



6 August 2007

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Dear Customer,

**Product Recall – Apomorphine HCl (APO-go<sup>®</sup>) Solution for injection 20mg/2ml**

After consultation with the Therapeutic Goods Administration, Mayne Pharma Limited is conducting a company sponsored recall of two batches, Z006 and Z007 of Apomorphine Hydrochloride (APO-go<sup>®</sup>) Injection 20 mg / 2 mL.

This recall is a result of 2 customers identifying crystals in the APO-go ampoules. These crystals are caused by a premature lowering in the pH of the solution. This lower than usual pH (normally 3-4) could result in some patients experience a slight burning sensation upon administration, and may lead to an increase in nodule formulation. These adverse effects are more likely with “intermittent injection” administration than with continuous infusion as dilution of Apomine with normal saline for infusion helps to buffer the product.

To date Mayne Pharma has not been advised of any patient experiencing any adverse events due to this pH issue despite the ampoules in question being in the market for over a month.

We are actively initiating this recall to prevent any patients experiencing these adverse events. It is worth noting that a recall was not instigated in the UK.

**Ongoing APO-go Supply**

Mayne Pharma has this week released another batch of APO-go ampoules that is within specifications. We have also spoken to our suppliers and steps have been put in place to ensure future batches are always within specifications.

I have attached for your information the TGA approved recall letter and fax back form that will be sent to every wholesaler and pharmacy that purchases Apomorphine.

If you have any queries regarding the recall or ongoing supply please feel free to contact me directly on the number below or via email.

Regards,

A handwritten signature in black ink, appearing to read 'Adrian Jones', with a stylized flourish at the end.

Adrian Jones

Product Manager – Neurology

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