

Food supplements containing black cohosh that may be detrimental to liver to be withdrawn from market

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According to the European Agency for the Evaluation of Medicinal Products (EMA) and the Committee on Herbal Medicinal Products (HMPC) working under EMA, black cohosh may be detrimental to liver. On the basis of available information, HMPC has assessed that cases of severe liver failure have been associated with use of black cohosh products.

EMA and the Finnish National Agency for Medicines published a statement on the matter on 18 July 2006, and advised consumers that if they have any symptoms to discontinue the use of products that contain black cohosh and to seek medical treatment immediately. More information is available at:

<http://www.nam.fi/ajankohtaista/uutiset/tahkakimikki.html>

Black cohosh is widely used in plant drugs. The Finnish Food Safety Authority Evira has received notifications of two food supplements that contain black cohosh (*Cimicifugae racemosea rhizoma*, *Black Cohosh*, root), which may be detrimental to liver.

The food supplement notifications concern the following products:

1. **Womeno** black cohosh rhizome extract
Manufactured for: Fenno Natura Oy, Tuusula, Finland
Package size: 60 tablets/ 24.6 g
Best before date: 08-2008
Batch code: 5649
2. **Vitamore Total** herb, zinc and vitamin E product
Manufactured for: Laerton Oy, Helsinki, Finland

The Finnish National Agency for Medicines has classified this product as a medicine by a decision issued in November 2005. The classification decision is legally valid, and the product in question may no longer be marketed as a foodstuff.

With the classification decision, the matter has fallen under the jurisdiction of the National Agency for Medicines. In June 2006, the Company submitted a notification to the Food Safety Authority to the effect that the composition of the product has been changed. According to the notification, black cohosh is no longer used as an ingredient, for example. The notification is still under examination at the Food Safety Authority. The Authority believes, however, that there may still be products in the market that contain black cohosh. According to the Internet site of the Company, among others, the product still contains black cohosh.

Pursuant to the Food Act (23/2006, Section 7), foodstuffs shall in terms of their chemical, physical and microbiological composition and health properties be suitable for human consumption and harmless to human health. In the opinion of the Food Safety Authority, black cohosh no longer meets the requirements specified for the safety of foodstuffs, due to its suspected liver toxicity.

The so-called General Food Law Regulation of the EU (178/2002/EC) stipulates that if a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them.

Fenno Natura Oy has initiated the withdrawal of the product from the market and will inform consumers about the matter. For more information, please contact the Managing Director of Fenno Natura Oy, Mr. Christer Fallström, tel. +358 (0) 50 3872 102

More information:



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At the Finnish Food Safety Authority Evira, the matter is dealt with by

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