Ketosteril® Research Award 2016

sponsored by Fresenius Kabi

This research grant supports original work directly relevant to the field of the therapeutic relevance of keto/amino acids and protein restriction in the scope of chronic kidney disease (CKD).

At a glance

Eligibility:	New and established institutions
Amount of the grant:	€ 100,000.00 or Euro equivalent
Duration of financial support:	2 years
Deadline for submission:	November 15, 2015
Start date of project:	July 1, 2016

Description

The grant is offered to institutions to support clinical research projects in the area of nutritional therapy with focus on keto/amino acid metabolism and protein restriction in CKD. The grant is for 2 years. By the end of the first year a progress report (interim analysis) has to be submitted before May 1, 2017. On the basis of the report the Ketosteril® Research Award Committee will decide on further financing of a second year by the grant. The Ketosteril® Research Award Committee reserves the right to terminate the grant if the grantee does not comply with the terms and purpose of the grant.

Objective

To stimulate research of clinical relevance in the area of nutritional therapy in CKD by permitting investigators to obtain new data.

Qualification

Investigators of the institutions must possess medical doctor degree or comparable academic degree (e.g. nutritionist) and/or convincing research work published in recognised academic journals. Candidates may not hold awards on a similar topic from other external parties.

Award Overlap

If an award recipient receives notification of another award with overlapping scientific objectives, prior to the start date of the Ketosteril® Research Award, the applicant must choose between the two awards.

Requirements

- Language skills: investigators must have a good proven knowledge of English.
- The grant must be used to support expenses that are **directly** related to the research project (e.g. equipment, analyses); it may not be used for other expenses which includes without limitation tuition, lab assistant pay, consultant fees, travel costs or personal expenses. If the research project involves the use of human volunteers, payment for volunteers would be accepted within the local legal framework.
- Established investigators who are applying for this award to support a new initiative should state explicitly how the initiative is different from their previous line of research or justify continuation of previous work.
- Approval from the appropriate ethic committee for use of humans or animals. If approval is not necessary, an explanation must be provided.
- The applicant guarantees that the project will be accomplished and reported within two years.

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Review Process

All eligable applications will be reviewed and ranked by the Ketosteril® Research Award Committee consisting of established investigators. As part of the review process, information provided by the applicant for peer review will be shared with scientists independent from Fresenius Kabi.

Selection Criteria

Proposals will be selected on the basis of originality, scientific validity, clinical implication and overall interest.

Application

1. Applications are only possible, if Ketosteril® is an approved drug in the country of the applicant. Applications to use Ketosteril® in sensitive populations, e.g. pregnancy or children, are excluded.
2. All applications will be examined for eligibility.
3. Applicants must use the official application form, which has to be signed by the principal investigator and his supervisor.
4. The research plan should be divided into the following parts:
   A: Clear study hypothesis
   B: Clinical significance and background (literature review)
   C: Preliminary studies
   D: Research design and methods
   - Primary and secondary endpoints
   - Methods
   - Techniques
   - Data documentation and management
   - Data analysis (including appropriate statistical methods, power and sample size calculation of the primary endpoint)
   - Feasibility of the research plan (patient recruitment in a reasonable time)

   E: References
   F: Maximum 2-page Curriculum Vitae (including scientific publications, presentations and research)
4. Decisions will be based upon the quality of the submitted information.
5. The Ketosteril® Research Award recipient will be announced in March 2016 by mail and will be officially honoured in a ceremony at the XVIII International Congress on Metabolism and Nutrition in Renal Disease, Okinawa/Japan, April 2016.
6. In 2018 (at the XIX International Congress on Metabolism and Nutrition in Renal Disease) the results of the research project shall be presented.

Submission Instructions: Deadline: November 15, 2015

This is a firm deadline, no applications will be accepted after this date. The complete application will contain:

i) Grant application form
ii) Detailed research plan (application body A-F: total 10 pages)
iii) Affirmative letter of ethics committee approval, if already available

Applications will be returned to the applicant if received without all applicable documents. The letter of the ethics committee approval can be provided subsequently. However, if the grant is awarded, no funds will be sent until all requirements of the grant contract are fulfilled.
All grant components must be submitted on A4 paper, with margins of at least 2 cm on all four sides. Use Arial, Times New Roman, or a similar style font in size 12. Be sure to utilise headings and formatting as needed, to improve clarity and readability.

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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**

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