

High-Strength Insulin Preparations

Several new high-strength insulin products have been approved for use throughout the EU since 2013*. High-strength insulin products contain a concentration of insulin which exceeds the standard 100 units/ml (e.g. they may contain 200 units/ml or 300 units/ml) and provides for a better dissolution profile over the duration of action, helping to meet an increasing need for higher doses while reducing the number and volume of injections. However, there are important differences in the way that high-strength insulin products are used compared with existing standard-strength insulin formulations. There is therefore a risk of medication error and accidental mix-up. Information and recommendations for use can be found in the product information (Summary of Product Characteristics (SmPC) and Package Leaflets (PLs)) for the individual insulin preparations.

The packaging and pre-filled syringes or pre-filled pens for high-strength insulins have been designed to mitigate the risk of medication error and mix-ups, with devices calibrated to ensure the correct dose of insulin is delivered. It is essential that insulins are not extracted from these devices for delivery by an insulin syringe. In addition, educational materials are available for the various high-strength insulin products which provide information on dosing, dose adjustment, and the need for dose conversion when switching between standard and high-strength products (if necessary), interchangeability and monitoring as appropriate to the individual product.

Healthcare professionals and patients therefore need to understand the insulin strength of these products and how to use them correctly in order to minimise the risk of medication errors such as administering the wrong insulin dose. Prescribers should specify the strength in the prescription and ensure it is differentiated from the dose, for any products where both strengths are available. When dispensing products where there are two strengths available, pharmacists should confirm the strength, liaise with patients to reinforce advice as necessary. Patients should be reminded that the dose is in units on the pen and no calculations need to be made. Patients should also be advised to carefully check the units on the pen and use them to dial up their dose in units, seeking assistance if needed.

The European Medicines Agency (EMA) has published guidance on prevention of medication errors with high-strength insulins which provides further important information and guidance on the safe and effective use of these medicines. This was recommended as part of the [risk minimisation strategy for high-strength and fixed-combination insulin products](#) which is also available on the EMA website.

Electronic versions of educational materials approved by the HPRA for specific medicinal products on the Irish market are available on the HPRA website under [Educational Materials for Medicines](#). Hard copy versions of these materials are available directly from the marketing authorisation holder of the specific product.

Key Message

Healthcare professionals and patients should be aware of the availability of high-strength insulin products coming onto the Irish market and that some product ranges may include both standard-strength and high-strength insulin preparations.

Prior to starting treatment with any of these products or when switching from a standard-strength insulin to a high-strength insulin, prescribers should consult the product information (SmPC and PL) and any educational materials provided with these medicinal products.

Healthcare professionals should ensure that patients and/or carers read and understand the package leaflet and any patient educational material provided with the product and receive appropriate training on the correct use of the product prior to use.

Any reports of suspected adverse reactions associated with use of these products should be notified in the usual way.

**High-Strength insulin products include Tresiba, Humalog, and Toujeo. Further details on these products are available on www.hpra.ie and www.ema.europa.eu*