Package leaflet: Information for the user

Dipeptiven Concentrate for solution for infusion
N(2)-L-alanyl-L-glutamine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Dipeptiven is and what it is used for

Dipeptiven supplements the protein part of nutrition in conditions when there is an increased need. It is given to you as an infusion (IV).
Dipeptiven is usually used as part of a balanced intravenous and/or enteral diet, together with salts, trace elements and vitamins.

2. What you need to know before you are given Dipeptiven

You should not be given Dipeptiven:
- if you have a severely impaired liver or kidney
- if you have metabolic acidosis - a state in which the blood pH is low
- if you are in circulatory shock – a state in which the blood flow in the body is low
- if you have hypoxia – a state in which oxygen level is low
- if you have multiple organ failure – a state in which two or more organs do not function normally
- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6). Symptoms of an allergic reaction may include a high temperature, shivering, rash or shortness of breath.
- if you are pregnant or breastfeeding

Dipeptiven **must be diluted before use.** Dipeptiven will be added to another solution before it is given to you. Your doctor or nurse will make sure the solution is prepared correctly before you receive a solution containing Dipeptiven.

Warnings and precautions
Your doctor may want to do regular blood tests to check your condition and to make sure your body is using Dipeptiven correctly. Experience with the use of Dipeptiven for longer periods than nine days is limited.

Other medicines and Dipeptiven
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding
You should tell your doctor if you are pregnant, if you think you are pregnant or if you are breast-feeding. This medicine should not be given to you in these cases.

Driving and using machines
Dipeptiven has no effect on driving or using machines.

3. How you are given Dipeptiven

You will receive your medicine by infusion (IV drip) into a vein.
The dose of Dipeptiven depends on your bodyweight in kilograms and your body's ability to break down nutrients and your amino acid requirement.
Your doctor will decide on the correct dose for you to receive.

If you are given more Dipeptiven than you should
It is very unlikely that you will receive more infusion than you should as your doctor or nurse will monitor you during the treatment. However if you think that you have received too much Dipeptiven, inform your doctor or nurse immediately. Signs of overdose include: chills, nausea and vomiting.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Side effects with Dipeptiven are very rare and unlikely to happen.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

UK
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

5. How to store Dipeptiven

Keep this medicine out of the sight and reach of children.
Your doctor and hospital pharmacist are responsible for the correct storage, use and disposal of Dipeptiven infusion. Do not store above 25°C. Keep container in the outer carton.
Do not use this medicine after the expiry date which is stated on the label.
Any solution remaining after treatment should be disposed of via approved hospital procedures.

6. Contents of the pack and other information

What Dipeptiven infusions contains
50 ml of Dipeptiven contains:
10 g (N2)-L alanyl-L-glutamine (= L alanine 4.10 g, L-glutamine 6.73 g).
100 ml of Dipeptiven contains:
20 g N(2)-L-alanyl-L-glutamine (=8.20 g L-alanine, 13.46 g L-glutamine)
Dipeptiven also contains water for injections.

What Dipeptiven looks like and contents of the pack
Dipeptiven is a clear, colourless solution. It is available in glass bottles with a rubber closure that contain 50 ml or 100 ml of the concentrate.
Not all pack sizes may be marketed.

Marketing authorisation holder (Ireland):
Fresenius AG D-61346 Bad Homburg vdH Germany

Marketing authorisation holder (UK)
Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, UK

Manufacturerer:
Fresenius Kabi Austria GmbH, Hafnerstrasse 36, A-8055 Graz, Austria.

This leaflet was last revised in February 2023.

The following information is intended for healthcare professionals only:

Warnings and precautions for use
For a safe administration the maximum dose of Dipeptiven should not exceed 2.5 ml (corresponding to 0.5 g N(2)-L-alanyl-L-glutamine) per kg body weight per day.

Dipeptiven should only be used as part of clinical nutrition, and its dosage is limited by the amount of protein/amino acids provided by nutrition. Whenever the clinical condition does not allow nutrition (e.g., circulatory shock, hypoxia, unstable critically ill patients, severe metabolic acidosis) Dipeptiven should not be administered.

Oral/enteral intake of glutamine-supplemented formulas in combination with parenteral nutrition should be taken into consideration for calculation of the prescribed dose of Dipeptiven.

It is advisable to regularly monitor liver function parameters in patients with compensated hepatic insufficiency.

Serum electrolytes, serum osmolarity, water balance, acid-base status, creatinine clearance, urea, as well as liver function tests (alkaline phosphatase, ALT, AST) and possible symptoms of hyperammonaemia should be controlled.

The choice of a peripheral or central vein depends on the final osmolarity of the mixture. The generally accepted limit for peripheral infusion is about 800 mosmol/l but it varies considerably with the age and general condition of the patient and the characteristics of the peripheral veins.

Experience with the use of Dipeptiven for longer periods than nine days is limited.

Method of administration
Solution for infusion after mixture with a compatible infusion solution.
Solutions of mixtures with an osmolarity above 800 mosmol/l should be infused by the central venous route.

<u>Adults</u>
Dipeptiven is administered parallel with parenteral nutrition or enteral nutrition or a combination of both.
Dosage depends on the severity of the catabolic state and on amino acids/protein requirement.
A maximum daily dosage of 2 g amino acids and/or protein per kg body weight should not be exceeded in parenteral/enteral nutrition. The supply of alanine and glutamine via Dipeptiven should be taken into

consideration in the calculation. The proportion of the amino acids supplied through Dipeptiven should not exceed approx. 30% of the total amino acids/protein supply.

Dipeptiven is an infusion solution concentrate which is not designed for direct administration.

Patients with total parenteral nutrition
The rate of infusion depends on that of the carrier solution and should not exceed 0.1 g amino acids/kg body weight per hour.
Dipeptiven should be mixed with a compatible amino acid carrier solution or an amino acid containing infusion regimen prior to administration.

Patients with total enteral nutrition
Dipeptiven is continuously infused over 20-24 hours per day. For peripheral venous infusion, dilute Dipeptiven to an osmolarity ≤ 800 mosmol/l (e.g. 100 ml Dipeptiven + 100 ml saline).

Patients with combined enteral and parenteral nutrition
The full daily dosage of Dipeptiven should be administered with the parenteral nutrition, i.e. mixed with a compatible amino acid solution or an amino acid containing infusion regimen prior to administration.
The rate of infusion depends on that of the carrier solution and should be adjusted according to the proportions of parenteral and enteral nutrition.

Duration of administration
The duration of use should not exceed 3 weeks

Precautions for disposal
The container and the solution should be inspected visually prior to use. Use only clear, particle-free solution and undamaged container.

For single use only. Unused solution should be disposed of.

Compatibility
The addition of the concentrate to the carrier solution prior to application should take place under aseptic conditions. Thorough mixing and compatibility must be ensured.

Shelf-life
To be used immediately after the bottle is opened.

Shelf-life after mixing
Dipeptiven is not to be stored after addition of other components.