PATIENT INFORMATION LEAFLET

NEFRASİN Amino Acid IV Solution for Infusion

Sterile

Administered intravenously.

- ***Active substance:*** Each 100 mL solution contains 0.25 g L-Histidine, 0.56 g L-Isoleucine, 0.88 g L-Leucine, 0.64 g Lysine (0.90 g L-Lysine Acetate), 0.88 g L-Methionine, 0.88 g L-Phenylalanine, 0.40 g L-Threonine, 0.20 g L-Tryptophan, 0.64 g L-Valine and less than 0.02 g L-Cysteine hydrochloride monohydrate.
- ***Excipients:*** Sodium bisulfite, sodium hydroxide 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.*

What is in this Leaflet:

Headings are included.

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

- NEFRASİN is a solution that contains amino acids, which are the building blocks of proteins, which are nourishing substances for the body. It is available in 500 mL bottles.

NEFRASİN is used to provide the necessary nutritional support in renal patients who cannot tolerate the administration of general purpose amino acids.

2. What you need to know before you use NEFRASİN

DO NOT USE NEFRASİN in the following cases;

If,

- If you have previously had an allergic reaction when you took NEFRASİN or one of its ingredients, that is, if you suddenly developed symptoms such as shortness of breath, wheezing, skin rash, itching or swelling in your body (if you are not sure whether you have allergies, consult your doctor);
- If the salt and acid-base balance in your body is seriously disturbed;
- - If you have higher than normal levels of ammonia, which is a very harmful substance for the nervous system, which is formed in the blood as a result of the breakdown of amino acids (hyperammoniemia);
- If the volume of blood circulating in your veins has dropped below critical levels;
- If the production and destruction of amino acids (amino acid metabolism) is congenitally damaged, DO NOT use this medicine.

USE NEFRASİN CAREFULLY for the following cases;

- If you have severe hepatic impairment or liver coma;
- If you have been receiving intravenous nutrition or fluid administration for a long time and you have excessive fluid accumulation in your body (edema) or fluid accumulation in your lungs;
- If you have asthma;
- If you have heart failure;
- If you are using this medicine with other nutrients and you have diabetes or a predisposition to this disease;
- If this product is given to you through the veins in your arms or legs (In this case, NEFRASİN will be diluted in the appropriate proportion and will be given with sufficient calories).

Your doctor will perform blood tests or clinical evaluations at regular intervals in cases where you have been fed intravenously for a long time and will use additional drugs in case of deviation from normal values.

In addition, if NEFRASİN is used in pre-term (premature) infants or children with low birth weight; your doctor will pay special attention when using this medication and perform tests at certain intervals during treatment more often.

If these warnings are valid for you, even at any time in the past, please consult your doctor.

Use of NEFRASİN with food and drink

During intravenous nutrition, you can consume your normal food and drinks.

Pregnancy

Consult your doctor or your pharmacist before using the drug.

Your doctor will decide whether you can use NEFRASİN during pregnancy or not, after comparing the benefits of this treatment with the possible harms.

If you notice you are pregnant during treatment, consult your doctor or pharmacist immediately.

Breast-feeding

When you are breastfeeding your baby, if your doctor thinks that the benefits of this drug are more than the possible harms, you can use the drug with the decision of your doctor.

Consult your doctor or pharmacist before using this medication.

Driving and using machines

It is not possible to drive and use machines during intravenous feeding. It has no effect on the ability to drive and use machines after your treatment is terminated.

Important information about some excipients found in the composition of NEFRASİN

If you do not have a hypersensitivity to the substances contained in NEFRASİN, a negative effect is not expected against these excipients.

This product contains sodium bisulfite as an excipient. Sulfide can lead to allergic reactions, anaphylaxis, or a severe and life-threatening asthma attack in some sensitive people. Although the general prevalence of sensitivity to sulfite in society is unknown, it is estimated to be very low. Sulfide sensitivity is more common in people with asthma than in those who do not.

Use with other medicines

Please tell your doctor if you are planning, taking, or have recently taken any other medications, including non-prescription drugs, vaccines, and herbal medications.

Your physician will check whether any medication he / she adds is compatible with the solution. In cases where any drug is added to NEFRASİN or the drug is mixed with other nutrients, the mixture should be administered immediately.

If you are using or have recently used any type of prescription or non-prescription drugs, please inform your physician or your pharmacist.

3. How to use NEFRASİN

Instructions for appropriate use and dose/administration frequency:

The frequency of administration of your medication, the amount to be administered each time, and how long you will continue intravenous administration will be determined by your doctor.

In general, 250-500 mL of NEFRASİN per day is sufficient. You should also get enough calories.

Method of administration:

NEFRASİN is used intravenously with the help of a plastic tube (catheter) placed in your veins. Intravenous administration can be done from the veins in your arms or legs or from large veins in your neck area.

Various age groups

Pediatric Use:

Your doctor will calculate the total volume and rate of administration of the feeding fluid individually based on the child's age, body weight and renal function. If the patient is a newborn and a small baby, your doctor will closely monitor many blood values, including blood sugar levels.

Geriatric Use:

Older patients are known to be more prone to fluid loading and salt imbalances than younger ones. This condition may be associated with impaired renal function, which is more common in the elderly. As a result, careful monitoring is more necessary during liquid-salt treatments in the elderly.

Although there is no specific dose set for the elderly, during all parenteral nutrition practices, your doctor will individually determine the dose of your drug from case to case in all patients, including the elderly, based on your body weight, clinical status, and the results of laboratory tests performed during monitoring.

It will also start your treatment with the lowest effective dose, taking into account that liver and heart function are lower in older patients than in younger ones; other diseases and drug use are more frequent together.

Special use cases:

Renal/ Hepatic impairment:

Administration of amino acid in cases of renal dysfunction can further increase the elevated blood

urea nitrogen.

NEFRASİN can be used safely in these patients, as it is specifically formulated to provide the necessary nutritional support for kidney diseases that cannot tolerate general-purpose amino acid infusions.

Administration of amino acid solutions for general use in patients with hepatic insufficiency can lead to an imbalance of amino acids in the blood, an increase in ammonia, loss of consciousness and coma. For this reason, solutions specifically formulated (such as HEPASELAMİN, etc.) should be used to provide the necessary nutritional support for liver diseases that need to be fed through the vascular way and do not tolerate general-purpose amino acids.

Talk to your doctor or pharmacist if you have the impression that the effect of NEFRASİN is too strong or weak.

If you have used more NEFRASİN than you should

If you have used NEFRASİN more than you should, talk to a doctor or pharmacist.

If you forget to use NEFRASİN

Do not forget to take your medication on time.

Do not administer a double dose to make up for forgotten doses.

Effects that may occur when treatment with NEFRASİN is concluded

Your doctor will tell you how long your treatment with NEFRASİN will last. Do not stop treatment early because you will not get the desired result.

If you are using high-density dextrose (glucose) solutions with NEFRASİN, your treatment will be continued for some time with less dextrose-containing solutions (for example, 5% dextrose solution) so that you do not experience a blood sugar drop (rebound hypoglycemia) that may occur when your treatment is terminated.

4. What are the possible side effects?

Like all medicines, there may be side effects in people who are sensitive to the substances contained in NEFRASİN.

Side effects are listed as shown in the following categories:

Very common : It can be seen in at least one of 10 patients.

Common : less than one in 10 patients, but more than one in 100 patients.

Uncommon : less than one in 100 patients, but more than one in 1000 patients.

Rare : less than one in 1,000 patients can be seen.

Very rare : less than one in 10,000 patients.
Unknown : Cannot be estimated from the available data.

Unknown:

- Hypersensitivity reactions (itching, redness, swelling, burning sensation in some or all parts of the body; respiratory distress, wheezing, chest pain; excessive heat or cold feeling in the body; swelling of hands, feet, lips, face or whole body; dizziness fainting feeling).

These are all very serious side effects.
If you have one of these, it means you have a serious allergy to NEFRASİN. You may need urgent medical attention or hospitalization.
All of these very serious side effects are very rare.
Apart from hypersensitivity reactions, the following side effects may also occur:
Unknown:

- A type of anemia (Acute hemolytic anemia)
- Spasms, cramps in your muscles
- Increase or decrease in salt levels in your body
- Increased levels of ammonia in the blood (hyperammonemia)
- Increased levels of amino acids in the blood (hyperketonemia)

Redness, swelling or pain around the applied vein (phlebitis, thrombosis); All these are serious side effects. It may depend on your medication or intravenous administration. Emergency medical attention may be required.

If you experience any side effect not mentioned in this patient information leaflet, inform your doctor or your pharmacist.

Reporting of suspected adverse reactions
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 will contribute to obtaining more information about the safety of the drug that you are using.

5. How to store NEFRASİN

Keep NEFRASİN out of the sight and reach of children, and in its packaging.

Use in compliance with the expiry date.

The shelf life of NEFRASİN is two years. An expiration date is written on the label on each bottle. If this date has passed, you will not be given this medicine.

Do not use NEFRASİN after the expiration date stated on the packaging/ Use before the expiry date.

Do not store at temperatures above 25°C. Protect from extreme heat and freezing. Protect from light until use. Do not use solutions that are not clear and leaky. Dispose of incomplete solutions; do not re-use the unused part.

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

Marketing Authorization Holder and Manufacturing Site:

OSEL İlaç San. ve Tic. A.Ş.
Akbaba Mah. Maraş Caddesi No:52 34820
Beykoz/İSTANBUL

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