

IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Chief Pharmacists, NHS Boards
3. Hospital Pharmacy Managers
4. Medical Directors NHS Boards
5. Chief Executives NHS Boards

Dear Healthcare Professional,

**DRUG ALERTS NO 27 – CLASS 4**

Please find attached revised drug safety information from the Medicines and Healthcare Products Regulatory Agency (MHRA) for onward transmission (see list below).

1. Please could Directors of Pharmacy forward this alert to:-
  - Hospital pharmacists
  - Chief Pharmacists to forward on to Medicines Information Pharmacists
2. Please could Medical Directors forward the message on to :-
  - Chief Executives NHS Boards

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY  
Pharmacy Division

\* NB: Drug alerts have the following classifications:

1. Action now (including out-of-hours);
2. Action within 48 hours;
3. Action within 5 days;
4. Caution in use

**Safeguarding public health**  
**Defective Medicines Report Centre**  
**Market Towers**  
**1 Nine Elms Lane**  
**London**  
**SW8 5NQ**  
**Telephone: +44 (0)20 7084 2574**

**Fax: +44 (0)20 7084 2676**

# **DRUG ALERT**

## **CLASS 4 MEDICINES DEFECT INFORMATION**

**Caution in Use**  
**For distribution to hospital pharmacists**

Date: 07 October 2009

EL (09)A/27

Our Ref: MDR 02-10/09

Dear Healthcare Professional,

### **FOCUS PHARMACEUTICALS LIMITED**

**Fluconazole 2mg/ml Solution for Infusion**

**PL 20046/0055**

**(Fluconazole)**

<b>Batch Number</b>	<b>Expiry Date</b>	<b>Pack Size</b>	<b>First Distributed</b>
0802849	08/2013	25ml	01/12/2008
0802740	08/2013	100ml	01/12/2008
0802760	08/2013	100ml	24/09/2009
0802773	08/2013	100ml	24/09/2009
0802818	08/2013	100ml	02/10/2009
0802834	08/2013	100ml	02/10/2009

Focus Pharmaceuticals Limited has informed the MHRA that there is an error in the patient information leaflet (PIL) supplied in the above batches of Fluconazole 2mg/ml Solution for Infusion, concerning the dose to be administered to **children** for the indication mucosal candidiasis. The leaflet text reads:

Treatment of mucosal candidiasis - the usual dose is 3-12mg/kg per day. 6mg/kg may be given on day 1.

The text should read:

Treatment of mucosal candidiasis – the usual dose is 3mg/kg per day. 6mg/kg may be given on day 1.

The remaining text of the leaflet is correct, as is the labelling of the product and the SPC.

#### **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)

#### **Medicines and Healthcare products Regulatory Agency**

Market Towers 1 Nine Elms Lane London SW8 5NQ

T 020 7084 2000 F 020 7084 2353 www.mhra.gov.uk

An executive agency of the Department of Health

Date: 07 October 2009

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Due to current product shortages, these batches are not being recalled. Focus Pharmaceuticals Limited has confirmed that no further batches containing the incorrect PIL will enter the market.

**Further Information**

For further enquiries, please telephone Focus Pharmaceuticals Limited on 01283 495280

Recipients of this Drug Alert are requested to bring this to the attention of relevant professionals by copy of this letter.

Yours faithfully

Alison Bunce  
Pharmaceutical Assessor, DMRC