**IMPORTANT PRESCRIBING INFORMATION**

**Phase-out of Actrapid®, Insulatard®, Mixtard® 30, Levemir® and NovoMix® 50 in Saudi Arabia due to Global Product Consolidation by 2026.**

| Products | Presentations being phased-out | Presentations remaining available |
|---|---|---|
| Actrapid®, Insulatard®, Mixtard® 30 (Regular human insulin, insulin NPH, biphasic human insulin 30) | Penfill® | Vials |
| Levemir® (Insulin Detemir) | FlexPen® | None |
| NovoMix® 50 (Biphasic insulin Aspart 50) | FlexPen® | None |

***Direct Healthcare Professional Communication***

Dear Healthcare professional,

This information is being disseminated in accordance with the national

authority.

At Novo Nordisk Saudi Arabia we want to deliver medicines that will best serve the greatest number of patients globally. In order to better meet patient demand with a stable product supply, we are consolidating our portfolio. As part of the portfolio consolidation, Actrapid®(Penfill®), Insulatard® (Penfill®)and Mixtard® 30 (Penfill®), Levemir® (FlexPen®) and NovoMix® 50(FlexPen®) will be phased out in Saudi Arabia by end of 2026. The phase out is not a consequence of any safety or quality related issues.

We acknowledge that this will be disruptive to people living with diabetes who rely on our treatments. However, by doing this now, we will increase the number of patients we reach with our insulin portfolio by many millions in the next decade.

As we strive not to leave any patients without alternative treatment options, either from Novo Nordisk or other companies, it is important to us that the transition to other device or treatment options is as smooth as possible for patients. We are therefore doing everything we can to liaise early with and support healthcare professionals, wholesalers, and patients in the transition to other treatments.

In relation to that, Novo Nordisk Saudi Arabia would like to inform you of the following:

**Summary and background information**

- Actrapid® (Penfill®) Insulatard® (Penfill®), Mixtard®30 (Penfill®) products are insulins are indicated for treatment of diabetes mellitus. Levemir® (FlexPen®) is indicated for treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above, and NovoMix® 50 (FlexPen®) is indicated for treatment of diabetes mellitus in adults.

- If patients are not timely switched to an appropriate alternative treatment option, this could result in patients missing the required doses, which may lead to serious clinical consequences, specifically hyperglycemia that may eventually progress to diabetic ketoacidosis.

- Healthcare professionals (HCPs) are urged to ensure that patients using Actrapid® (Penfill®), Insulatard® (Penfill®), Mixtard® 30 (Penfill®), Levemir® (FlexPen®) and NovoMix® (FlexPen®) are made aware of this and safely switched to alternative insulins/insulin delivery systems at HCP's discretion and based on local routine clinical practices.

- We are informing regulatory authorities, physicians, healthcare providers and patient organizations well in advance to help ensure patients transition safely to alternative options for continuity of care.

**Mitigating actions**

To better manage the situation, the mitigating actions outlined below should be considered:

- Transitioning between different types of insulin/insulin delivery systems or to another brand or manufacturer of insulin should be done in consultation with the physician and requires strict medical supervision.

- HCPs are requested to provide clear instructions regarding the new insulin regimen and/or usage of the new insulin delivery system to the patient upon transition.
- HCPs are requested to follow product SmPCs/labels for dosing recommendations while switching patients to alternative products.[1-7]
- The patients should be fully informed about the reason for the change in insulins/insulin delivery systems and the potential need for change in dose and additional glucose monitoring.
- Ensure that HCPs discuss potential dose adjustments and the need for continuous glucose monitoring during the transition period.
- HCPs are requested to remind their colleagues of these actions, particularly if they are known to be prescribers of the affected product/presentation.
- We are informing regulatory authorities, physicians, healthcare providers and patient organizations well in advance to help ensure patients transition safely to alternative options for continuity of care.

## Call for reporting

Adverse events including medication errors relating to any Novo Nordisk products should be reported to:

**National Pharmacovigilance Center (NPC) - Saudi Food and Drug Authority (SFDA)**
SFDA call center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: http://ade.sfda.gov.sa/
**Novo Nordisk Saudi Arabia**
E-mail: nngulfsafety@novonordisk.com
Website: https://www.novonordisk.com.sa/

## Company contact point

Further information can be obtained by contacting nngulfsafety@novonordisk.com

Yours Sincerely

Shoug Alamer

Qualified Person for Pharmacovigilance

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Novo Nordisk Saudi Arabia

## Annexes

**References**

1. Actrapid® Summary of Product Characteristics.
2. Mixtard® Summary of Product Characteristics.
3. Insulatard® Summary of Product Characteristics.
4. Levemir® Summary of Product Characteristics.
5. NovoMix® Summary of Product Characteristics.