



Medicines and Healthcare products
Regulatory Agency

Medicines and Healthcare Products Regulatory Agency
Defective Medicines Report Centre
Market Towers
1 Nine Elms Lane
London
SW8 5NQ

Safeguarding public health Telephone: 020 7084 2574

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DRUG ALERT

CLASS 2 MEDICINES RECALL

Action within 48 Hours
PHARMACY (or equivalent) LEVEL RECALL

Date: 28 July 2005

EL(05)A/11

Our Ref: MDR 23-07/05

Dear Healthcare Professional,

Counterfeit Product

Product: Lipitor Tablets 20mg

PL 16051/0002

Atorvastatin (as calcium trihydrate)

Batch Number	Expiry Date	Pack Size	First Distributed
004405K1	11 2007	28	Not known

The MHRA, with assistance offered by Pfizer Ltd, is recalling **any** remaining stock of the above batch of Lipitor. This is due to the discovery of counterfeit material with the same batch number as genuine Pfizer material in the legitimate supply chain. **No other lots are affected.**

Although there are some distinguishing features between genuine and counterfeit product it has been decided that patient risks will be minimised by recalling **all** remaining stock of this lot. There is no evidence of any other lots of counterfeit material in the legitimate supply chain but if you have concerns about any suspicious material please contact the DMRC on 020 7084 2574 for further advice.

The initial results of analysis performed by the MHRA on the counterfeit material do not indicate that this material poses an immediate risk to patients.

To make arrangements to return **any stock from this lot only** please contact the Customer Services department of Pfizer Ltd on 01304 646600.

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For questions of a medical nature please contact Pfizer Medical Information on 01304 616161

Pfizer have confirmed that there should be adequate stocks of Lipitor 20mg available to supply against new orders.

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

Yours faithfully,

Ian Holloway
DMRC Manager

Two further advice sheets are attached

MHRA Distribution (further recipients by cascade):
Regional Contacts for NHS Trusts and Provider Units
Chief Pharmacists: England, Scotland, Wales, Northern Ireland
Prison Health Policy Unit (DH)
Medical Supplies Agency (MOD)
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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QUESTIONS AND ANSWERS FOR PROFESSIONALS AND PATIENTS

How will patients be made aware?

The MHRA has issued a press release which will inform the media of the recall.

Why is this batch of product being recalled?

Product with this batch number is counterfeit (fake) material that has probably been made in poor conditions and not tested in the same way as authorised medicines.

Where can the batch number be found on the pack?

The batch number is printed on the end of the box and is next to the expiry date. It is also printed on the foil backing of the blister strip containing the tablets

What should I do if I have any product with this batch number?

Do not take any more. Return them to where you obtained them and obtain a replacement of genuine Pfizer Lipitor as prescribed by your doctor. If you are concerned, consult your healthcare professional (doctor/pharmacist).

Should I take any precautions before starting further treatment with replacement stock?

Patients are advised to leave 24 hours between receiving their last tablet of Lot 004405K1 and their first tablet of a new supply of Lipitor 20mg. The patient will not be aware if their previous medication was genuine or counterfeit and this advice applies to all previous medication.

What happens if I have taken tablets from this batch?

Initial tests performed by the MHRA on this counterfeit material do not indicate that it poses an immediate risk to patients. Do not take any more. Return the product to where you obtained it (e.g. pharmacy), obtain a replacement of genuine Pfizer Lipitor as prescribed by your doctor and continue to take your replacement medication as prescribed by your doctor. If you are concerned, consult your healthcare professional (doctor/pharmacist).

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If the product does not have any safety problems, why is it being recalled?

There are two reasons:

- It is a fake, not legally on the market and not provided by the authorised manufacturer
- As a counterfeit product there is no guarantee of its quality or effectiveness

If I am worried about side effects what should I do?

Consult your doctor or pharmacist who may wish to report these to the MHRA as associated with a possible counterfeit medicine.

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