

Safeguarding public health
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MHRA

DRUG SAFETY INFORMATION

For immediate dissemination during working hours

Date: 23 January 2012

EL (12)A/04

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Dear Healthcare Professional,

MHRA Safety Information for Vigantoletten (1000 IU Colecalciferol) Tablets

(Merck Serono, Germany)

The above unlicensed product is imported in significant quantities into the UK.

Importers of medicines that are unlicensed in the UK must notify the MHRA in accordance with The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005/2789. For further information, please see also Guidance Note 14, available on the MHRA Website (<http://www.mhra.gov.uk>).

Notifications for importation of unlicensed medicines are assessed by the MHRA and objections may be raised where there are prohibitive safety or quality concerns, or in the case of non-objections to import, advice issued where users need to be aware of safety or quality issues.

Although importers are advised that the prescriber must be made aware that Vigantoletten tablets contain soya oil, and are contraindicated for patients with allergies to this ingredient, it has come to the attention of the MHRA that not all users may be aware of these safety issues. This is of particular concern because packs and leaflets are in the German language. Although there is currently no legal requirement for imported medicines to be labelled in English, the expectation in the National Health Service is that suitable English language labelling will be provided as a matter of good practice. NHS guidance has been issued which reflects this.

Allergy to soya oil may lead to severe allergic reactions including anaphylaxis. Recipients are therefore asked to bring this information to the attention of relevant professionals.

Yours faithfully,

Graham Matthews

Senior Pharmaceutical Assessor, **Unlicensed Medicines**

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