PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S 3**

DIPEPTIVEN

Concentrate for solution for infusion

N(2) – L – alanyl – L – glutamine

Sugar free

Read all of this leaflet carefully before you are given DIPEPTIVEN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other health care provider.

What is in this leaflet:

1. What DIPEPTIVEN is and what it is used for

DIPEPTIVEN supplements the protein part of nutrition in conditions where there is an increased need.

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

DIPEPTIVEN should not be administered to you:

- If you are hypersensitive (allergic) to alanine/glutamine or any of the other ingredients of DIPEPTIVEN (listed in section 6).
- If you have severe liver or kidney problems.
- 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 the 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 pregnant or are breastfeeding your baby.

DIPEPTIVEN should not be given to children.

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**.**

Other medicines and DIPEPTIVEN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before receiving DIPEPTIVEN.

Driving and using machines

DIPEPTIVEN should not affect your ability to drive or use machinery.

3. How DIPEPTIVEN will be administered to you

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself DIPEPTIVEN. It will be given to you by a person who is qualified to do so.

You will receive DIPEPTIVEN 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 requirements.

Your doctor will decide on the correct dose for you to receive and for how long to treat you.

If you have the impression that the effect of DIPEPTIVEN is too strong or too weak, tell your doctor.

If you receive more DIPEPTIVEN than you should

Since a health care provider will administer DIPEPTIVEN, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive DIPEPTIVEN

Since a health care provider will administer DIPEPTIVEN, it is unlikely that the dose will be missed.

4. Possible side effects

DIPEPTIVEN can have side effects.

Not all side effects reported for DIPEPTIVEN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving DIPEPTIVEN, please consult your health care provider for advice.

If any of the following happens, tell your doctor or healthcare professional immediately:

Chills, nausea and vomiting.

Your doctor may stop the infusion in such a case and will treat your symptoms.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of DIPEPTIVEN.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

5. How to store DIPEPTIVEN

Store all medicines out of reach of children.

Store at or below 25 ºC

6. Contents of the pack and other information

What DIPEPTIVEN contains

- The active substance is N(2) – L – alanyl – L – glutamine 20 g/100 mL, corresponding to L-alanine 8,2 g and L-glutamine 13,46 g
- The other ingredient is water for injection.

What DIPEPTIVEN looks like and contents of the pack

DIPEPTIVEN is a clear solution.

DIPEPTIVEN is presented in a 50 mL or 100 mL glass bottles, in boxes of 10.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

FRESENIUS KABI SOUTH AFRICA (PTY) LTD

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Access to the corresponding Professional Information

The professional information will be printed and packaged with the product.

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