

Use in special population • Paediatric: Safety and effectiveness of ABKETO-DS in paediatric patients have not been established. • **Geriatric:** Safety and effectiveness of ABKETO-DS in geriatric patients have not been established. • **Liver impairment:** There is limited information available on the use of ABKETO-DS Tablet in patients with liver disease. Please consult your doctor. • **Renal failure:** ABKETO-DS Tablet is safe to use in patients with kidney disease. Limited data available suggests that dose adjustment of ABKETO-DS Tablet may not be needed in these patients. Please consult doctor. • **Pregnancy and lactation:** Human and animal studies are not available for safety and efficacy in pregnancy and breast feeding. Please consult doctor before use.

Effects on ability to drive and use machine Patients should be cautioned against engaging in activities requiring complete mental alertness, and motor coordination such as operating machinery until their response to ABKETO-DS is known.

Undesirable effects If hypercalcaemia occurs, the intake of vitamin D should be reduced. In case of persisting hypercalcaemia, the dose of ABKETO-DS® as well as the intake of any other calcium sources has to be reduced.

Overdose There is limited experience of overdose with ABKETO-DS Tablets. Initiate general symptomatic and supportive measures in all cases of overdosages where necessary.

Pharmacological properties

Mechanism of action Prevention and treatment of damages due to faulty or deficient protein metabolism in chronic kidney disease in connection with a limited dietary protein intake of 40 g/day or less (adult). Usually this applies to patients whose glomerular filtration rate (GFR) is less than 25 mL/min. • **Nitrogen free analogues of essential amino acids** • Administered for nutrition therapy in chronic kidney disease. • Relieves uremic states, improve nutritional states, slow down illness progression and protect kidney functions • With low protein diets can delay or prevent dialysis by relieving metabolic complications

Pharmacodynamic properties ABKETO-DS® tablets are administered for nutrition therapy in chronic kidney disease. ABKETO-DS® allows the intake of essential amino acids while minimising the amino-nitrogen intake. Following absorption, the keto- and hydroxy-analogues are transaminated to the corresponding essential amino acids by taking nitrogen from non-essential amino acids, thereby decreasing the formation of urea by re-using the amino group. Hence, the accumulation of uraemic toxins is reduced. Keto and hydroxy acids do not induce hyperfiltration of the residual nephrons. Ketoacid containing supplements exert a positive effect on renal hyperphosphataemia and secondary hyperparathyroidism. Moreover, renal osteodystrophy may be improved. The use of ABKETO-DS® in combination with a very low protein diet allows reducing nitrogen intake while preventing the deleterious consequences of inadequate dietary protein intake and malnutrition.

Pharmacokinetic properties The plasma kinetics of amino acids and their integration in the metabolic pathways are well established. It should nevertheless be noted that in uraemic patients, the cause of the changed plasma levels, which occur frequently in these patients, does not seem to be the absorption of the supplied amino acids, i. e. the absorption itself is not disturbed. The changed plasma levels seem to be due to impaired post-absorptive kinetics, which can be detected in a very early stage of the disease. In healthy individuals, the plasma levels of ketoacids increase within 10 min after oral administration. Increases of up to the 5-fold the baseline levels are achieved. Peak levels occur within 20-60 min, and after 90 min levels stabilise in the range of the base levels. Gastrointestinal absorption is thus very rapid. The simultaneous increases in the levels of the ketoacids and the corresponding amino acids show that the ketoacids are transaminated very rapidly. Due to the physiological utilisation pathways of ketoacids in the body it is likely that exogenously supplied ketoacids are very rapidly integrated into the metabolic cycles. Ketoacids follow the same catabolic pathways as classical amino acids. No specific study on ketoacid excretion has been performed to date. **6. Nonclinical properties**

Animal Toxicology or Pharmacology NA.

Description Alpha Ketoanalogue belongs to a class of drugs called nutritional supplements. It follows same catabolic pathways as amino acids and works by improving the metabolism of protein in the body, thereby improving the renal function. It prevents the unnecessary increase in urea levels in the blood due to the intake of non-essential amino acids in patients of kidney failure. Alpha Ketoanalogue is a combination of various essential amino acids.

Pharmaceutical particulars

Incompatibilities There are no known incompatibilities.

Shelf-life 18 months.

Packaging Information ABKETO-DS is available in the pack of 10 tablets. **8.4 Storage and handling instructions** Keep in cool and dry place. Protect from light. Keep away from children. **9. Patient Counselling Information**

Adverse Reactions Refer part 4.8 **9.2 Drug Interactions** Refer part 4.5