

Notice Information: Medical Devices - Recall

14 March 2005

Part 1. Product Information

- a) Title: Durex Extra Safe 12 Pack Condoms and Durex Fetherlite 12 Pack Condoms
- b) Product Name/Type: Durex Extra Safe 12 Pack Condoms and Durex Fetherlite 12 Pack Condoms
- c) Reference: SN2005(02)
- d) Serial/Batch Number & Expiry Date: Product Name: Durex Extra Safe 12 Pack Condoms Batch Number: 20602503 Expiry Date: 2007/11 Product Name: Durex Fetherlite 12 Pack Condoms Batch Number: VR3073 U / VR3073 C / VR3073 E / VR3073 € Expiry Date: 2008/02
- e) Manufacturer/Supplier: Consumer Public

Part 2. Target Audience

- a) Target Audience: Consumer Public

Part 3. Problem/Issue

- a) Problem/Issue: The two above specified batches of condoms bearing the Durex brand name are counterfeit products that do not meet the requirements of the European standard for condoms.

Part 4. Background Information

a) Background Information:

The Irish Medicines Board (IMB) has become aware that there are two batches of counterfeit product that bear the Durex brand name on the Irish market. All Irish pharmacies have been advised of the issue and a recall is underway. Initial testing of the counterfeit product indicates that the product may not provide an effective barrier and therefore cannot be guaranteed to prevent transmission of sexually transmitted diseases or work as an effective means of contraception.

Part 5. Action to be taken

a) Action to be taken:

The IMB advises that you: Check both the outer packet and the condom foil to see if the details given above are the same as those outlined on the product in your possession. If you have identified that you have product with the details above return any such affected product in your possession to your local pharmacy. If you think you may have used the affected condoms and have any health concerns, please consult your General Practitioner for their advice. Please be advised that this notice only applies to the 12 pack size of condoms specified above and not to any other pack size.

Part 6. Enquiries

a) All enquiries should be made to:

If you have any enquiries relating to the above you may contact the Medical Devices Department of the Irish Medicines Board at:
Medical Devices Department Irish Medicines Board Earlsfort Centre
Earlsfort Terrace Dublin 2 Telephone: 01-6764971 Fax:
01-6344033 Email: medicaldevices@imb.ie SN2005(02):
Durex Extra Safe 12 Pack Condoms and Durex Fetherlite 12 Pack Condoms

Part 7. Keywords

a) Keywords:

Durex Extra Safe 12 Pack Condoms and Durex Fetherlite 12 Pack Condoms