

References:

1. Summary of product characteristics in KSA on Saudi Drugs Information system (SDI) website: (<https://sdi.sfda.gov.sa/>).
2. Diabetes UK, 2024. Side effects of insulin. [online] Available at: <https://www.diabetes.org.uk/about-diabetes/looking-after-diabetes/treatments/insulin/side-effects> [Accessed 20 September 2024].

Disclaimer:

This educational guide is designed for informational and risk minimisation purposes only and should not be construed as promotional or marketing material.

Kindly report side effects through the following channels:

- Saudi Food & 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/>

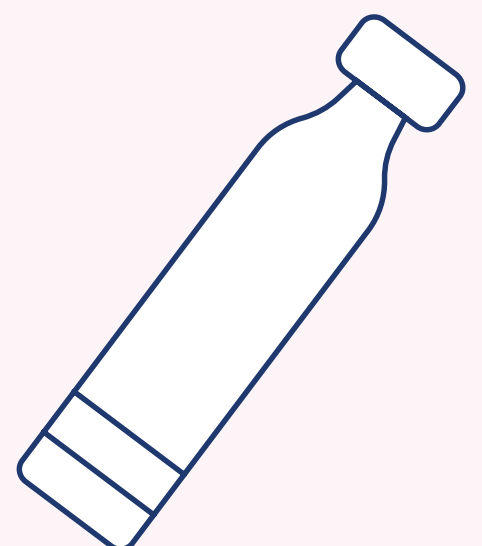


Important Risk Minimization Information for Patients:

Phase-out of Actrapid®, Insulatard®, Mixtard® 30 (Penfill)

1. This information is intended for patients with diabetes who have been prescribed for Actrapid®, Insulatard® or Mixtard® 30 (Penfill®). This transition ensures patients continue to receive the best treatment options.
2. You should speak to your doctor at the earliest opportunity to discuss alternative treatment options suitable for you and prepare for the switch of insulin and/or device.

This leaflet provides information on the phase-out of Novo Nordisk human insulins in (Penfill®) and what this means for you.



Why are these human insulin products being phased out?

Novo Nordisk wants to deliver medicines that will benefit and ultimately best serve the greatest number of patients globally. Due to the increasing number of people living with diabetes and our need to better meet patient demand with a stable product supply, we are consolidating our portfolio.

As a result, we will be phasing out:

- **Actrapid® (Penfill®)**
- **Insulatard® (Penfill)**
- **Mixtard® 30 (Penfill®)**

We know that this will be disruptive to people with diabetes who rely on our treatments. However, by doing this now, we will increase the number of patients we reach by many millions over the coming decade. We strive not to leave patients without alternative treatment options, either from Novo Nordisk or other companies. We remain committed to working closely with health authorities and the medical community and will adhere to applicable local regulations to ultimately ensure patients have access to the medication they need.



When will my insulin be phased out?

- In Saudi Arabia, Actrapid®, Insulatard® and Mixtard® 30 (Penfill®) will be phased out by 2026. Vials will continue to be available for Actrapid®, Insulatard® and Mixtard® 30 (Penfill®).
- You should speak to your doctor at the earliest opportunity to switch to an alternative insulin and/or device to avoid any interruptions to our treatment.

My insulin is being phased out, what should my next steps be?

- If you use any of the affected products listed on the opposite page, you should **speak with your doctor about transitioning to an alternative insulin and/or device.**
- Your doctor will help you switch to the vial form of your current insulin or to a different insulin using their clinical judgement, awareness of your medical history and individual needs, and finally, knowledge of what products are available in the country where you live.
- They will also monitor you closely as you switch to a new insulin and/or device to ensure a safe transition.

What to consider when switching insulins:

- As with all prescribed medication, everyone reacts differently.
- Check the patient information leaflet supplied with your insulin to see what the side effects are. Remember, you're unlikely to experience all of them.
- You should let your healthcare professional know if you have headaches, nausea or flu-like symptoms within the first 72 hours of starting any new insulin.