



SIGMA PHARMACEUTICALS LIMITED
ABN 15 088 417 403

Members of Sigma Group of Companies:
Sigma Pharmaceuticals (Australia) Pty Ltd
ABN 88 004 118 594
Fawns & McAllan Proprietary Limited
ABN 16 004 296 066

Dear Doctor / Pharmacist,

Safety Alert
Possible glass fragments in bottles
ONLY PRODUCTS IN 30 mL AMBER GLASS BOTTLES AFFECTED

Sigma Pharmaceuticals Ltd wishes to advise of infrequent defects in some 30 mL amber glass bottles containing tablets. Attached is Schedule 1 of 1 that assists with identifying products possibly affected.

There have been some isolated instances of bottle moulding defects. In some cases, easily identifiable amber glass fragments have been found in bottles.

There have been no reports of injury and we believe that the risk of patient harm is low. Product quality, efficacy and supply of these products is **not** affected.

We have worked closely with the Therapeutic Goods Administration (TGA) and would like to ensure that the patients who use the products are informed about this matter.

Pharmacists can assist by checking the 30 mL bottles at the time of dispensing and by informing patients who use these products of this caution. Patients should also be asked to check the bottles during use.

Should you discover or be made aware of a defective bottle, or if you or your patients have any other questions or concerns, please contact Sigma on the toll free number **1800 003 013**.

Sigma sincerely regrets any inconvenience caused. Thank you for your cooperation.

Yours Sincerely

A handwritten signature in black ink, appearing to read 'Ovais Siddiqui', written over a light grey rectangular background.

Ovais Siddiqui, M.Pharm, Ph.D.
Regulatory & Medical Affairs Manager
31st October 2006

Please address all correspondence to :
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SCHEDULE 1 of 1: 30 mL AMBER GLASS BOTTLE- PRODUCTS AFFECTED
(Attached to Sigma's Letter of 31/10/2006)

This caution **does not** apply to any Liquid or Cream preparations.

Product	AUST R	Pack Size	Affected Batches of Product BETWEEN the Expiry dates indicated below:
ANGININE glyceryl trinitrate 600 microgram tablet bottle	AUST R 11086	30s 100s	04/2007 – 12/2008 04/2007 – 12/2008
LYCINATE glyceryl trinitrate 600 microgram tablet bottle	AUST R 94215	100's	08/2007 – 12/2008
NILSTAT ORAL TABLETS nystatin 500,000 I.U. tablet bottle	AUST R 15227	50's	12/2006 – 12/2008
LANOXIN PG digoxin 62.5 microgram tablet bottle	AUST R 11108	200's	12/2006 -12/2008
SIGMAXIN PG digoxin 62.5 microgram tablet bottle	AUST R 90114	200's	11/2006 – 12/2008
OROXINE thyroxine sodium 50, 100, 200 microgram tablet bottle	AUST R 10984 AUST R 10985 AUST R 10986	5 bottles x 40's	05/2007 – 12/2008
EUTROXSIG thyroxine sodium 50 , 100, 200 microgram tablet bottle	AUST R 90765, AUST R 90766 AUST R 90767	5 bottles x 40's	05/2007 – 12/2008
Phenobarbitone B.P. 30 mg tablet bottle	AUST R 19758	200's	11/2006 – 12/2008
TRIPRIM trimethoprim 300 mg tablet bottle	AUST R 11009	7's	12/2006 – 12/2008
UREX-M frusemide 20 mg tablet bottle	AUST R 13475	50's	10/2007 – 12/2008