Irish Medication Safety Network

Safety Alert

Patient Safety First
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Risks associated with High-Strength Insulin Preparations

Issue:

Insulin is a high risk drug which has the potential to cause serious harm if it is not used correctly.[1] Until recently, all insulin available on the European market contained 100 units / mL. A high-strength insulin is one which contains insulin at a concentration of more than the standard 100 units / mL.[2] These high-strength insulin products may contain, for example, **200 units / mL** or **300 units / mL.** There is a potential for harm if these products are not prescribed, dispensed, and administered properly.

Brand Name	Insulin Type	Strength	Dose counter	Range of units per injection
Tresiba® (100)	*Insulin Degludec*- long acting	100 units / mL	1 unit increments	1 – 80 units
Tresiba® (200)	*Insulin Degludec*- long acting	200 units / mL	2 unit increments	2 – 160 units
Toujeo®	*Insulin Glargine*- long acting	300 units / mL	1 unit increments	1 – 80 units
Caution: While both Lantus® and Toujeo® contain insulin glargine, they are not bioequivalent and are not interchangeable. If switching between these brands, consult the product literature for advice.[3]				
Humalog® (100)	*Insulin Lispro*- short/ rapid acting	100 units / mL	1 unit increments	1-60 units
Humalog® (200)	*Insulin Lispro*- short/ rapid acting	200 units / mL	1 unit increments	1-60 units
Caution: Do not confuse with other Humalog® preparations which are not High-Strength insulins, such as Humalog® Mix 25 and Humalog® Mix 50.				

Evidence of Harm:

There is a risk of accidental mix-up with a variety of concentrations of insulin, and multiple branded products containing the same insulin[4]. It is not possible to accurately prescribe, dispense or administer these products solely with the name of the active substance (e.g. insulin lispro, insulin glargine, insulin degludec). It has also been identified that some patients and health care professionals have extracted insulin from pen devices using an insulin syringe and needle which can, in the case of high-strength insulin, lead to the administration of an insulin overdose because insulin syringes are calibrated for 100 units / mL insulin only.[2,5,6] This practice must be avoided with all insulin pens as it can lead to dosing errors in general and if a pen is used to provide insulin to more than one patient it can lead to transmission of blood borne viruses.

How to Reduce the Risks:

Safe Prescribing

- Always prescribe these insulins by brand name, and strength in cases where multiple strengths of the same brand exist.
- The word 'units' must be written in full. The abbreviation 'u' or 'iu' must never be used for units[7].
- Circle the strength of the high-strength insulin when prescribing e.g. Tresiba® (100) or Tresiba® (200).

Safe Supply, Storage, and Labelling

- Supply on a named patient basis: where possible, directly from the Pharmacy Department.
- Select and check the correct product by (1) brand name, and (2) strength where multiple strengths exist.
- In order to prevent missed doses, ensure sufficient supply (check total volume of pen and consider total units)

Safe Administration

- Check the brand and the strength against the insulin prescription
- Only administer using the pen device with appropriate needle attached. Never extract insulin from a pen device with a needle and syringe.
- Visually verify the dialled units on the dose counter of the pen, against the units prescribed.

Patient Factors

- Tresiba®: In order to self-inject, patients must be able to read the dose counter on the pen. Tresiba® (200) dials up in 2 unit increments so there is a danger of overdose if the visual verification step is skipped.

Governance

- Ensure awareness/education of clinical staff on the correct use of all insulin including high-strength insulin.[2]
- Ensure staff have access to technical information about how to administer insulin using pens, pen devices and vials.[5]
- Ensure a policy / procedure / guideline is in place regarding the correct use of insulin preparations. This should include information on the safe use of high-strength insulin.

References

1. NPSA. Rapid Response Report NPSA/2010/RRR013: Safer administration of insulin. June 2010. http://www.webcitation.org/6m3q1n7Gs **2**. EMA. Risk minimisation strategy for high-strength and fixed combination insulin products October 2015. http://www.webcitation.org/6m3q7iYCf **3.** Toujeo SPC available via www.hpra.ie Last updated: 25/01/2016. Accessed: 27/10/2016. http://www.webcitation.org/6m3qF5sji **4.** HPRA. High-Strength Insulin Preparations. April 2016. http://www.webcitation.org/6m3qOu5U0 **5**. Welsh Government. Patient Safety Alert PSA 004. July 2016. http://www.webcitation.org/6m3qUYdLB **6.** ISMP Quarterly Action agenda July 2016. http://www.webcitation.org/6m3qcceEJ **7.** IMSN. Best Practice Guidelines for the Safe Use of Insulin in Irish Hospitals. May 2010. http://www.webcitation.org/6m3qgTXX0 **8.** MMUH Medication Safety Alert No 15. September 2016. Copy on file.

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