

SmofKabiven NTense®

Amino acids 6.5%, Lipids 2.9%, Glucose 8.5% & Electrolytes 0.7%

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SmofKabiven NTense®. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you given SmofKabiven NTense® against any benefits they expect it will have for you.

Please read this leaflet carefully. If you have any questions or are unsure about anything, please ask your doctor or pharmacist.

Keep this leaflet. You may need to read it again.

What is SmofKabiven NTense® used for

SmofKabiven NTense® is an emulsion for infusion given into your blood by a drip (intravenous infusion). The product contains amino acids (components used to build proteins), glucose (carbohydrates), lipids (fat) and salts (electrolytes) in a plastic bag.

A health care professional will give you SmofKabiven NTense® when other forms of feeding are not good enough or have not worked.

Before you are given SmofKabiven NTense®

You must NOT use this product:

- if you are allergic (hypersensitive) to any of the

ingredients of SmofKabiven NTense®

- if you are allergic to fish or egg
- if you are allergic to peanuts, soya or corn (maize) as SmofKabiven NTense® contains soya oil
- if you have too much fat in the blood (hyperlipidaemia)
- if you have serious liver disease
- if you have blood clotting problems (coagulation disorders)
- if your body has problems using amino acids
- if you have serious kidney disease without access to dialysis
- if you are in acute shock
- if you have too much sugar in your blood (hyperglycaemia) which is uncontrolled
- if you have high blood (serum) levels of the salts (electrolytes)
- if you have fluid in the lungs (acute pulmonary oedema)
- if you have too much body fluid (hyperhydrated)
- if you have heart failure that is not treated
- if you have a defect in your blood clotting system (haemophagocytotic syndrome)
- if you are in an unstable condition, such as after serious trauma, uncontrolled diabetes, acute heart attack, stroke, blood clot, metabolic acidosis (a disturbance resulting in too much acid in the blood), serious infection (severe sepsis), coma and if you don't have enough body fluid (hypotonic dehydration).

Special care has to be taken while this product is given to you. Tell your doctor if you have:

- kidney problems
- diabetes mellitus
- pancreatitis (inflammation of the pancreas)
- liver problems
- hypothyroidism (toxic goiter)
- sepsis (serious infection).

If during the infusion you get fever, rash, swelling, difficulty in breathing, chills, sweating, nausea or vomiting, tell the health care professional immediately because these symptoms might be caused by an allergic reaction or that you have been given too much of the medicine.

Your doctor may regularly need to check your blood for liver function tests and other values.

SmofKabiven NTense® is not used for newborn babies or children younger than 2 years of age.

Please tell your doctor if you have recently taken some medicines, even without prescription.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding. SmofKabiven NTense® should only be given to pregnant or breast-feeding women if the doctor finds it necessary.

How SmofKabiven NTense® is given

How much will be given

Your doctor will decide on the dose for you individually depending on your body weight and function. SmofKabiven NTense® will be given to you by a health care professional.

How is it given

SmofKabiven NTense® should be administered by continuous flow into a large main vein using a sterile tubing and a catheter needle. It should only be administered to you by qualified medical staff.

If you are given too much (overdose)

This rarely happens as SmofKabiven NTense® is usually administered under the care of a trained health care professional in a hospital or clinic setting.

Your doctor has information on how to recognise and treat an overdose. Ask your doctor if you have any concerns.

Otherwise immediately telephone your doctor or contact the Poisons Information Centre in your country:

Australia: 13 11 26

New Zealand: 0800 764 766

Side Effects

Like all medicines, SmofKabiven NTense® can cause side effects, although not everybody gets them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea and vomiting
- flatulence
- abdominal pain
- swelling of hands, ankles or feet
- fast heart beat
- difficulty in breathing
- lack of appetite

- low or high blood pressure
- slight increase in body temperature
- chills
- dizziness
- headaches
- hypersensitivity reactions (skin rash)
- sensations of hot and cold
- pain in the neck, back, bones, chest
- paleness.

If any of these side effects occurs, or if you notice any side effects not listed in this leaflet, please contact your doctor or a pharmacist.

Storage

SmofKabiven NTense® should be stored in its overpouch below 25°C and not be frozen. As with any medicine, SmofKabiven NTense® should be stored out of the reach of children.

Do not use infusion bags that have been used, have expired or the container is damaged.

Product Description

What it looks like

SmofKabiven NTense® comes in a 3-chamber plastic bag, each chamber contains glucose, amino acids with electrolytes and a lipid emulsion separately. The glucose and amino acid solutions are clear, colourless or slightly yellow and free from particles. The lipid emulsion is white and homogeneous.

Ingredients

SmofKabiven NTense® contains the active ingredients: Alanine, Arginine, Glycine, Histidine, Isoleucine, Leucine, Lysine Acetate, Methionine, Phenylalanine, Proline, Serine, Taurine, Threonine, Tryptophan, Tyrosine, Valine, Calcium Chloride Dihydrate, Sodium Glycerophosphate Hydrate, Magnesium Sulfate Heptahydrate,

Potassium Chloride, Sodium Acetate Trihydrate, Zinc Sulfate Heptahydrate, Glucose Monohydrate, Soya Oil, Medium-Chain Triglycerides, Olive Oil, and Fish Oil-rich in Omega-3 acids.

It also contains other inactive ingredients: Glycerol, Egg Lecithin, dl- α -Tocopherol, Sodium Hydroxide, Sodium Oleate, Glacial Acetic Acid, Hydrochloric Acid, and Water for Injections.

SmofKabiven NTense® does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

SmofKabiven NTense® does not contain any preservative.

SmofKabiven NTense® comes in a plastic bag (Biofine bag) in 5 pack sizes. They can be identified by the following AUST R numbers:

AUST R 313924: 506 mL

AUST R 314977: 1012 mL

AUST R 314978: 1518 mL

AUST R 314979: 2025 mL

AUST R 314980: 2531 mL

Further Information

More detailed information is available from your doctor or pharmacist. Therefore, if you have any concerns about the information or about SmofKabiven NTense®, please ask your doctor or pharmacist.

Sponsor

Fresenius Kabi Australia Pty Ltd.
Level 2, 2 Woodland Way
Mount Kuring-gai, NSW 2080
Australia
Telephone: (02) 9391 5555

Fresenius Kabi New Zealand Ltd,
c/o GNZCC,
HSBC Tower, Level 14,
188 Quay Street, Auckland 1010,
New Zealand.
Freecall: 0800 144 892

Date of information

September 2021.