INFORMATION ONLY

URGENT PRODUCT DEFECT ALERT
TGA Ref No. RC-2024-RN-00019-1

ARTGs: 169629, 169623, 133444, 169635, 143166 & 133445

Actrapid® Penfill®, NovoRapid® Penfill®, NovoRapid® FlexPen®, NovoMix® 30 FlexPen®, Mixtard® 30/70 Penfill®, Protaphane® Penfill®

19 January 2024

Dear Healthcare professional,

In order to maintain transparency and ensure patient safety, in consultation with the Therapeutic Goods Administration (TGA), Novo Nordisk Pharmaceuticals Pty Ltd (Novo Nordisk) is writing to inform you of a **potential product manufacturing issue**. Please note that this is **not a recall** of products.

The product issue is only affecting the 3mL glass cartridges which contain Actrapid®, NovoRapid®, NovoMix® 30, Mixtard® 30/70, and Protaphane®.

This notification does not impact all Novo Nordisk products and only relevant to the Novo Nordisk products above.

ISSUE

During manufacture, circular non-penetrating cracks on the outer surface around 4-6 mm below the "shoulder" of the glass cartridge were found. These outer surface cracks do not compromise the integrity of the cartridge. As the integrity of the cartridge remains intact, there is no risk of evaporation or contamination of the product.

If the cartridge cracks whilst being handled, the product will leak and be detectable by the patient. The pen will not work if the cartridge is cracked.

The manufacturing root cause that created this issue has been identified and resolved.

ASSESSMENT

The TGA has assessed this to be a 'Class II' risk. This being a situation in which the use of or exposure to the deficient therapeutic good(s) may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote.

RECOMMENDED ACTION

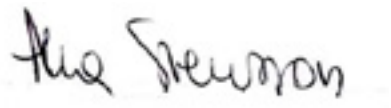
- Where possible pharmacists should inspect cartridges prior to dispensing and should defect product be found return it to the wholesaler for replacement.
- Patients are to continue to take their medication as normal unless they observe a crack in, or of, the glass cartridge. Patients should not use the product and may return it for a replacement.
- Ensure relevant staff members are informed of this communication.
- Place this letter in a prominent position for at least one month.

PRODUCT COMPLAINTS OR ADVERSE EVENTS

Product Complaints or adverse events relating to this issue should be reported to Novo Nordisk via **aunrccc@novonordisk.com**.

For any other information, please contact Customer Care Centre on **1800 668 626**.

Sincerely,



Dr Ana Svensson
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