

DIPEPTIVEN

Concentrate for solution for infusion

Composition :

Each 100 ml contains :

Active ingredient :

L-alanyl-L-glutamine 20 g

PHARMACEUTICAL FORM

Concentrate for solution for infusion.

A clear colourless solution

PHARMACOLOGY

The Dipeptiven L-alanyl-L-glutamine is endogenously split into the amino acids glutamine and amine and allows possible the supply of glutamine with infusion solution for parenteral nutrition. The released amino acids flow as nutrients into their respective body pools and are metabolized according to the needs of the organism. Many disease conditions, in which parenteral nutrition is indicated, are accompanied by an glutamine depletion, which Dipeptiven counteracts.

In a large multicenter study, critically ill adult patients with at least two organ failures at admission and requiring mechanical ventilation received either supplemental glutamine alone, antioxidants, glutamine and antioxidants, or placebo. Overall, mortality for the entire study population at 28 days, the primary endpoint, was not statistically significantly different between the groups. However, 6-month mortality, in a retrospective analysis, was tendentially increased in patients receiving the combined very high total dose of glutamine during unresuscitated shock and renal failure; glutamine and nutrition should not be used in unresuscitated shock accompanied by renal failure (see Overdose section). Under these specific circumstances the patient's ability to metabolize glutamine seems to have been exceeded (see also section Special warnings and precautions for use).

INDICATIONS

Dipeptiven is indicated as part of an intravenous parenteral nutrition regimen as a supplement to amino acid solution or and amino acid containing infusion regimen in patients whose condition requires additional glutamine. Such patients include those in hypercatabolic and hypermetabolic states.

POSODOLOGY

Dipeptiven is designed for intravenous infusion following additional to a compatible carrier solution. Dosage depends of the severity of the catabolic state an or amino acid requirements. A maximum daily dosage of 2 g amino acids / kg body weight should not be exceeded in parenteral nutrition. The supply of alanine and glutamine via Dipeptiven should be taken into consideration in the calculation; the

proportion of the amino acid supplied through Dipeptiven should not exceed approx. 20 % of the total supply.

DAILY DOSE :

1.5 – 2.0 ml Dipeptiven per kg body weight (equivalent to 3.0 – 0.4 g L-alanyl-L-glutamine per kg body weight). This equates to 100 to 140 ml Dipeptiven for a patient of 70 kg body weight.

Maximum daily dose :

2.0 ml Dipeptiven per kg body weight. The following adjustments thus result for the amino acids supply through the carrier solution : Amino acid requirement 1.5 g / kg body weight per day : 1.2 g amino acid + 0.3 g L-alanyl-L-glutamine per kg body weight Amino acid requirements 2 g / kg body weight per day : 1.6 Amino acid + 0.4 g L-alanyl-L-glutamine per kg body weight.

The rate of infusion depends on that of the carrier solution and should not exceed 0.1 gram Amino acid/kg body weight per hour. Dipeptiven is an infusion solution concentrate which is not designed for direct administration. It should be mixed with a compatible Amino acid carrier solution or an Amino acid containing infusion regimen prior to administration. One volume part Dipeptiven is to be mixed with at least 5 volume part carrier solution (e.g. 100 ml Dipeptiven + at least 500 ml Amino acid solution).

The maximum concentration should not exceed 3.5 %.

The duration of use should not exceed 3 weeks.

PRECAUTIONS

For a safe administration the maximum dose of Dipeptiven should not exceed 2.0 ml (corresponding to 0.4 g N(2)-L-alanyl-L-glutamine) per kg body weight per day (see sections Posology and method of administration, Overdose and Pharmacology) 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 (see section Posology and method of administration).

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.

tory 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.

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 enzymes alkaline phosphatase, SGPT, SGOT and Acid – base balance should be monitored. When mixed with a carrier solution. It is imperative to ensure injection under hygienic conditions, through mixing and compatibility.

Further drugs should not be added to the mixture.

Dipeptiven is not to be stored after addition of other components.

SIDE EFFECTS

None known when correctly administered.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system (national center of pharmacovigilance/MESO) and/or through the following contact: pv.indonesia@fresenius-kabi.com.

Overdose

As with other infusion solutions, chills, nausea and vomiting can occur, when the infusion rate of Dipeptiven is exceeded. Infusion shall be stopped immediately in this case.

Experience from a study in critically ill patients with at least two organ failures at admission, receiving the maximum approved daily intravenous infusion of Dipeptiven (0.5 g alanyl glutamine/kg/day) together with a high dose of enteral glutamine (30 g) provided as a mixture of alanyl-glutamine and glycyl-glutamine and without appropriate clinical nutrition, has shown an increase in serious side effects.

CONTRA INDICATION

Dipeptiven should not be administered to patients with severe renal insufficiency (creatinine clearance < 25 ml / minute), severe hepatic insufficiency, circulatory shock, hypoxia, multiple organ failure, severe metabolic acidosis or known hypersensitivity to the active substances or to any of the excipients.

It is advisable to regularly monitor liver function parameters in patients with compensated hepatic insufficiency. As there is currently insufficient data on administration of Dipeptiven to pregnant women, nursing mothers, children, administration of the preparation in these patient groups is not recommended.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Not applicable

INTERACTION WITH OTHER PRODUCT

No interactions with other drugs have been observed to date.

LIST OF EXCIPIENTS

Water for injection

DO NOT STORE ABOVE 25°C

HARUS DENGAN RESEP DOKTER

PACKAGE

Bottles 100 ml REG No DK11281203249A1

PRODUCED BY ;

Fresenius Kabi Austria GmbH

Hafnerstrobe 36

A-8055 Graz, Austria

For

Fresenius Kabi Deutschland, GmbH

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IMPORTED BY :

PT. Fresenius Kabi Combiphar

Bandung Barat - Indonesia

Dipeptiven

L-Alanyl-L-Glutamine

Konsentrat untuk larutan infus

Baca keseluruhan isi leaflet dengan hati-hati sebelum Anda menggunakan obat ini.

- Simpan leaflet ini. Anda mungkin perlu untuk membacanya lagi.
- Jika Anda memiliki pertanyaan lebih lanjut, silahkan bertanya kepada dokter, apoteker atau perawat Anda.
- Jika Anda mengalami efek samping, tolong sampaikan pada dokter, apoteker atau perawat Anda. Hal ini termasuk efek samping yang tidak tercantum pada leaflet. Lihat bagian 4.

Dalam leaflet ini tercantum :

1. Apa itu Dipeptiven dan apa kegunaannya
2. Yang perlu Anda ketahui sebelum Anda diberikan Dipeptiven
3. Bagaimana Anda akan menerima Dipeptiven
4. Efek samping yang mungkin terjadi
5. Bagaimana menyimpan Dipeptiven
6. Isi kemasan dan informasi lainnya

1. APA ITU DIPEPTIVEN DAN APA KEGUNAANNYA

Dipeptiven memenuhi kebutuhan protein sebagai bagian dari nutrisi pada kondisi saat terjadi peningkatan kebutuhan. Dipeptiven diberikan kepada Anda melalui infus (IV).

Dipeptiven biasanya digunakan sebagai bagian dari regimen nutrisi parenteral intravena yang seimbang, bersama dengan garam, *trace element* dan vitamin.

2. YANG PERLU ANDA KETAHUI SEBELUM ANDA DIBERIKAN DIPEPTIVEN

Anda tidak boleh diberikan Dipeptiven:

- Jika Anda memiliki kerusakan liver atau ginjal yang parah
- Jika Anda memiliki asidosis metabolik – situasi di mana pH darah rendah
- Jika Anda mengalami syok sirkulasi – situasi di mana aliran darah ke tubuh rendah
- Jika Anda memiliki hipoksia – situasi di mana kadar oksigen rendah
- Jika Anda memiliki kegagalan organ ganda – situasi dimana dua atau lebih organ tidak berfungsi normal
- Jika Anda alergi terhadap zat aktif atau bahan lainnya pada obat ini (lihat bagian 6). Gejala reaksi alergi dapat berupa peningkatan suhu tubuh, menggigil, ruam atau nafas pendek.
- Jika Anda hamil atau menyusui.

Dipeptiven **harus diencerkan sebelum digunakan**. Dipeptiven akan ditambahkan ke larutan lain sebelum diberikan ke Anda. Dokter atau perawat Anda akan memastikan larutan sudah dipersiapkan secara baik sebelum Anda menerima larutan yang mengandung Dipeptiven.

Peringatan dan perhatian

Dokter Anda mungkin akan melakukan pemeriksaan darah regular untuk mengecek kondisi Anda.

Obat lain dan Dipeptiven

Sampaikan kepada dokter atau apoteker Anda jika Anda sedang mengonsumsi, atau baru saja mengonsumsi atau akan mengonsumsi obat-obatan lain.

Kehamilan dan menyusui

Sampaikan kepada dokter Anda jika Anda sedang hamil, mengira Anda sedang hamil atau jika Anda sedang menyusui. Obat ini tidak akan diberikan kepada Anda pada kondisi tersebut.

Mengemudi dan mengoperasikan mesin

Dipeptiven tidak memiliki efek pada kemampuan mengemudi atau mengoperasikan mesin.

3. BAGAIMANA ANDA DIBERIKAN DIPEPTIVEN

Anda akan menerima obat Anda melalui infus (*IV drip*) ke pembuluh vena.

Dosis Dipeptiven bergantung kepada berat badan dalam kilogram dan kemampuan tubuh Anda untuk memecah nutrisi dan kebutuhan asam amino Anda.

Dokter Anda akan memutuskan dosis yang tepat untuk Anda terima.

Jika Anda diberikan Dipeptiven melebihi yang seharusnya Anda terima

Gejala overdosis diantaranya menggigil, mual dan muntah. Sangat kecil kemungkinan Anda menerima infus lebih dari yang seharusnya karena dokter atau perawat akan memantau Anda selama pengobatan. Namun jika Anda merasa menerima Dipeptiven lebih dari yang seharusnya informasikan hal tersebut kepada dokter atau perawat Anda sesegera mungkin.

Jika Anda memiliki pertanyaan lebih lanjut tentang produk ini, tanyakan kepada dokter, apoteker, atau apoteker Anda.

4. EFEK SAMPING YANG MUNGKIN TERJADI

Sebagaimana semua obat, obat ini dapat menyebabkan efek samping, meskipun tidak semua orang mengalaminya.

Efek samping Dipeptiven sangat jarang dan kemungkinan kecil untuk terjadi.

Pelaporan efek samping

Apabila ada keluhan efek samping atau kondisi tidak nyaman selama dan setelah penggunaan obat, konsultasikan ke dokter, apoteker, atau perawat. Anda dapat juga melaporkan keluhan efek samping atau kondisi tidak nyaman tersebut secara langsung melalui kontak berikut: pv.indonesia@fresenius-kabi.com. Dengan melaporkan efek samping, Anda dapat membantu memberikan informasi lebih lanjut mengenai keamanan obat

5. BAGAIMANA MENYIMPAN DIPEPTIVEN

Jauhkan dari jangkauan dan penglihatan anak-anak.

Dokter dan apoteker Anda di rumah sakit bertanggung jawab atas penyimpanan, penggunaan, dan pembuangan yang benar terhadap infus Dipeptiven. Jangan disimpan pada suhu di atas 25 °C.

Jangan gunakan obat ini setelah tanggal kadaluarsa yang tercantum pada label.

6. INFORMASI LAINNYA

Apa yang terkandung dalam infus Dipeptiven

100 ml Dipeptiven mengandung:

20 g L-Alanyl-L-Glutamin (= 8,2 g L-alanine, 13,46 g L-glutamine).

Dipeptiven juga mengandung air untuk injeksi.

Apa tampilan Dipeptiven dan isi kemasan

Dipeptiven adalah larutan jernih tidak berwarna. Dipeptiven tersedia dalam botol kaca dengan penutup karet yang mengandung 100 ml konsentrat.

HARUS DENGAN RESEP DOKTER

Diproduksi oleh :

Fresenius Kabi Austria GmbH

Graz – Austria

Untuk

Fresenius Kabi Deutschland GmbH

Bad Homburg - Jerman

Diimpor oleh

PT Fresenius Kabi Combiphar

Bandung Barat – Indonesia

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