PATIENT INFORMATION LEAFLET

NEUROSETAM 1g/5ml I.V. solution for infusion
Applied into the vein.
Sterile

- ***Active substance:*** Each vial contains 1 g of piracetam.
- ***Excipients:*** Sodium acetate trihydrate, acetic acid (k.m), 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.*

The following subjects are covered herein:

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

NEUROSETAM is a clear and colorless solution. Each box contains 12 vials.

NEUROSETAM is in the nootropic drug group. Nootropics develop cognitive processes such as learning, memory, attention and awareness without being associated with a soothing or stimulating effect.

NEUROSETAM;
In adults

- Symptomatic (symptomatic) treatment of psycho-organic syndromes with memory loss, attention deficit and loss of ability to drive,
- Treatment of cortical-induced myoclonus (short or sudden "flash-like" muscle contractions) in one or more limbs or trunk (alone or in combination with other drugs),

- Used for dizziness and associated disturbances of balance (except for a feeling of drowsiness or vasomotor).

In Childrens

- It is used in the treatment of dyslexia (read / write difficulty) with appropriate approaches such as speech therapy in children aged 8 and over.

2. Before you are given NEUROSETAM

DO NOT USE NEUROSETAM under the following circumstacnes

If:

- The active substance of NEUROSETAM can be used in piracetam or other pyrrolidone derivatives, or
- If you are allergic to any of the excipients it contains,
- If you have brain hemorrhage,
- If you have end-stage kidney disease,
- If you have Huntington's Chorea disease, do not use this medicine.

Inform your physician before taking **NEUROSETAM.**

USE NEUROSETAM with CAUTION if

If;

- If you have a hemorrhage-related disorder due to a particular disease, if you are suffering from bleeding due to a particular disease, if you have a bleeding hemorrhage, if you are suffering from blood clotting, if your are using drugs which prevents blood clothing including low doses of aspirin, or if you are a patient with severe bleeding and a major surgical procedure,
- Use NEUROSETAM carefully if you have kidney failure.
- If you are elderly and have been using NEUROSETAM for a long time, your kidney function should be monitored regularly by your doctor and dose adjustment should be made if necessary.
- If you are taking NEUROSETAM for myoclonus, be sure to follow the dose prescribed and instructions given to you by your doctor.

If these warnings apply or applied to you, please consult your physician.

Using NEUROSETAM with food and beverages

NEUROSETAM has no interaction with food and beverages.

Pregnancy

Please consult your physician or pharmacist before taking the drug.

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

There is insufficient data on the use of NEUROSETAM in pregnant women. NEUROSETAM should not be used in pregnant women unless determined as necessary by the physician.

If you are taking this medicine, you should be protected from pregnancy effectively in order not to become pregnant.

If you realize that you are pregnant during your treatment, immediately consult your physician or pharmacist.

Lactation
Please consult your physician or pharmacist before taking the drug.

As NEUROSETAM passes into breast milk, mothers who use NEUROSETAM should stop breast-feeding or discontinue the drug during breastfeeding.

Ability to drive and use machines
Be careful when driving and using machines as NEUROSETAM may cause dizziness, drowsiness or fatigue.

Vital information regarding some of the excipients contained in NEUROSETAM
Each vial of this medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is essentially “sodium free”.

Use in combination with other drugs
When piracetam was used concurrently with a thyroid extract (T3 + T4), confusion (irritability), irritability (overstimulation) and sleep disturbance were observed.

It may increase the effects of drugs that reduce blood clotting (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 dose of 20g per day for 4 weeks did not alter the peak and baseline serum levels of antiepileptic drugs (carbamazepine, phenytoin, phenobarbitone, sodium valproate) which are taken in fixed doses in epilepsy patients.

Concurrent alcohol use did not alter piracetam serum levels. 1.6 g of piracetam taken orally has no effect on the alcohol level. However, alcohol consumption during treatment with NEUROSETAM is not recommended.

If you are currently taking or recently took any prescribed or over-the-counter drugs, please inform your physician or pharmacist.

3. How you will be given NEUROSETAM?

Instructions regarding correct use and dosage/administration frequency:

Depending on your disease, your doctor will determine the dose of your medicine and apply it to you.

NEUROSETAM vial form is administered intravenously in cases where taking oral ly is not possible such as difficulty in swallowing or loss of consciousness.

Method of administration:
NEUROSETAM should be administered by medical personnel by intravenous injection.

Various age groups:

- **Use in the elderly:**

It is recommended that the doctor adjust the dose in elderly patients with renal dysfunction.

- **Use in children:**

NEUROSETAM is not recommended for children under 8 years of age.

Special usage cases:
Renal /Hepatic failure:
In patients with renal impairment, the dose should be adjusted by the doctor.

Only patients with hepatic impairment do not need to adjust the dose. Dose adjustment is recommended if there is renal failure with liver failure.

If you are under the impression that the effect NEUROSETAM is too strong or weak, consult your physician or pharmacist.

If you have taken more NEUROSETAM than you should have:

If you have used NEUROSETAM more than you should have or more than prescribed, consult a physician or a pharmacist.

If you forget to take NEUROSETAM
Do not double-dose to make up for forgotten doses.

Possible effects once NEUROSETAM treatment is concluded:
The duration of treatment with NEUROSETAM depends on the severity of the symptoms, the type and the response of the patient to the treatment. Do not discontinue treatment without the advice of your doctor, as this may cause the symptoms of the disease to recur or worsen. Your doctor should decide on the termination of treatment with NEUROSETAM.

4. Possible side effects

Like all medicines, NEUROSETAM may have side effects in people who are sensitive to the substances contained in its contents.

If you notice any of the following rare but serious side effects, stop using NEUROSETAM and talk to your doctor immediately or contact the emergency department of the hospital nearest you:

- Anaphylactoid reaction,
- Hypersensitivity
- Coordinated movement disorder (Ataxia),
- Balance disorder,
- Exacerbation of epilepsy,
- Seeing or hearing things that are not real (Hallucination),
- Angioneurotic edema (hands, feet, wrists, swelling of the face, lips or especially swelling of the mouth or throat to make swallowing or breathing difficult)

These are all very serious side effects. If you have one of these, you have a serious allergy to NEUROSETAM. You may need immediate medical intervention or hospitalization.
All of these very serious side effects are very rare.

If you notice any of the following, tell your doctor immediately or contact the emergency department of the hospital nearest you:

- Hyperactivity (Hyperkinesis),
- Irritability,
- Extreme Unrest (Agitation),
- Anxiety (Anxiety),
- Confusion;
- Thrombophlebitis,
- Drop in blood pressure (hypotension)
- Bleeding disorder

All these are serious side effects. Emergency medical intervention may be required. Severe side effects are rare.

Tell your doctor if you notice any of the following:

- Weight gain,
- Depression,
- Fatigue (Asthenia),
- Vertigo,
- Abdominal pain,
- Upper abdominal pain,

- Diarrhea,
- Nausea,
- Vomiting,
- Headache,
- Insomnia,
- Skin inflammation of the upper layer (dermatitis),
- Itching,
- Hives (Urticaria),
- Pain in the injection site
- Fever

These are the slight side effects of NEUROSETAM.

If you notice any side effect not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting side-effects

If any side-effects occur, regardless of whether they have been listed in the Patient Information Leaflet, please contact your physician, pharmacist or nurse. In addition, please kindly report the side effects to Turkish Pharmacovigilance Center (TÜFAM) by clicking on "Drug Side Effect Reporting" icon on the website www.titck.gov.tr or by calling the phone line 0 800 314 00 08. By reporting side-effects, you will contribute to the collection of additional information regarding the safety of the medicine you are using.

5. How to store NEUROSETAM

Keep the NEUROSETAM out of the sight and reach of children, and in its original package.
Store at room temperature below 25ºC.

Use in accordance with expiration dates.

Do not use NEUROSETAM after the expiration date printed on its packaging. If you notice any irregularities in the product and/or its packaging, do not use NEUROSETAM.

5% glucose, 10% glucose, 20% glucose, 5% fructose, 10% fructose, 20% fructose, 0.9% NaCl, Dextran 40 (10% in 0.9% NaCl solution), Ringer, 20% Mannitol, 6% HEPP (hydroxyethyl starch), 10% HH (hydroxyethyl starch) solutions are physically, chemically and microbiologically compatible for 24 hours provided that they are stored at room temperature below 25 °C.

Do not throw away any expired or unused medicines! Give to the collection system determined by the Ministry of Environment and Urbanization.

Marketing Authorisatıon Holder: POLİFARMA İLAÇ SAN. VE TİC. A.Ş.
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These instructions were approved on 19.11.2019.