

**Notice Information: - Warning
05 February 2009**

Part 1. Product Information

- a) Title: 2 Day Diet Capsules
- b) Product Name/Type: 2 Day Diet Capsules
- c) Active Substance: The following substances are listed on the labelling of this product:
Ling Zhi, Ebony, Fox Nut, Tuckahoe, Seman Pruni, Dioscoreae,
Wheat Germ and Nature Substance

This product has been found to be adulterated; samples from the Irish market were tested and were found to contain the active ingredient sibutramine, which is a medicine used as part of weight loss treatments. Note that sibutramine is an active substance that is under prescription control in Ireland.

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- d) Reference: IMB Reference: QDR-H-09-030
- e) Serial/Batch Number & Expiry Date: Licence Number(s): None
Serial/Batch Number(s): All batches
Licence Holder: None – this is not an authorised medicine
Expiry Date: Various
Recall Required: Yes, if product is identified on the Irish Market
Timeframe: Ongoing
- f) Authorisation Number: None
- g) Manufacturer/Supplier: Manufacturer/Supplier: Unknown

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

Part 3. Problem/Issue

a) Problem/Issue:

The Irish Medicines Board (IMB) wishes to advise that it has recently learned that the above adulterated product has been found on the Irish marketplace. We are issuing this statement as a precautionary measure.

The adulterant is sibutramine, a medicine used for the treatment of obesity. This medicine is a prescription-only medicine in Ireland and should not be present in this unauthorised product. This product (2 Day Diet Capsule) 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.

The product comes in a plastic tub with the name 2 DAY DIET in white text on a red and white label. There is both English and Chinese text on the label. The bottle label also shows a graphic of mushrooms and the words "slimming formula", "fat burner", "expelling of toxin" and "relieving constipation". The bottle contains roughly 60 purple capsules with no markings. The bottle has a screw-off security lid.

The IMB, as a precautionary measure, is alerting the general public, users of Traditional Chinese Medicinal Products, Suppliers and Retailers of Traditional Chinese Medicinal Products and Practitioners of Traditional Chinese Medicine of this issue, so that the actions stated below can be taken.

Part 4. Action to be taken

a) Action to be taken:

- Any patients or members of the public who are using the above 2 DAY DIET product are advised to immediately cease taking the product and to consult with their pharmacist or doctor. 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 any of this 2 DAY DIET product, or who have supplied any packs of this product to others, or who may have packs of this product in their possession, 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 IMB 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 this product to contact their customers, where possible, 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 medicinal product, including Traditional Chinese Medicinal Products. Medicinal products such as this 2 DAY DIET 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 or by any other route.

Part 5. Enquiries

- a) All enquiries should be made to:

The IMB contact person for this issue is:

Mr. Rob Smyth,
Market Compliance Technical Officer,
Irish Medicines Board,
Earlsfort Terrace,
Dublin 2,
Ireland

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Part 6. Keywords

- a) Keywords:

2 Day Diet Capsules