

Notice Information: Human Medicines - Warning

24 August 2007

Part 1. Product Information

- a) Title: Xie Gan Wan Tablets - Traditional Chinese Medicinal Product
- b) Product Name/Type: Xie Gan Wan Tablets
- c) Active Substance: Aristolochic Acids
- d) Reference: IMB Reference: QDR-H07-335
- e) Serial/Batch Number & Expiry Date: All Batches with varying expiry dates
- f) Authorisation Number: None
- g) Authorisation Holder: None
- h) Recall Classification: Yes, if product is identified on the Irish Market

Part 2. Target Audience

- a) Target Audience: The General Public and Users of Traditional Chinese Medicinal Products Suppliers and Retailers of Traditional Chinese Medicinal Products Practitioners of Traditional Chinese Medicine Pharmacists

Part 3. Problem/Issue

a) Problem/Issue:

The Irish Medicines Board (IMB) wishes to advise that it has recently learned that Xie Gan Wan tablets, a potentially harmful aristolochic acid-containing Traditional Chinese Medicinal Product, has been found in the UK marketplace. Given the close proximity of the UK to Ireland, it is possible that this product may also be on sale or in use in Ireland. Aristolochic acids are a component of the herb *Aristolochia manshuriensis*, which is known to be toxic to the kidney, and is regulated in Ireland as a prescription only substance. Xie Gan Wan tablets are not authorised in Ireland as a medicinal product. While Xie Gan Wan tablets have not been found to date on the Irish market by the IMB, as a precautionary measure, the IMB is alerting the general public, users of Traditional Chinese Medicinal Products, Suppliers and Retailers of Traditional Chinese Medicinal Products, Practitioners of Traditional Chinese Medicine, and Pharmacists of this issue, so that the actions stated below can be taken.

Part 4. Background Information

a) Background Information:

Other aristolochia acid-containing Traditional Chinese Medicinal Products (in tablet and capsule form) have been found in the UK market over recent years, including the products Longdan Xie Gan Wan, Guan Xin Su He, Longdan Qiegan Wan, Longdan Xie Gan Wan, Jingzhi Kesou Tanchuan, Guanxin Suhe and Qing Re An Cang Wan. These have all been confirmed to have contained one or more potentially harmful aristolochia acids. In Ireland, Longdan Xiegan Wan capsules were found in the Irish marketplace in 2006. This product was removed from the market at that time, and an alert was issued by the IMB on October 19th, 2006 in this regard.

Part 5. Action to be taken

a) Action to be taken:

Any patients or members of the public who are using, or have used, Xie Gan Wan tablets, are advised to immediately cease taking this product and to consult with their pharmacist or doctor, even if they have stopped using the product. When speaking to their doctor or pharmacist, patients or members of the public may find it helpful to take a copy of this IMB notification with them. This can be downloaded from the IMB website at www.imb.ie. Patients should continue to take any medication prescribed by their doctor. Any persons holding stock of Xie Gan Wan tablets, or who have supplied this product to others, or who may have packs of this product in their possession, should put the product in a safe place immediately and notify the IMB at the contact details below. The IMB is also alerting trade and other relevant organisations representing companies or individuals supplying, selling or using Traditional Chinese Medicinal Product today to advise them of this issue, so that their members can be made aware of this information as soon as possible. In this regard, the IMB requests trade and other relevant organisations to bring the information in this Warning notice to the attention of their members, so that their members may cease supplying/selling/using this product, and contact the IMB. Any packs of Xie Gan Wan tablets should be immediately quarantined. The Irish Medicines Board is also requesting any retailers and suppliers of this product to try and contact their customers, so that they can be advised of the above. The IMB wishes to advise that vigilance should always be exercised in relation to the purchase, sale and/or use of any Traditional Chinese Medicinal Product that may contain, or that may be derived from, the herb species *Aristolochia manshuriensis*. The IMB contact person for this issue is: Kevin O'Donnell, Market Compliance Manager, Irish Medicines Board, Earlsfort Terrace, Dublin 2, Ireland Tel: +353-1-6764971 (office) Fax: +353-1-6764061

Part 6. Keywords

a) Keywords:

Xie Gan Wan Tablets, traditional chinese medicine