Product Sheet for Cetolán

Generic Name: Alpha-keto analogs of amino acids
Pharmaceutical Form: Tablet
Presentation: Box with 100 tablets of 360 mg

Formula:
Each tablet contains:

- DL-3-methyl-2-oxo-valerate calcium (alpha-keto analog of DL-isoleucine)
- 4-methyl-2-oxo-valerate calcium (alpha-keto analog of leucine)
- 2-oxo-3-phenyl-propionate calcium (alpha-keto analog of phenylalanine)
- 3-methyl-2-oxo-butyrate calcium (alpha-keto analog of valine)
- DL-2-hydroxy-4-methylthiobutyrate calcium (alpha-hydroxy analog of methionine Monoacetate of L-lysine)
- L-threonine
- L-tryptophan
- L-histidine
- L-tyrosine
- Excipient q.s.

Indications:
CETOLÁN is a mixture of essential amino acids and their ALPHA KETO and HYDROXY ANALOGS indicated for the treatment of damage caused by protein metabolism failure or alteration.
Complementary treatment in the following conditions:

- Portosystemic encephalopathy
- Congenital hyperammonemia
- McArdle disease
- Chronic kidney disease

Usage (Dosage):
Route of administration: oral
If not otherwise prescribed, take 4 to 8 tablets 3 times a day during meals (1 tablet for every 5 kg of body weight per day, divided into 3 doses or at each meal). Swallow whole. This dose applies to adults weighing 70 kg/ BW. The maximum dose is 50 tablets per day.
In chronic kidney failure: Generally, 3 times a day during meals, swallow 4 to 8 tablets.
In compensated renal insufficiency: Generally, 4 to 6 tablets 3 times a day with a low-protein, high-calorie diet (characterized by 0.5 to 0.6 g of protein and 35 to 45 kcal per kg of body weight/day).

In decompensated renal insufficiency: Generally, 4 to 8 tablets 3 times a day with a low-protein, high-calorie diet (characterized by 0.5 to 0.6 g of protein and 35 to 45 kcal per kg of body weight/day).
Duration: Coated tablets are administered while the glomerular filtration rate is between approximately 5 and 15 ml/min. Simultaneously, food should contain 40 g/day of protein or less (adults). 0.4 to 0.6 g of protein per day per kg of body weight.

Mode of Action (Pharmacodynamics):
Alpha-keto and hydroxy acids are called amino acids without a group (deaminated amino acids or amino acid analogs). The body constantly produces alpha-keto acids (deaminated amino acids) through tissue deaminases, and hydroxy acids are also produced by deaminases. In all transamination processes from the corresponding amino acids, exogenously administered alpha-keto acids (alpha keto analogs) participate in these same metabolic transamination processes, supplementing the body with the structural elements of proteins without generating an additional nitrogen load, thus allowing the "de novo" synthesis of essential amino acids.
In uremic patients, the requirements for essential amino acids are increased. Besides L-isoleucine, L-leucine, L-lysine, L-methionine, L-phenylalanine, L-threonine, L-tryptophan, L-valine, are considered essential, in uremic patients, L-Histidine and L-tyrosine are also needed. It contains all these amino acids or their analogs in the recommended proportion to meet the metabolic demand characteristic of people living with renal insufficiency.
The nitrogen that accumulates in uremic patients due to impaired renal function can be reused by binding to the alpha-keto acids to synthesize the corresponding L-amino acids. Nitrogen-amino reuse can follow two paths: a. The first consists of the direct incorporation of amino nitrogen before forming the urea molecule. In this case, the amino groups produced in the deamination processes are immediately reincorporated into the synthesis of essential and non-essential amino acids. b. The second consists of the reuse of urea nitrogen released in the enterohepatic cycle of urea. In this other case, amino groups derived from urea, through the action of bacterial urease, return to the hepatic metabolic pool, making them available for use. Together with a low-protein and high-calorie diet, CETOLÁN allows: a. Supplementing "nitrogen-free essential amino acids." b. Reusing nitrogen catabolites. Inducing protein anabolism with a simultaneous decrease in serum urea. c. Improving nitrogen balance and serum amino acids. This improves uremic symptoms and signs, even allowing dialysis to be postponed in some cases.

Frequently Asked Questions:

1. **What is Cetolan indicated for?**
   For treating Protein-Energy Wasting and lowering blood nitrogen levels in patients with Chronic Kidney Disease.

2. **What does Cetolan contain?**
   Cetolan is composed of alpha-keto analogs of essential amino acids.

3. **How does Cetolan contribute to the management of Chronic Kidney Disease?**
   It helps to slow the progression of the disease and improve metabolic complications.

4. **What type of diet should be followed with Cetolan?**
   A personalized low-protein diet, low in protein, of 0.8 g/kg of body weight in stages I to III of CKD.

5. **Is Cetolan suitable for all stages of CKD?**
   Yes, but the specific needs of the patient vary in stages IV and V.

6. **What other treatments are recommended alongside Cetolan for CKD?**
   Control of glucose, lipid, blood pressure levels, use of Calcium Citrate for Metabolic Acidosis, and the use of Inulin or probiotics for intestinal dysbiosis.

7. **What is the presentation of Cetolan?**
   It is presented in tablets, with packs of 100 units.

8. **What is the role of alpha-keto analogs in Cetolan?**
   They control Protein-Energy Wasting and reduce blood nitrogen levels.

9. **What should be monitored in patients taking Cetolan?**
   Glucose, lipid, and blood pressure levels.

10. **Are there specific recommendations for the use of Cetolan in advanced stages of CKD?**
    Yes, the patient's needs must be individually assessed in stages IV and V.

11. **What is the role of a low-protein diet with Cetolan?**
    The low-protein diet helps prevent the deterioration of Glomerular Filtration Rate and kidney damage.

12. **What should be done in case of Metabolic Acidosis in CKD patients?**
    The use of Calcium Citrate is recommended.

13. **What treatment is suggested for intestinal microbiota dysbiosis in CKD patients?**
    The use of Inulin and/or probiotics is recommended.

14. **How does Cetolan affect the reduction of blood nitrogen levels?**
    It contributes to reducing blood nitrogen levels, thus improving kidney function.

15. **Is Cetolan a standalone treatment or part of a broader regimen for CKD?**
    It is part of a broader regimen that includes glucose, lipid, blood pressure control, and a specific diet.

16. **What are the advantages of Cetolan over its competitor, Ketosteril?**
    While Cetolan and Ketosteril share similarities in composition and purpose, Cetolan may offer advantages in its specific formulation and integration with personalized diets for patients at different stages of Chronic Kidney Disease. Additionally, Cetolan may have a slightly different side effect profile that could be more suitable for certain patients, depending on their individual needs and conditions