

PRODUCT ALERT
Cal.D.Forte Tablets

(1.25mg Colecalciferol BP per tablet – Equivalent to 50,000 IU Vitamin D3)

Dear Healthcare Professional,

PSM Healthcare Limited, trading as API Consumer Brands has recently had the Provisional Consent for Cal.D.Forte, a high dose vitamin D3 tablet, renewed until February 2016, ensuring continuity of supply.

Cal.D.Forte tablets have been shown to have stability issues and it is possible that the tablets may be sub-potent and contain variable amounts of Vitamin D3 during the shelf life of the product. As the benefits of supply versus risk associated with these issues are indefinable, it is recommended that practitioners monitor patients through blood tests (as outlined in the Data Sheet) if they have any concerns.

These are high potency vitamin D3 tablets, with a typical dosage regime of 1 tablet per month. Following administration, the body stores and releases the vitamin D3 as required and therefore, should the product be slightly sub-potent, there is unlikely to be any therapeutic deficiency or adverse effect, when used as directed. In the event of an adverse reaction being reported, please follow the usual reporting process through the Centre for Adverse Reactions Monitoring (CARM).

API have been working on a new formulation to specifically address this stability issue. A new formula, based on the BP specifications, was completed earlier this year. However, more stringent USP standards have since been published (USP #37 1/5/14) and, in consultation with Medsafe, we are adjusting our new formulation to meet this new, and higher, 2014 USP standard. Based on stability trials and current data, this new formulation should be available for prescription within the 18 month provisional consent period.

If you have concerns or queries regarding this product, or for guidance on routine patient monitoring, please refer to the Data Sheet which can be found at: www.medsafe.govt.nz/profs/Datasheet/c/CalDFortetab.pdf

This letter has been written in consultation with Medsafe.

Mitch Cuevas



General Manager, PSM Healthcare Ltd (trading as API Consumer Brands)

For any direct product queries, please contact: Sharon Furlong, Regulatory Affairs Manager
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