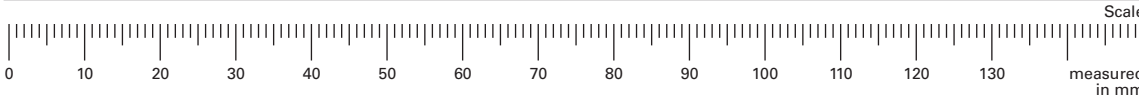




<div><div>MODEL</div><div>Model Kramp GmbH</div><div>Otto-Hahn-Straße 41</div><div>63456 Hanau</div><div>Tel. +49 6181-6750-0</div></div>	Job No.: me4016326		Created at: 02.09.2021		Operator: ul			
	Size: 148 x 210 mm (w x h x d)				1. AC: 07.09.2021 mf		5. AC:	
	MN XXXXX		MC XXXX		2. AC:		6. AC:	
	AM 45123		MZ/AZ 0000		3. AC:		7. AC:	
					4. AC:		8. AC:	
Hepa-Merz 3000 Granulat Indonesien GA		Typestyle: Helvetica BQ		Type size: 6,8 pt				
		Black Stanze						



reading direction

Laetus-Copy

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic group:

Hepatotherapeutics, ATC code: A05BA

In vivo, L-ornithine-L-aspartate exerts its effects through the amino acids, ornithine and aspartate, via two key methods of ammonia detoxification: urea synthesis and glutamine synthesis.

Urea synthesis takes place in the periportal hepatocytes. In these cells, ornithine serves both as an activator of the enzymes ornithinecarbamoyltransferase and carbamoyl phosphate synthetase and also as the substrate of urea synthesis.

Glutamine synthesis is localised in the perivenous hepatocytes. Particularly under pathological conditions, aspartate and other dicarboxylates, including the metabolic products of ornithine, are absorbed into the cells and used there to bind ammonia in the form of glutamine.

Glutamate is an amino acid that binds ammonia under both physiological and patho physio logical conditions. The resulting amino acid glutamine not only represents a form for the excretion of ammonia, but also activates the important urea cycle (intercellular glutamine exchange).

Under physiological conditions, ornithine and aspartate are not limiting for urea synthesis.

Animal studies suggest that the ammoniareducing effect of L-ornithine-L-aspartate is caused by enhanced glutamine synthesis. Individual clinical studies have shown an improved branched-chain amino acid/aromatic amino acid quotient.

Pharmacokinetic properties

L-ornithine-L-aspartate is rapidly absorbed and cleaved to form ornithine and aspartate. Both amino acids have a short elimination half-life of 0.3–0.4 hours. A fraction of the aspartate is recovered in unmetabolised form in the urine.

Preclinical safety data

Preclinical data, based on safety pharmacological studies and chronic toxicity and mutagenicity studies, do not suggest any particular risk to humans following correct administration.

No studies into any carcinogenic potential have been performed.

In a dose-finding study, L-ornithine-L-aspartate was insufficiently investigated in terms of its toxicity in relation to reproduction.

STORAGE

Store below 30°C.

This product should not be used after the expiry date.

PACKAGING

Box,10 sachets containing 5 g granules

Reg. No. DK10691300222A1

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

ON MEDICAL PRESCRIPTION ONLY

HARUS DENGAN RESEP DOKTER

Manufactured by:

Klocke Pharma-Service GmbH, Appenweier, Germany

Released by:

Merz Pharma GmbH & Co. KGaA, Reinheim, Germany

Imported by:

PT Combiphar, Bandung Barat, Indonesia

MN XXXXX, XXXXXXXXXX, MC XXXX

Laetus-Copy

reading direction

	Approved for printing	(Variation) Procedure No.	Identical to approved texts	Compliant with national requirements	Double checked	Date, Signature
Research and Development	<input type="checkbox"/>					
Regulatory Affairs	<input type="checkbox"/>		Yes <input type="checkbox"/>	Yes <input type="checkbox"/>	Yes <input type="checkbox"/>	
Information Officer	<input type="checkbox"/>					
Legal Department	<input type="checkbox"/>					

DISETUJUI OLEH BPOM : 20/09/2021

EREG100217VR12100095

me4016326\_XXXXX-XXXXXXXXXX\_HepaMerz3000\_GA\_Klocke\_ID.indd 2

07.09.21 14:36