Ketosteril® Research Award 2016

sponsored by Fresenius Kabi

Deadline: November 15, 2015

Application form

The application will only be considered if all parts of the form are completed.

You may complete this electronic form electronically.

Full name of applicant:

Qualifications:

Date of birth:

Present position:

Supported by if applicable, e.g. other support by third parties:

Institution:

Address:

Telephone No. (+ country code):

Fax No. (+ country code):

E-Mail address:

Project

Title of the project:

Dates of entire proposed project period (maximum 2 years):

Start

End (study report)

Place (Institution, laboratory) in which the study will be performed:

The project will be supervised by:

How much time per week will the applicant dedicate to this research project?

Clearly state the reasons for requesting financial support:

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Budget (Euro)

Materials/Equipment (give an itemised breakdown of realistic costs in relation to the protocol outlined). This must be done.

1. year	2. year

Publication

1. year	2. year

Other expenses

1. year	2. year

Grant total for entire proposed project period:

Are other research funds being sought for the same project? (YES/NO)

If so, from whom? Which amount have been requested and/or committed?

What other facilities are available which make success of the project likely?

Ethics committee:

The responsible ethics committee has approved the project or the vote is expected by: (date)

Supervisor**:**
I hereby guarantee that the work that is necessary to complete this research proposal will be carried out under my supervision and can be completed in the time frame specified.

Name	Signature

Principle investigator:
I hereby agree that if I am awarded the Ketosteril® Research Award, I will receive it at the XVIII Congress on Metabolism and Nutrition in Renal Disease 2016 and will present the aims and results of this research within 2 years at the XIX Congress on Metabolism and Nutrition in Renal Disease 2018.

Name	Signature

Please return this application form by e-mail **before November 15, 2015 to:** ketosteril.research.award@fresenius-kabi.com with the subject heading: Ketosteril® Research Award Application. An acknowledgement of receipt of the application will be sent to you.

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Name of the medicinal product: Ketosteril® film-coated tablets. **Composition:** One film-coated tablet contains: (RS)-3-methyl-2-oxovaleric acid (α-ketoanalogue to DL-isoleucine, Ca-salt) 67 mg; 4-methyl-2-oxovaleric acid (α-ketoanalogue to leucine, Ca-salt) 101 mg, 2-oxo-3-phenylpropionic acid (α-ketoanalogue to phenylalanine, Ca-salt) 68 mg, 3-methyl-2-oxobutyric acid (α-ketoanalogue to valine, Ca-salt) 86 mg, (RS)-2-hydroxy-4-methylthio-butyric acid (α-hydroxyanalogue to DL-methionine, Ca-salt) 59 mg, L-lysine acetate 105 mg (= 75 mg L-lysine), L-threonine 53 mg, L-tryptophan 23 mg, L-histidine 38 mg, L-tyrosine 30 mg, total nitrogen content per tablet 36 mg, calcium content per tablet 1.25 mmol = 50 mg. **Excipients:** Maize starch, crospovidone type A, talc, silica (colloidal anhydrous), magnesium stearate (Ph.Eur) [vegetable], macrogol 6000, quinoline yellow E104, basic butylated methacrylate copolymer, triacetine, titanium dioxide E171, povidone K 29-32. **Therapeutic indications:** 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. **Posology and method of administration:** If not otherwise prescribed the dose for adults (70 kg body weight) is 4 to 8 tablets three times daily during meals. The tablets must not be chewed. Ingestion during meals facilitates proper absorption and the metabolisation into the corresponding amino acids. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients, hypercalcaemia and disturbed amino acid metabolism. **Special warnings and precautions for use:** The serum calcium level should be monitored regularly. A sufficient supply of calories should be ensured. No experience has been gained so far with the administration in paediatric patients. In the presence of hereditary phenylketonuria, attention should be given to the fact that Ketosteril® contains phenylalanine. Monitoring of the serum phosphate levels is needed in case of concomitant administration of aluminium hydroxide. **Interaction with other medicinal products and other forms of interaction:** Concomitant administration of calcium-containing drugs may cause or aggravate elevated serum calcium levels. Drugs that form hardly soluble compounds with calcium (e.g. tetracyclines, quinolines such as ciprofloxacin and norfloxacin as well as drugs containing iron, fluoride or estramustine) should not be taken at the same time with Ketosteril® to avoid disturbed absorption of the active substances. An interval of at least two hours should elapse between the ingestion of Ketosteril® and these drugs. The susceptibility to cardioactive glycosides, and hence the risk for arrhythmia will increase if Ketosteril® produces elevated serum calcium levels. Uraemic symptoms improve under therapy with Ketosteril®. Thus, in case of aluminium hydroxide administration, the dose of this drug has to be reduced if necessary. Serum phosphate levels should be monitored for a decrease. **Pregnancy and lactation:** There are no adequate data from the use of Ketosteril® in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. No experience has been made so far with the use during lactation. **Undesirable effects:** The intake of Ketosteril® may very rarely lead to hypercalcaemia. If hypercalcaemia occurs, the intake of vitamin D should be reduced. In case of persisting hypercalcaemia, the dose of Ketosteril® as well as the intake of any other calcium sources has to be reduced. **Overdose:** No case of overdose has been reported. **Special precautions for handling/storage:** Do not use Ketosteril® after expiry date! Keep out of the reach of children! Do not store above 25°C. Store in the original package and keep the blisters tightly closed to protect contents from moisture. **Issue of information:** March 2009. **Regarding further details, please refer to the national SmPC**

(08/2015)

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