

Safety Alert 03/06



August 2006

Distributed to:

- Chief Executives
- Directors of Clinical Operations
- Directors of Corporate Services

Action required by:

- Directors of Clinical Operations
- Directors of Corporate Services

For response by:

- Directors of Clinical Operations

We recommend you also inform:

- Directors of Imaging— diagnostic and interventional
- Directors of Pharmacies
- Heads of Purchasing
- Medical and nursing staff, as appropriate.

Deadline for completion of action 1

5.00 p.m.

Friday, 4 August 2006

Quality and Safety Branch
NSW Department of Health

Tel (02) 9391 9200
quality@doh.health.nsw.gov.au

SCHERING RECALL— ULTRAVIST – 370

Ultravist is a contrast agent for use with X-ray examinations

ULTRAVIST – 370 BOTTLES

Aust R:

47383 15.377g 20mL	48498 56.665g 75mL
47384 23.066g 30mL	48499 76.88g 100mL
15681 38.443g 50mL	48501 153.77g 200mL

ALL BATCHES

Issue

Schering Pty Limited following consultation with the Therapeutic Goods Administration (TGA) is recalling all batches of ULTRAVIST – 370. This extends the recall of two batches of the product (Batches 52501A, 52501B) reported to affected customers on 8 May 2006.

This recall does not include other concentrations of ULTRAVIST (- 150, - 240, - 300).

The reason for this recall is that particulate matter in conjunction with crystallisation may be present in single bottles of the product.

Please examine your current ULTRAVIST - 370 stocks immediately, isolate all bottles, and quarantine them to prevent usage. Your Schering representative will contact you in the next few days to arrange collection and replacement of the goods.

Please retain this Safety Alert in a prominent position for one month in case of stock in transit.

Questions regarding Schering's recall should be directed to Dr Andreas Schulz, Medical Director, Schering Pty Limited, on (02) 9317 8620.

Please note that this information is also being distributed by Health Procurement.

Actions required by Area Health Services

1. Please examine your current ULTRAVIST- 370 stocks immediately, isolate all bottles and quarantine them to prevent usage.
2. Instruction for return of goods attached.

**PLEASE FOLLOW THESE INSTRUCTIONS TO ARRANGE
RETURN OF GOODS**

TO:	SCHERING PTY LIMITED
ATTENTION:	Dr Andreas Schulz - Medical Director
FACSIMILE NO:	(02) 9317 8703
POSTAL ADDRESS:	Locked Bag, Alexandria, NSW 1435
SUBJECT:	RECALL OF ULTRAVIST® 370 - ALL PACKS

FROM: (name of institution)	
CONTACT PERSON: (please print)	
TELEPHONE NO.	
FACSIMILE NO.	

PLEASE TICK RELEVANT BOX AND FAX BACK FORM TO (02) 9317 8703

WE DO NOT HAVE STOCK WHICH IS SUBJECT TO THIS RECALL

WE DO HAVE STOCK WHICH IS SUBJECT TO THIS RECALL

UNUSED STOCK YOU STILL HAVE ON HAND OF ULTRAVIST® 370

ULTRAVIST 370 PACK	QUANTITY (BOTTLES)	BATCH NUMBERS
20mL.....	
30mL.....	
50mL.....	
75mL.....	
100mL.....	
200mL.....	

**IT IS IMPORTANT YOU DO NOT USE THIS STOCK – IT MUST BE
QUARANTINED AND RETURNED TO SCHERING IMMEDIATELY.**

**TO RETURN STOCK, PLEASE CONTACT TNT ON TEL: 131150,
QUOTE ACCOUNT NO. TNT20507356 AND REFERENCE "RECALL"**