

INSTRUCTION FOR USE - READ CAREFULLY!

Fresenius Kabi Deutschland GmbH

D-61346 Bad Homburg v. d. H.

Ketosteril® tablets

Film-coated tablets

1 film-coated tablet contains:	(DL)-3-methyl-2-oxovaleric acid	67 mg
	(α -ketoanalogue to DL-isoleucine), calcium salt	
	4-methyl-2-oxovaleric acid	101 mg
	(α -ketoanalogue to leucine), calcium salt	
	2-oxo-3-phenyl propionic acid	68 mg
	(α -ketoanalogue to phenylalanine), calcium salt	
	3-methyl-2-oxobutyric acid	86 mg
	(α -ketoanalogue to valine), calcium salt	
	(DL)-2-hydroxy-4-methylthiobutyric acid	59 mg
	(α -hydroxyanalogue to DL-methionine), calcium salt	
	L-Lysine monoacetate (\triangle Lysin 75 mg)	105 mg
	L-Threonine	53 mg
	L-Tryptophan	23 mg
	L-Histidine	38 mg
	L-Tyrosine	30 mg
	Total nitrogen content/tablet	36 mg
	Calcium/tablet	1.25 mmol \triangle 0.05 g

Fields of application: Prevention and therapy of damages due to faulty or deficient protein metabolism in chronic renal insufficiency in connection with limited protein in food of 40 g per day (for adults) and less; i.e. generally in patients with a glomerular filtration rate (GFR) below 25 ml/min.

Contra-indications: Hypercalcemia, disturbed amino acid metabolism. In case of hereditary phenylketonurie it has to be taken into account that this product contains phenylalanine.

Note: No experience has been made so far with the application in pregnancy and paediatrics.

Side-effects Hypercalcaemia may develop.
Notes: Monitor regularly the serum calcium level.
Ensure the sufficient supply with calories!

Interactions with other drugs

The simultaneous administration of medicaments containing calcium (e. g. acetolyte) may lead to pathological increases of the serum calcium level or intensification thereof. As the uremic symptoms improve under Ketosteril® tablets, a possible administration of aluminium hydroxide should be reduced. Pay attention to a reduction of serum phosphate. In order not to interfere with absorption, do not take drugs together with Ketosteril® tablets that form sparingly soluble compounds with calcium (e. g. tetracyclines, chinolone like Ciprofloxacin and Norfloxacin, iron-, fluoride- and estramustin-containing drugs). Between the intake of Ketosteril® tablets and drugs from the mentioned categories a period of at least 2 hours should pass. If the blood calcium concentration raises by the intake of Ketosteril® tablets the susceptibility towards certain drugs enhancing the heart strength (heart/cardiac-active glycosides) will increase and the risk of heart rhythm disturbance will increase.

Dosage and application

For oral use.

If not otherwise prescribed, take 4 to 8 tablets three times a day during meals. Swallow whole.

This dosage applies to adults (70 kg/BW).

Duration of application

Ketosteril® tablets are given as long as the glomerular filtration rate is below 25 ml/minute. Simultaneously food should contain 40 g/day protein or less (adults).

Precautions

Keep out of the reach of children!

Do not use Ketosteril® tablets after expiry date!

Presentation

Pack containing 100 or 300 film-coated tablets

Storage condition

Store at temperature not exceeding 25°C.

Store in the original package.



**FRESENIUS
KABI**

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