

Irish Medicines Board Safety Notification

Concerning a potentially harmful illegal Medicinal Product:

LiDa Daidaihua Capsules

Manufactured by:

Kunming Dali Industry & Trade Co. Ltd.,
No. 372 West Renmin Road, Kunming, Yuman, China

September 16th, 2008

Dear Sir or Madam,

This communication is a follow-up to the letter we issued to you on July 14th, 2008, concerning LiDa Daidaihua Capsules, a potentially harmful and illegal medicinal product.

In our July communication, we advised users of Traditional Chinese Medicinal Products, suppliers and retailers of Traditional Chinese Medicinal Products, practitioners of Traditional Chinese Medicine and Pharmacists that packs of LiDa Daidaihua Capsules, a potentially harmful and illegal medicinal product, had been identified on the Irish market. We also issued a statement to the general public via the IMB website (www.imb.ie) warning against the use of this product.

In the July communication, we advised that this product was not authorised for marketing in Ireland as a medicinal product, and that it was not being supplied in accordance with applicable regulations. We advised that another EU competent authority had found that the product contained a substance called sibutramine hydrochloride and a related degradation product. Note that products containing Sibutramine hydrochloride are prescription-only medicinal products in Ireland. The packaging of LiDa Daidaihua Capsules does not indicate that the capsules contain this substance or any related analogue, and thus, this product cannot be regarded as being safe. (The IMB has to date received two complaints relating to possible safety concerns regarding this product on the Irish market.)

With this present communication, we wish to provide the following new information.

- Samples of LiDa Daidaihua Capsules have now been analysed by the Irish Medicines Board.
- Some capsules 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 LiDa Daidaihua Capsules on the Irish market have been found to be adulterated with a prescription only-substance.
- This product is an illegal medicinal product – it has not been authorised for marketing in Ireland and it cannot be considered as safe.

With this communication, we are requesting that you please do the following:

- Please make your members aware of this up-dated IMB communication.

- If this product is identified by your members as being in their possession, your member(s) should be asked to immediately quarantine the product and notify the IMB at the contact details below. The IMB will arrange for the collection of the product from your members. (The IMB urges any person in possession of this product not to send the product out of the country and not to pass it on to any other person.)
- If any of your members have supplied this product to their customers, patients or other persons, the IMB is requesting that your members immediately try to identify and make contact with those persons, so that any unused product can be quarantined by them. Your members should then immediately contact the IMB to discuss this and further actions.
- Any customers or patients who received this product from your members should be advised to immediately cease taking this product and to consult with their pharmacist or doctor. When speaking to their doctor or pharmacist, customers/patients 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.

The following information is intended to be helpful in identifying the product 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.
- There is both English and Chinese text on the box, and there are several holographic features on the box.
- The name *Li Da Daidaihua Jiao Nang* appears on the front of the box in silver-coloured lettering, along with the name of the manufacturer, Kunming Dali Industry & Trade Co. Ltd.

See the Warning notice posted on the IMB website (www.imb.ie) to view photographs of the product in question.

Any suspected adverse reactions notified in association with the use of this product should be reported 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 also to advise that vigilance should always be exercised by your members in relation to the purchase, sale and or use of this type of product.

The IMB contact person for this issue is Kevin O'Donnell, whose contact details are stated below. Thank you for your co-operation in this matter.

Yours sincerely,

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