PATIENT INFORMATION LEAFLET

NUTRICLIN N7-1000 E Amino Acid Solution with Electrolyte, Glucose Solution and Lipid Emulsion for IV Infusion

Administered intravenously.

Sterile

- ***Active substances:*** Each 100 milliliters of nutritional mixture contains the following amounts of active ingredient:

Refined olive oil (80%) + Refined soybean oil (20%)	: 4 g
L-Alanine	: 0.828 g
L-Arginine	: 0.460 g
Glycine	: 0.412 g
L-Histidine	: 0.192 g
L-Isoleucine	: 0.240 g
L-Leucine	: 0.292 g
L-Lysine (as 0.290 g L-Lysine HCl)	: 0.232 g
L-Methionine	: 0.160 g
L-Phenylalanine	: 0.224 g
L-Proline	: 0.272 g
L-Serine	: 0.200 g
L-Threonine	: 0.168 g
L-Tryptophan	: 0.072 g
L-Tyrosine	: 0.016 g
L-Valine	: 0.232 g
Sodium acetate $3H_2O$	: 0.245 g
Sodium glycerophosphate $5H_20$	: 0.214 g
Potassium chloride	: 0.179 g
Magnesium chloride $6H_20$	: 0.045 g
Glucose (as 17.6g glucose monohydrate)	: 16 g
Calcium chloride $2H_2O$	: 0.030 g

- ***Excipients:*** Pure egg phosphotides (from chicken egg yolk powder), glycerol, sodium oleate, sodium hydroxide, glacial acetic acid, hydrochloric acid and water for injection.

Read all of this LEAFLET carefully before you start using this medicine because it contains important information for you.

- *Keep this leaflet. You may need to read it again later.*
- *If you have any further questions, please consult your doctor or pharmacist.*
- *This medicine has been prescribed for you only; do not pass it on to others.*
- *If you visit the doctor or hospital during the use of this medicine, inform them of your use of this medicine.*
- *Please exactly follow the instructions in this leaflet. Do not use **high or low** dosage other than the dose recommended to you for the drug.*

In this leaflet:

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1. What is NUTRICLIN N7-1000 E and what is it used for?

- NUTRICLIN N7-1000 E is a sterile product containing amino acids, electrolytes, glucose and oils. These components are essential building blocks for the body.
- NUTRICLIN N7-1000 E is presented in sizes of 1000, 1500 and 2000 milliliters in three-compartment plastic bags. The temporary separators between the compartments are removed to mix three separate liquids in the compartments and the product is used thereafter.
- NUTRICLIN N7-1000 E is a nutritional mixture **administered intravenously** when children over 2 years of age and adults cannot be fed orally. The medicine is used only through a plastic tube (set) suitable for this purpose into the vein and under medical supervision.

2. Before you use NUTRICLIN N7-1000 E Do NOT use NUTRICLIN N7-1000 E

- If the patient is under 2 years of age, breastfed or premature infant.
- If you have hypersensitivity (allergy) to egg, soybean or peanut proteins or the active or inactive ingredients of NUTRICLIN N7-1000 E.
- If there is a problem with your body using the building blocks of proteins called amino acids.
- If fat levels in your blood are increased (hyperlipidemia).
- If you have a severely high blood sugar level (hyperglycemia).
- In cases where any of the substances called electrolytes (sodium, potassium, magnesium, calcium, phosphate and acetate) contained in NUTRICLIN N7-1000 E are abnormally high.

In any case, your doctor will decide whether you will use this medicine or not, based on your age, body weight and clinical condition, as well as your test results.

TAKE SPECIAL CARE WITH NUTRICLIN N7-1000 E

If you have a fever, chills, skin rash or any allergic symptom such as difficulty in breathing, excessive sweating, nausea and headache, the administration of the medicine will be stopped immediately. This drug contains soybean and egg phosphatide proteins. Soybean and egg proteins may cause hypersensitivity reactions (allergy). It was reported that people with peanut allergy can also be allergic to soybean.

During your treatment, your doctor will monitor your triglyceride levels, a type of fat in your blood, at regular intervals.

You may develop an infection or sepsis (bacteria in your blood) when a tube (intravenous catheter) is placed in your veins to administer this medicine to you. Some medications and diseases increase your risk of developing infections or sepsis. People who need to be fed intravenously are more susceptible to developing infections. This risk can be reduced by using "aseptic techniques" ("germ-free technique") in catheter placement and maintenance and in the preparation of nutritional formulations.

Special care should be taken when administering NUTRICLIN to patients with liver or kidney problems, blood clotting problems, increased blood density (increased osmolarity), insufficiency of the adrenal gland, heart failure, lung dysfunction, abnormal water retention or dehydration, and those with severe injury, untreated diabetes, sudden heart failure, heart attack, severe metabolic acidosis (a condition in which the blood becomes too acidic) and those in unstable condition due to septicemia (common infections in the body) or patients in coma.

It has been reported that fat overload syndrome can be seen with similar products. Inability to remove the oils in the NUTRICLIN composition from the environment may result in "fat overload syndrome" (See Section 4. Possible side effects).

No additions should be made to the bag of your medicine before checking whether it is compatible. Small particles in the bag or resolution in the fat-containing compartment may be observed. This condition may cause obstruction in your blood veins.

If your blood sugar is too high, your doctor will reduce the administration rate of NUTRICLIN or administer insulin to you.

If you have a severe nutritional disorder that requires you to be fed through the vascular access, this intravenous feeding should be started slowly and carefully.

Before starting treatment with this medication, existing metabolic disorders of your body with fluid and salt, if any, should be corrected. During your treatment, your doctor will monitor your condition and may change the dose of your medicine or prescribe additional nutritional substances (e.g. vitamins), additional electrolytes and substances called trace elements, when necessary.

Your doctor will sometimes review your clinical condition and apply some blood tests to you to determine whether this medicine is still effective and safe while using it. Also, if you have been using this drug for a long time, you will be followed up with blood tests at regular intervals.

These tests will especially be performed if you have a liver disease or kidney disease, have a problem in using the building blocks of proteins called amino acids, if your blood is more acidic than normal, if your blood fat and cholesterol levels are higher than normal, if you have diabetes, if you have anemia or if your bleeding is difficult to stop.

Special care will be taken to administer the correct dosage if the person to whom the drug is administered is a child. Additional vitamins or trace elements may be required to be added to the treatment according to the dose and duration of the administration of the medicine. In addition, since children are more prone to an inflammatory condition (infectious disease), precautions will be more stringent.

Taking NUTRICLIN N7-1000 E with food and drink

NUTRICLIN N7-1000 E is an intravenous drug; there is no interaction with food and drink in terms of administration method.

Pregnancy

Ask your doctor or pharmacist for advice before taking the medicine.

Do not use NUTRICLIN N7-1000 E during pregnancy unless it is particularly deemed appropriate by your doctor.

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

Breast-feeding

Ask your doctor or pharmacist for advice before taking the medicine.

Tell your doctor if you are breastfeeding your baby. Do not use NUTRICLIN N7-1000 E during breastfeeding unless it is particularly deemed appropriate by your doctor.

Driving and using machines

NUTRICLIN N7-1000 E has no effect on the ability to drive or use machinery.

Important information about some of the ingredients of NUTRICLIN N7-1000 E

If you do not have sensitivity to the excipients contained in NUTRICLIN N7-1000 E, no adverse effects are expected due to these substances.

Using with other medicines

If you plan to take any other medicines, including over-the-counter medications, vaccines and herbal remedies, if you are taking them or have recently taken them, please tell your doctor.

NUTRICLIN N7-1000 E should not be given from the same set as the blood.

NUTRICLIN N7-1000 E contains calcium. It should not be given with ceftriaxone, an antibiotic, as it may cause particles to form in your medicine.

NUTRICLIN N7-1000 E contains olive oil and soybean oil, vitamin K1, which can interact with drugs called coumarin and warfarin. These drugs are medicines that prevent your blood from clotting.

If you undergo some tests before the fats contained in your medicine are excreted from your body, the results of these tests may be affected (these fats are generally cleared from the body 5 to 6 hours after stopping fat intake).

NUTRICLIN N7-1000 E contains potassium. Special attention is required in patients who take diuretics, angiotensin converting enzyme (ACE) inhibitor or angiotensin II receptor antagonist for high blood pressure and those who use drugs that suppress the immune system. These types of medications can cause an increase in sodium level in your blood.

Please tell your doctor or pharmacist if you are taking or have recently taken any other prescription or non-prescription medicines.

3. How to use NUTRICLIN N7-1000 E

Instructions for proper use and dose/frequency of administration:
Only adults and children over 2 years of age should use NUTRICLIN N7-1000 E. It is only administered through a plastic tube inserted into a large vein in your chest.

It can be used as long as your doctor prescribes, depending on your condition.

NUTRICLIN N7-1000 E is for single use only, the remaining part in the bag should not be reused.

Dosage in adults

Your doctor will decide what amounts of this medicine you need and when to administer it. This will depend on your age, body weight, and the reason for this drug to be administered to you. Follow these instructions unless otherwise specified by your doctor.

You can take up to 36 milliliters of NUTRICLIN N7-1000 E per kilogram of your body weight in a day. For example, if your body weight is 70 kg, you can use a maximum of 2520 mL NUTRICLIN N7-1000 E a day.

Dosage in children older than 2 years

For children, the dosage and how long it will be used is decided by the doctor. Your doctor will make this decision according to the child's age, body weight, height, clinical condition, and daily fluid volume, energy and nitrogen needs.

Children can take up to 75 milliliters of NUTRICLIN 7-1000 E per kilogram of body weight in a day. For example, if the body weight is 30 kg, a maximum of 2250 mL NUTRICLIN N7-1000 E can be used in a day.

Your doctor will tell you how long your treatment will take with NUTRICLIN N7-1000 E. Do not stop the treatment early because you cannot get the expected result.

Route and method of administration:

It is administered through a plastic tube (catheter) suitable for your veins.

Special conditions for use:

There is no special condition for use.

If you notice that the effect of NUTRICLIN N7-1000 E is too strong or weak, consult your physician or pharmacist.

If you have used more NUTRICLIN N7-1000 E than you should:

If NUTRICLIN N7-1000 E was administered at a dose higher or at a rate faster than you should have been given, the amino acids contained may make your blood more acidious than usual and increase the amount of liquid in your circulating blood. The glucose content of the drug may increase the sugar levels in your blood or urine. The fat in the medicine may cause increased levels of triglycerides in your blood. As a result of the rapid or excessive administration of the drug, you may have nausea, vomiting, tremors and disturbances in electrolyte levels in your blood. In such cases, the administration should be stopped immediately. Excessively rapid administration of nutritional fluids used for total parenteral nutrition (the condition that all nutrition is delivered through the vein) may lead to death.

In some severe cases, your doctor may perform a temporary dialysis to help your kidneys remove these excessive substances.

To prevent these situations, your doctor will regularly examine your condition and give you some blood tests.

If you used NUTRICLIN N7-1000 E more than you should have used, please consult a doctor or pharmacist.

If you forget to use NUTRICLIN N7-1000 E:

Do not take a double dose to make up for a forgotten dose.

Effects that may occur when treatment with NUTRICLIN N7-1000 E is discontinued:

Not applicable.

4. Possible side effects

Like all medicines, there may be side effects in people sensitive to the ingredients of NUTRICLIN N7-1000 E.

Side effects are listed as shown in the following categories: Very common : may affect more than 1 in 10 people.
Common : may affect fewer than 1 in 10, but more than 1 in 100 patients.
Uncommon : may affect fewer than 1 in 100 patients, but more than 1 in 1000 patients. Rare : may affect fewer than 1 in 1,000 people.
Very rare : may affect fewer than 1 in 10,000 people.
Not known : Frequency cannot be estimated from the available data.

Unknown frequency:

- **Hypersensitivity reactions** (itching, redness, swelling, burning sensation in administration site; Breathing difficulty, wheezing, pain in the chest; Excessive temperature or coldness in the body; Swelling of hands, feet, lips, face or whole body; Dizziness, fainting; palpitations).

- Symptoms such as fever and chills in your body while the administration continues. All of the above are very serious side effects.

If you have one of these, you have a serious allergy to NUTRICLIN N7-1000 E. You may need for an emergency medical intervention or to be hospitalized.

All of these very serious side effects are seen rarely.
Apart from hypersensitivity reactions, the following side effects may also occur with unknown frequency:

- Headache
- Fever
- Trembling
- Diarrhea
- Abdominal pain, chest pain, back pain, arm or leg pain
- Abnormal skin rash
- Excessive sweating
- Abnormal results in tests that measure your liver function

- Increase in the volume of your liver, enlargement (hepatomegaly)
- Jaundice (yellowing of the skin and whites of the eyes due to a problem with your liver or blood)
- Nausea, vomiting
- Thrombophlebitis (blood clot that occurs in the vein where the administration is performed and causes pain, swelling and redness)
- The decrease in the number of blood platelets in your blood test (the decrease in the number of these platelets responsible for blood clotting may cause bleeding like nosebleeds).
- Pain, swelling in the administration site
- Fluid buildup around the administration site
- Increase in blood sugar
- Increase in blood triglyceride (fat) levels
- If there is a deficiency in the removal of the lipid content of NUTRICLIN N7-1000 E from the body, 'fat overload syndrome' may occur. This situation may occur after the use of the drug at higher than normal doses, or at the beginning of the treatment, even if the instructions for use are followed. The clinical condition of the patient deteriorates suddenly. Typical symptoms of fat overload syndrome include increased lipid levels in your blood (hyperlipidemia), fever, fatty liver and reaching a larger than normal volume (liver enlargement; hepatomegaly), anemia, decreased levels of white blood cells (leukocytes) and platelets in your blood, clotting disorders and/or coma. These symptoms are usually reversible and regress when the drug administration is stopped.
- It has been reported that white blood cells (leukocyte) and platelet levels decrease in children.

These are all serious side effects. You may need urgent medical attention.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of 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 NUTRICLIN N7-1000 E

Keep NUTRICLIN N7-1000 E out of the sight and reach of children and in its package.

Store at room temperature below 25°C. Do not freeze.
After mixing by opening the separators between the compartments, it has been shown to maintain stability at 2-8°C for 7 days and under 25°C for a maximum of 2 days. However, it is recommended to use it as soon as possible after mixing.

For single use only. Partially used medication should not be stored.

Do not throw expired or unused drugs in garbage bin! Hand them over to the collection system specified by the Ministry of Environment and Urbanization.

Please use this medicine consistent with its expiry date.

Do not use NUTRICLIN N7-1000 E after the expiry date on the package.

Do not use NUTRICLIN if you notice any defects in the products and/or its packaging

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FOLLOWING INFORMATION IS FOR HEALTHCARE PROFESSIONALS WHO WILL ADMINISTER THIS DRUG.

Only bags that are undamaged, whose compartments are not opened, whose parts containing glucose and amino acid solution are clear, colorless or slightly yellow, that do not contain visible particles, and whose part where the lipid emulsion is in a homogeneous milk appearance should be used.

NUTRICLIN N7-1000 E should be brought to room temperature before use.

It should be administered only after opening the temporary separators between the 3 compartments

and mixing as shown below.

1.

The protective packaging is torn out.

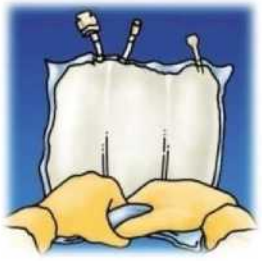
2.

After the packaging is removed and discarded, the oxygen absorbent, if any, is also removed and discarded.

3.

The integrity of the bag and separators is checked. It should only be used if the bag is not damaged, if the separators between the compartments are intact (the liquids in the compartments are not mixed together), the amino acid and glucose solutions are clear, and the emulsion is homogeneous.

4.



The bag is folded starting from the top (the side with the sling). Separators will begin to be separated from places close to application entrances. The bag should continue to be folded so that the separators are opened halfway through the bag.

5.

The bag should be turned over at least 3 times to mix the liquids.

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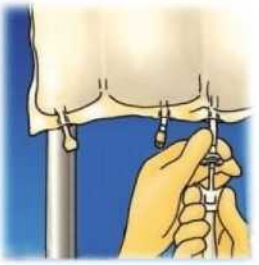

The bag is hanged. The plastic shield on the administration port is removed. The spike of the infusion set is firmly inserted into the administration port.

The bag should be used immediately after opening. The opened bag should not be stored for use in another infusion.

Partially used bags should not be readministered.

It should not be used with serial connection in order to avoid air embolism that could occur due to air in the first bag.

For single use only. Any unused product or material and all devices used in the application must be disposed of in accordance with the medical waste procedures of the health institution where intravenous administration is performed.

Medicine additions:

No drug should be added to any of the 3 compartments that make up NUTRICLIN N7-1000 E without first assessing the compatibility and the stability of the resulting mixture (especially the stability of the lipid emulsion).

Despite this, if necessary, electrolyte, trace element or vitamin can be added to NUTRICLIN.

The bags have enough capacity to add vitamins, electrolytes and trace elements.

Any additions, including vitamins, can be made after mixing has been achieved by separating the separators. Vitamin additions can also be made into the glucose chamber before mixing is carried out.

After any addition to the formulation, the osmolarity of the final mixture formed should be measured before administration through peripheral veins.

The following additions can be made into NUTRICLIN N7-1000 E:

- Electrolytes (electrolytes contained in the bag should be considered): The final mixture has been shown to remain stable up to the upper values of 150 mmol sodium, 150 mmol potassium, 5.6 mmol magnesium and 5 mmol calcium per liter.
- Organic phosphate: The mixture has been shown to remain stable with additions of up to 15 mmol per bag.
- Trace elements and vitamins: The mixture has been shown to remain stable in additions with commercially available vitamin and trace element preparations containing up to 1 mg of iron.

Additions of micronutrients should be done under aseptic conditions by qualified personnel. These additions should be made with a needle from the injection tip of the bag:

- The injection tip is prepared.
- The administration is performed by entering the injection tip with the needle.
- The contents of the bag are mixed with the medicine added.