1200 mg, 200 mg/ml)

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What NOOTROPIL is used for

- Treatment of the elderly with some degree of cerebral functional impairment such as loss of memory, a lack of concentration or alertness and feeling of dizziness.
- Nootropil is indicated for patients suffering from myoclonus of cortical origin, irrespective of aetiology and should be used in combination with other anti-myoclonic therapies.

How NOOTROPIL works

Nootropil 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 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.

Before you use NOOTROPIL

- When you must not use it

Do not take Nootropil if:

- You are allergic (hypersensitive) to piracetam, other pyrrolidone derivatives or to any of the other ingredients of Nootropil (see section **Product Description**).
- You have ever had serious kidney problems
- You have ever experienced a brain haemorrhage

- You suffer from Huntington's Disease (also known as Huntington's Chorea)

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

- Before you start to use it

Check with your doctor before taking Nootropil 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.

If you are pregnant, trying to become pregnant or breast-feeding ask your doctor or pharmacist for advice before taking Nootropil. If you are taking this medicine, use contraception to avoid becoming pregnant. If you are taking Nootropil and you think you may be pregnant, consult your doctor immediately.

- Taking other medicines

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

- Thyroid extract or thyroxine
- Anticoagulants such as acenocoumarol
- Low dose aspirin
- Any other medicine, including medicines obtained without a prescription. Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while taking medication.

How to use NOOTROPIL

- How much to use

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.

Tablets (for adults)

The usual starting dose is 7.2 g each day. It is best to split the dose so that the tablets are taken on two to four divided doses with a maximum dose per day of 24 g.

Solution

The usual starting dose is 7.2 g. It is best to split the dose so that the solution is taken on two to four occasions during the day with a maximum dose per day of 24g.

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.

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

If you are elderly, and you take Nootropil for a long time, your doctor may recommend additional examination and modify the dosage.

- When to use it

Always take Nootropil exactly as your doctor has told you. NOOTROPIL may be taken with or without food.

- How long to use it

Continue taking Nootropil for as long as your doctor recommends.

Do not stop taking Nootropil 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 the medicine, ask your doctor or pharmacist.

- If you forget to use it

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

- If you use too much (overdose)

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

While you are using it

- Things you must do

Check with your doctor or pharmacist before taking your medicine and take it as prescribed by your doctor.

Inform your doctor if you suffer from: bleeding, stomach or intestinal ulcer, bleeding disorder, haemorrhagic stroke, or if you plan major surgery (including dental surgery) and if you use medications for blood thinning effects including low dose aspirin.

Tablets

Swallow your tablet whole with a glass of water. Do not break or chew the tablets. 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.

- Things you must not do

Do not stop taking the medicine abruptly as this may induce seizures in some patients.

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.

- Things to be careful of

Driving and using machines

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

Warning about some of the ingredients in Nootropil solution

Nootropil solution contains propyl parahydroxybenzoate and methyl parahydroxybenzoate which may cause allergic reactions (possibly delayed). Nootropil solution contains about 3.5 mmol or 80.5 mg sodium per 24 g dose of piracetam. To be taken into consideration if you are on a controlled sodium diet. Also contains glycerol which may cause headache, stomach upset and diarrhoea.

Side Effects

Like all medicines Nootropil 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
- Excessive abnormal movement
- Confusion
- Nervousness
- Sleepiness
- Depression
- Weakness
- Vertigo
- Weight increase
- Stomach pain
- Diarrhoea
- Nausea, vomiting
- Headache
- Being unable to sleep
- Swelling of the skin
- Skin rash and itching

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of NOOTROPIL

- Storage

Keep out of the reach and sight of children.

Store below 25°C.

Do not use Nootropil after the expiry date on the carton. The expiry date refers to the last day of that month.

- Disposal

Medicines should not be disposed of via wastewater or household waste.

Return any medicine you no longer need to your pharmacist.

Product Description

- What it looks like

Nootropil Tablet 800 mg

White oblong film-coated tablet imprinted with a bisect line and N/N.

Nootropil Tablet 1200 mg

White oblong scored film-coated tablet marked N/N.

Nootropil Solution 20%

Clear colourless solution, characteristic flavour

- Ingredients

- Active ingredient(s)
Piracetam

- Inactive ingredient(s)

Nootropil Tablet 800 mg

Nootropil Tablet 1200 mg

Macrogol 6000, Opadry Y-1-7000 White, Opadry OY-S 29019 Clear, Sodium Croscarmellose, Colloidal anhydrous silica (Aerosil), Magnesium Stearate

Nootropil Solution 20%

Propyl Parahydroxybenzoate, Apricot flavour 52247/A, Glacial acetic acid, Methyl Parahydroxybenzoate, Glycerol (85%), Caramel Flavour 052929A7, Purified water, sodium acetate, saccharin sodium

- MAL number

Nootropil Tablet 800 mg

- MAL07021408AZ

Nootropil Tablet 1200 mg

- MAL07021409ARZ

Nootropil Solution 20%

- MAL19861245ACZ

Manufacturer

Nootropil Tablet 800 mg and 1200 mg

UCB Pharma SA

Chemin du Foriest

B – 1420 Braine-l'Alleud

Belgium

Nootropil Solution 20%
NextPharma SAS,
17, Route de Meulan,
F-7850, Limay, France

Product Registration Holder

GlaxoSmithKline Pharmaceutical Sdn.
Bhd.
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Selangor, Malaysia

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01 April 2016

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