



URGENT MEDICINE RECALL

ASTRAZENECA Xylocaine 4% Topical Solution 30ml bottle, Packs of 1.

Batch Number: 1294883
Expiry Date: June 2012
AustR: 124858

Batch Number: 1299209
Expiry Date: June 2012
AustR: 124858

Dear Wholesaler / Chief Pharmacist / Medical Practitioner / Dentist,

After consultation with the Therapeutic Goods Administration, AstraZeneca is conducting a sponsor-initiated recall of two batches of **Xylocaine 4% Topical Solution 30mL bottle packs of 1**, batch numbers 1294883 and 1299209. The recall is being undertaken because AstraZeneca has determined that the fill volume in some bottles is slightly higher than the in process specification resulting in the active ingredient assays being below the registered specification.

The batch number is displayed on the end flap of the outer carton and on the bottle.

Please inspect your stocks and quarantine all units from the above batch numbers, then complete the attached Facsimile Reply Form and fax it to us so that we may arrange for your stock to be recovered and a credit note issued. Please complete the Facsimile Reply Form even if you have no stock that is subject to recall, as we require this information to reconcile the recall process.

If any of the recalled stock could have been transferred from your facility to another, please immediately let that facility know of the recall. Please then telephone AstraZeneca Customer Services on 1800 226 591 so that we can make contact with that person or facility supplied from your facility.

Please retain this letter in a prominent position for one month in case stock is in transit.

AstraZeneca regrets any inconvenience caused by this recall and thanks you for your co-operation.

Should you require any further details or assistance, please do not hesitate to contact AstraZeneca Customer Services on 1800 226 591.

Yours sincerely,

Win Kenyon
Product Quality Manager

PLEASE COPY AND CIRCULATE THIS LETTER TO ALL MEDICAL STAFF IN YOUR FACILITY

Facsimile Reply Form

TO: AstraZeneca Pty Ltd
ATTENTION: Customer Service Department
FACSIMILE NUMBER: 1800 242 920
SUBJECT: Recall of the following product:

ASTRAZENECA Xylocaine 4% Topical Solution 30ml bottle, Packs of 1.

AstraZeneca Code: 00603
Batch Number: 1294883
Expiry Date: June 2012
AustR: 124858

AstraZeneca Code: 00603
Batch Number: 1299209
Expiry Date: June 2012
AustR: 124858

Please update this form and fax back to AstraZeneca, contact the wholesaler you purchased the product from to arrange return and credit of RECALL PRODUCT ONLY.

FROM: _____
(name of institution)

CONTACT PERSON: _____
Position: _____
(please print)

TELEPHONE NO: _____

FACSIMILE NO: _____

WHOLESALER NAME: _____

We do/ do not have stock which is subject to this recall

Batch No: 1294883	Batch No: 1299209
Quantity of Stock received: _____	Quantity of Stock received: _____
Quantity of Unused Stock subject to recall: _____	Quantity of Unused Stock subject to recall: _____

Has this product been on sold through your Company? If so, please provide details.

Signature: _____ Date: _____