

Safeguarding public health
Defective Medicines Report Centre
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DRUG ALERT

CLASS 2 MEDICINES RECALL

Action within 48 hours

Pharmacy, Clinic and Wholesaler level recall

Date: 21 January 2013

EL (13)A/02

Our Ref: MDR 04-01/13

Dear Healthcare Professional,

Stock from MSD (Merck Sharp & Dohme Ltd) and Parallel Distributors

Tredaptive modified-release tablets

EU/1/08/459/002 and

EU/1/08/459/003

(Nicotinic acid and Laropiprant)

All unexpired stock of both originator and parallel-distributed packs of this product are being recalled to Pharmacy, clinic and wholesaler level irrespective of batch number, expiry date and pack size.

The product is being withdrawn throughout the EU after a study has shown a failure to reduce major vascular events and an increase in non-fatal serious adverse events. Both CHMP and the Pharmacovigilance Risk Assessment Committee have concluded that the benefits no longer outweigh the risks.

Our information from the European Medicines Agency indicates that one parallel-distributor, Swingward Ltd T/A Medihealth has registered as a parallel-distributor. Both originator and parallel-distributed stock is in the supply-chain and will need to be handled differently as outlined below.

No further Tredaptive tablets should be dispensed. Pharmacists should refer patients with new or repeat prescriptions to the treating physician to review their treatment plan on a non-urgent basis.

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 (MHRA)

151 Buckingham Palace Road London SW1W 9SZ UK

T 020 3080 6000 www.mhra.gov.uk

An executive agency of the Department of Health

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Any remaining stock of this product should be quarantined, identified as originator or parallel-distributed stock and returned to the original supplier in the normal way.

For enquiries relating to stock returns, **with originator product:** If you purchased Tredaptive from Alliance Healthcare Distribution Limited, they will be in contact with you shortly with details of the recall procedure. Should you have any questions, please contact your local Alliance Service Centre. If you did not purchase Tredaptive from Alliance, you should contact your supplier to arrange return

For enquiries relating to stock returns, **with parallel-distributed Swingward/Medihealth stock** please call Ms Brenda Greenwood on 01204 473136.

For **all** medical information enquiries, please call MSD Medical Information department on 01992 467272.

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

Ian Holloway

MHRA DMRC Manager