

Safeguarding public health
Defective Medicines Report Centre
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MHRA

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Hospital Pharmacy Level

Date: 28 November 2012

EL (12)A/35

Our Ref: MDR 29-11/12

Dear Healthcare Professional,

Organon Laboratories Limited

**Organon 750 anti-Xa units, solution for
injection**

PL 00065/0125

(Danaparoid sodium)

Batch Number	Expiry Date	Pack Size	First Distributed
166413001	Dec 2014	10 ampoules	14 Feb 2012
222239001	Jan 2015	10 ampoules	01 Mar 2012
22224001	Jan 2015	10 ampoules	10 Apr 2012
238587001	Feb 2015	10 ampoules	03 May 2012
296983001	Apr 2015	10 ampoules	28 Jun 2012
307099001	Jul 2015	10 ampoules	10 Sep 2012
335914001	Aug 2015	10 ampoules	08 Oct 2012

Merck Sharp & Dohme Limited (trading as Organon Laboratories Limited) has recently amended the package leaflet for the above product to include user tested text in the patient leaflet section. They have informed us that during this process the previous technical portion of the leaflet aimed at the Health Care Professional administering the product has been omitted.

To ensure continuity of supply, distribution of affected stock will continue and it will be necessary to release further batches.

Cont /...

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)

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An executive agency of the Department of Health

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The Technical part of this leaflet is the same as the SmPC for the product and Health Care Professionals needing full instructions for use are referred to the Electronic Medicines Compendium (eMC) (<http://www.medicines.org.uk/emc>) where they can access the latest SmPC for Orgaran.

Merck Sharp & Dohme Limited is working to resolve this situation as quickly as possible but it may be a few months before new stock containing both patient and technical leaflets is available.

For further information, please contact Merck Sharp & Dohme Medical Information team on 01992 467272

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

Yours faithfully

Alison Bunce

Pharmaceutical Assessor, DMRC