

Safeguarding public health  
Defective Medicines Report Centre  
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**MHRA**

## **DRUG ALERT**

### **CLASS 4 MEDICINES DEFECT INFORMATION**

**Caution in Use**  
**Distribute to Pharmacy Level**

Date: 20 September 2012

EL (12)A/31

Our Ref: MDR 14-09/12

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Dear Healthcare Professional,

### **Pfizer Limited**

**Diflucan 10 mg/ml powder for oral suspension**      **PL 00057/0343**

**Diflucan 40mg/ml powder for oral suspension**      **PL 00057/0344**  
**(Fluconazole)**

Pfizer Limited has recently amended the labels and Patient Information Leaflet (PIL) for the above products. They have informed us that there may be some confusion resulting from the new packaging, as follows:

- The PIL, which is common to both strengths, provides reconstitution instructions for a 175ml bottle. Pharmacists are asked to disregard these instructions as the 175ml presentation is not available in the UK. The only pack size in the UK is the 60ml bottle and instructions for reconstitution are provided in the PIL in the section containing information intended for medical or healthcare professionals
- For Diflucan 40mg/ml, batch A233306, the level mark on the label, which is referred to in the reconstitution instructions in the PIL, is missing. Pharmacists are asked to ensure that 24ml water is added. This produces 35ml of useable suspension.

To ensure continuity of supply, distribution of affected stock will continue and it will be necessary to release further batches. Steps are being taken to remedy this situation as quickly as possible, but it may be several months before the issue is resolved.

#### **MHRA Distribution:**

Regional Contacts for NHS Trusts and Provider Units  
Chief Pharmacists: England, Scotland, Wales, Northern Ireland  
Prison Health Policy Unit (DH)  
Chief Pharmacists: Jersey, Guernsey, Alderney, Sark, Isle of Man, Gibraltar  
Special Hospitals  
Healthcare Commission for distribution to Independent Health Care Establishments  
Primary Care Trusts (England)

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For further information, please contact Pfizer Medical Information team on 01304 616161.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Primary Care Trusts are asked to forward this to relevant clinics and to General Practitioners and Community Pharmacists for information.

Yours faithfully

Alison Bunce

Pharmaceutical Assessor, DMRC