

**Notice Information: Human Medicines - Warning
22 September 2008**

Part 1. Product Information

- a) Title:
- b) Product Name/Type:
- c) Active Substance:
- d) Reference:
- e) Serial/Batch Number & Expiry Date:
- f) Authorisation Number:
- g) Manufacturer/Supplier:
- h) Recall Classification:

Part 2. Target Audience

- a) Target Audience:

Part 3. Problem/Issue

a) Problem/Issue:

Further to the communication issued by the Irish Medicines Board (IMB) in July, 2008, concerning Li Da Dai Dai Hua Capsules, a potentially harmful and illegal medicinal product, the IMB wishes to provide you with the following new information. A number of samples of Li Da Dai Dai Hua Capsules obtained from the Irish marketplace have been analysed by the IMB. Some of the capsules analysed were found to contain Sibutramine Hydrochloride, and others were found to contain a related substance known as Desmethyl-Sibutramine. These laboratory results mean that packs of Li Da Dai Dai Hua Capsules on the Irish market have been found to be adulterated with a prescription only-substance. This product is an illegal medicinal product which has not been authorised for marketing in Ireland and cannot be considered as suitable for consumption due to potential safety concerns.

Part 4. Background Information

a) Background Information:

The following information is intended to be helpful in identifying the products of concern: ¶ This product is packaged in capsule form. ¶ The capsules are green in colour, and are contained within a blister-strip. ¶ The blister strip is silver in colour, with blue and purple Chinese markings. ¶ The blister strip is contained within an aqua-green coloured cardboard box, showing a picture on the front cover of a female behind a newspaper. [Click here to read the Finalised Letter to Trade and Professional Bodies 18-09-08](#)
Related Photographs of the product in question: [Blister Strip Capsule](#) [Lida Outer Carton Market Compliance Sample](#) [Lida Outer Carton Market Compliance Sample 2](#)

Part 5. Action to be taken

a) Action to be taken:

Any patients or members of the public who are using, or have used Li Da Dai Dai Hua Capsules, are advised to immediately cease taking that product and to consult with their pharmacist or doctor if they have any concerns. When speaking with their doctor or pharmacist, they 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. Any persons holding stock of the above product should put the packs 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 Products 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 this product should be immediately quarantined. The Irish Medicines Board is also requesting any retailers and suppliers of these products to contact their customers, where possible, so that they can be advised of the above. Any suspected adverse reactions associated with use of Li Da Dai Dai Hua Capsules should be notified to the IMB, via the on-line reporting system accessible from www.imb.ie and by following the link to 'on-line reporting'. A downloadable report form is also available from the website. The IMB wishes to advise that vigilance should always be exercised in relation to the purchase, sale and/or use of any medicinal product, including Traditional Chinese Medicinal Products. Medicinal products such as the above product are not authorised for use in Ireland, and cannot be regarded as safe. These types of products are illegal medicines and should not be purchased for use over the internet. The IMB contact person for this issue is: Kevin O' Donnell, Ph.D. Senior Inspector & Market Compliance Manager, Irish Medicines Board, Earlsfort Terrace, Dublin 2, Ireland Tel: +353-1-6764971 Fax: +353-1-6764061

Part 6. Keywords

a) Keywords:

Li Da Dai Dai Hua Capsules