

Date: 31 July 2007
Attention:
Medical Professionals
Chief Pharmacists



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MEDICINE RECALL

Apomorphine Hydrochloride (APO-go[®]) Solution for Injection 20 mg / 2 mL
Batch numbers: Z006, Z007
Expiries: Oct 09
PL 05928/0020
PA 454/2/2

Following consultation with the Therapeutic Goods Administration, Mayne Pharma Limited is conducting a sponsor initiated recall on the above two batches of Apomorphine Hydrochloride (APO-go) Injection 20 mg / 2 mL. Two customer complaints identified crystals forming in the ampoule. During the investigation into the customer concerns, some batches were found to be out of specification for pH.

No other batches are subject to this recall.

To identify whether product received by you is part of the implicated batches, please check your stock, the batch number is printed on the side of the outer carton and on the ampoule printing.

Inspect and quarantine all units with the above batch numbers, then complete the attached Facsimile Reply Form and fax it to Mayne Pharma (1800 808 358). We will then arrange for your stock to be recovered and a credit note or replacement stock will be issued.

Even if you have no stock that is subject to this recall, please complete and fax back to Mayne Pharma the Facsimile Reply Form, as Mayne Pharma requires this information for reconciliation purposes.

If any of the recalled product has been transferred from your facility to another, please immediately inform your customer or such other person of the recall and note the quantity and the customer or such other person on the Facsimile Reply Form you complete and fax back to Mayne Pharma.

Mayne Pharma Limited sincerely regrets any inconvenience caused to your medical facility and pharmacy and thanks you for your co-operation.

Should you require any further information please contact our Customer Service Department on 132 436.

Marina Giuliani
QA Compliance Manager