

23 January 2009

Proposal to widen access to multivitamins for use in the Ketogenic diet in children with epilepsy

Proposal summary

PHARMAC is seeking feedback on a proposal to amend the restrictions applying to multivitamin preparations in order to permit their use as a supplement to the Ketogenic diet in children with epilepsy.

This proposal has arisen from recommendations by the Pharmacology and Therapeutics Advisory Committee (PTAC) and the Special Foods Subcommittee of PTAC.

Key proposed changes that would apply to the Ketovite, Paediatric Seravit, Ketovite Syrup and Metabolic Mineral Mixture brands of multivitamin supplements are:

- The Special Authority criteria would be altered to include the criterion “For use as a supplement to the Ketogenic diet in patients diagnosed with epilepsy”
- The requirement for a specialist to apply for the Special Authorities would be removed and replaced with “any relevant practitioner.”
- Approvals would remain valid without further renewal unless notified.

The exact date at which these changes would take effect is yet to be determined, but it would likely be some time between 1 April and 1 July 2009.

Further details of the proposal can be found on the following pages.

Feedback sought

We welcome your feedback on this proposal. To provide feedback please submit an email, fax or letter by **4 pm, Wednesday 11 February 2009** to:

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All feedback received before the closing date will be considered when a decision is made on this proposal by PHARMAC's Board (or Chief Executive under delegated authority).

Details of the Proposal

Multivitamins: Ketovite, Paediatric Seravit, Ketovite Syrup

The Special Authority applying to Multivitamins would be amended as follows (additions in bold, deletions in strikethrough):

~~SA0600~~ **SAXXXX** Special Authority for Subsidy

Initial application ~~only from a relevant specialist~~ **from any relevant practitioner**. Approvals valid ~~for 3 years~~ **without further renewal unless notified for applications meeting the following criteria:**

Either:

- 1 The patient has** ~~where~~ inborn errors of metabolism; **or**
- 2 For use as a supplement to the Ketogenic diet in patients diagnosed with epilepsy.**

~~Renewal only from a relevant specialist or general practitioner on the recommendation of such a specialist. Approvals valid for 3 years for applications meeting the following criteria:~~

~~Both:~~

- ~~1 The treatment remains appropriate and the patient is benefiting from treatment; and~~
- ~~2 General Practitioners must include the name of the specialist and date contacted.~~

The Multivitamins listing would be moved from the “Multivitamin Supplements for Inborn Errors of Metabolism, Special Foods” section of the Pharmaceutical Schedule to the “Vitamins (Multivitamin Preparations), Alimentary Tract and Metabolism” section.

All current Special Authority approvals would remain valid.

The “Hospital Pharmacy [HP3]” restriction would be changed to “Retail Pharmacy”.

Note that Ketovite Syrup is not fully funded.

Aminoacid Formula With Minerals Without Phenylalanine: Metabolic Mineral Mixture

A new Special Authority would apply to Aminoacid Formula with Minerals without Phenylalanine as follows:

SAXXXX Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

- 1 Dietary management of phenylketonuria (PKU); or**
- 2 For use as a supplement to the Ketogenic diet in patients diagnosed with epilepsy.**

The current Special Authority (SA0733) for use in the dietary management of PKU would continue to apply to the listings of Foods for PKU and Supplements for PKU, but not Multivitamin and Mineral Supplements (except for existing approvals, per below).

All patients with a current SA0733 approval would be automatically issued an approval on the new form for Aminoacid Formula with Minerals without Phenylalanine.

The “Hospital Pharmacy [HP3]” restriction would be changed to “Retail Pharmacy”.