

PATIENT INFORMATION LEAFLET

NOOTROVER 1 g/5 mL ampoule containing solution for infusion
Administered intravenously.

- **Active ingredient:** Each 5 mL ampoule contains 1 g of piracetam
- **Excipient:** Sodium acetate trihydrate, glacial acetic acid and water for injection.

Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.

- *Keep this PATIENT INFORMATION 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.*
- *During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.*
- *Follow these instructions exactly as written. Do not use **higher or lower** dose other than your recommended dose.*

In this patient information leaflet:

1. *What NOOTROVER is and what it is used for?*
2. *Before you are given NOOTROVER*
3. *How to use NOOTROVER?*
4. *Possible side effects*
5. *How to store NOOTROVER?*

Headings are included.

1. What NOOTROVER is and what it is used for?

NOOTROVER is clear and colorless solution. Each box contains 12 ampoules.

NOOTROVER is in the nootropic drug group. Nootropics improve cognitive processes such as learning, memory, attention, and awareness without being linked to a sedative or stimulating effect.

NOOTROVER is used in the treatment of;

In adults

- Symptomatic treatment of psycho-organic syndromes with symptoms such as memory loss, attention deficit and loss of driving ability,
- Treatment of cortical myoclonus (short, sudden ("flash-like") muscle contractions in one or more limbs or trunk) (alone or in combination with other drugs),
- Used for dizziness and related balance disorders (excluding the feeling of dizziness of vasomotor or psychic origin).

In children

- Dyslexia (reading / writing difficulties) with appropriate approaches such as speech therapy in children aged 8 and above.

2. Before you are given NOOTROVER

DO NOT USE NOOTROVER in the following cases:

If;

- You are allergic (hypersensitive) to active substance piracetam or to other pyrrolidone derivatives or to any of the excipients of NOOTROVER.
- You have a brain hemorrhage,
- If you have end-stage renal disease,
- If you have Huntington's Chorea disease, do not use this drug.

Take SPECIAL CARE with NOOTROVER in the following cases:

- Because piracetam can prolong the bleeding time, if you have an underlying bleeding disorder, if you are at risk of bleeding due to a certain disease, if you have a cerebral hemorrhage, if you are taking medications that prevent blood clotting, including low doses of aspirin, or if you are a patient with heavy bleeding and major surgery,

- If you have renal failure, use NOOTROVER carefully.

- If you are elderly and have long-term use of NOOTROVER, your renal function should be monitored regularly by your doctor and dose adjustment should be made if necessary.

- If you are taking NOOTROVER for myoclonus, be sure to follow the dosage and instructions given by your doctor.

Please consult your doctor if you experienced in the past or have being experienced recently any of these conditions.

Taking NOOTROVER with food and drinks

NOOTROVER has no interaction with food and drinks.

Pregnancy

Consult your doctor or pharmacist before taking the medicine.

If you are pregnant or think you may be pregnant, please inform your doctor.

- There is not enough data regarding the use of NOOTROVER in pregnant women. NOOTROVER should not be used in pregnant women unless considered essential by the doctor.
- If you are using this medicine effectively to avoid getting pregnant, you must be protected from pregnancy.

Please consult your doctor or pharmacist if you notice that you are pregnant during your treatment.

Lactation

Consult your doctor or pharmacist for before taking this medicine.

- Because NOOTROVER passes into breast milk, mothers using NOOTROVER should stop breastfeeding or stop taking the drug during breastfeeding.

Driving and using machines

Be careful when driving or using machine, as NOOTROVER can cause dizziness, drowsiness, fatigue.

Important information about some of the ingredients of NOOTROVER

NOOTROVER contains sodium acetate as an excipient. But no dose-related adverse effects are expected.

Taking with other medicines

When piracetam was used concomitantly with a thyroid extract (T3 + T4), confusion, irritability (overreaction to stimulation) and sleep disturbance were observed.

It may increase the effects of drugs that reduce blood coagulation (coumarin group).

No significant effect of other drugs on piracetam is expected. Piracetam is not expected to affect the metabolism of other drugs.

Piracetam taken at a daily dose of 20g for 4 weeks did not alter the peak and baseline serum levels of antiepileptic drugs (carbamazepine, phenytoin, phenobarbitone, sodium valproate) taken in fixed doses in epilepsy patients.

Concomitant alcohol use did not alter piracetam serum levels. 1.6 g oral piracetam has no effect on alcohol level. However, alcohol consumption is not recommended during treatment with NOOTROVER.

If you are currently using or have recently used any prescribed or non-prescribed medicine, please inform your doctor or pharmacist.

3. How to use NOOTROVER?

- **Instructions for use and dose/frequency of administration:**

Your doctor will determine the dose of your medicine depending on your illness and administer it to you. NOOTROVER ampoule form is administered intravenously in cases where oral administration is not possible, such as difficulty in swallowing and loss of consciousness.

- **Route of administration and method:**

NOOTROVER ampoule should be administered by intravenous injection by a healthcare professional.

- **Different age groups:**

Use in the elderly:

In elderly patients with impaired renal function, the doctor is recommended to adjust the dose.

Use in children:

NOOTROVER is not recommended for use in children under 8 years of age.

Conditions of special use:**Renal /Hepatic impairment**

In patients with renal failure, the dose should be adjusted by the doctor.

Only in patients with hepatic insufficiency, the dose does not need to be adjusted. It is recommended to adjust the dose if there is renal failure along with hepatic failure.

If you have an impression that the effect of NOOTROVER is too strong or weak, please tell your doctor or pharmacist.

If you use more NOOTROVER than you should:

If you use more NOOTROVER than you should, talk to a doctor or pharmacist.

If you forget to use NOOTROVER:

Do not take double doses to make up for forgotten doses.

If NOOTROVER treatment ends, effects may occur:

The duration of treatment with NOOTROVER depends on the severity of the symptoms of the disease, the type and the patient's response to treatment. Do not discontinue treatment without your doctor's advice, as this may cause symptoms of the disease to reappear or worsen. Your doctor should decide whether to terminate treatment with NOOTROVER.

4. Possible side effects

Like all other medicines, NOOTROVER may cause side effects in patients with hypersensitivity to any component of the drug.

If one of following occurs, stop using NOOTROVER and tell your doctor IMMEDIATELY or consult nearest hospital emergency department:

- Anaphylactoid reaction,
- Hypersensitivity,
- Coordinated movement disorder (Ataxia),
- Balance disorder,
- Aggravation of epilepsy,
- Seeing or hearing things that are not real (hallucinations),
- Angioneurotic edema (swelling of the hands, feet, ankles, face, lips, or swelling of the mouth or throat that makes swallowing or breathing difficult)

All of these adverse effects are very serious. If you have one of these, it means you have a serious allergy to NOOTROVER. You may need urgent medical care or hospitalization.

All of these very serious side effects are very rare.

If you notice any of the following, inform your doctor immediately or contact the Emergency

Department of the hospital nearest you:

- Excessive mobility (Hyperkinesis),
- Nervousness,
- Extreme restlessness (agitation),
- Anxiety,
- Confusion,
- Thrombophlebitis,
- Low blood pressure (hypotension)
- Bleeding disorder

All these are serious side effects. Emergency medical attention may be required. Serious side effects are very rare.

If you notice any of the following, tell your doctor:

- Weight gain,
- Depression,
- Fatigue (Asthenia),
- Dizziness (Vertigo),
- Abdominal pain,
- Upper abdominal pain,
- Diarrhea,
- Nausea,
- Vomiting,
- Headache,
- Insomnia,
- Inflammation of the upper layer of the skin (Dermatitis),
- Itching,
- Hives (Urticaria),
- Pain at the injection site,
- Fever.

These are the mild side effects of NOOTROVER.

If you experience any side effects that are not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of the side effects:

If you get any side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly to your doctor or pharmacist. You can also report side effects directly to your country's related health authority. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store NOOTROVER

Keep NOOTROVER out of the reach and sight of children and store in the original package.

Store at room temperature below 25°C.

Use in accordance with the expiry date.

Do not use NOOTROVER after the expiration date which is stated on the package or label.

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