



Medicines Authority
Inspectorate and Enforcement Division
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Drug Alert

CLASS 1 MEDICINES RECALL

Action Now - including out of hours

Date: 2nd August 2006

Our Ref: MDR 5-7/06

Dear Healthcare Professional,

Alfred Gera & Sons Ltd c/o Schering AG Berlin

Ultravist-370 x 50ml
(iopromide)

PMA 185/02201

Batch Number	Expiry Date	Pack Size	First Distributed
All batches	Sep 07		April 2005

The Inspectorate and Enforcement Directorate within the Medicines Authority were informed by Schering AG Berlin (Marketing Authorisation Holder) and their local distributors Alfred Gera & Sons Ltd of a Class 1 recall that was initiated voluntarily by the same Schering AG for all batches of Ultravist-370.

The voluntary recall of the intravascular X-ray contrast agent **Ultravist-370** is due to the potential that particulate matter in conjunction with crystallization may be present in the product.

The 2 batches which have been distributed locally (43060C and 43060E) have been recalled by Alfred Gera & Sons Ltd. The recall was carried out under the supervision of the Medicines Authority.

Thanks and Regards

Karl De Marco

Medicines Inspector

Medicines Authority Distribution:
Department of Institutional Health
Government Pharmaceutical Services

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