



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Guidance on prevention of medication errors with high-strength insulins

A high-strength insulin is a medicine that contains insulin at a concentration of more than the standard 100 units/ml, which for many years has been the only strength available across the EU. Medicines containing high-strength insulin may allow patients to receive a high dose in a single injection, and help meet an increasing need for higher doses of insulin. However, there are differences in the way high-strength insulin products are used compared with existing insulin formulations of standard-strength and there is therefore a risk of medication errors and accidental mix-ups.

Patients and healthcare professionals are therefore advised to take extra care when using high-strength insulin medicines and to carefully follow the recommendations given below.

Recommendations for patients and carers

- If the concentration of insulin stated on your medicine pack is **higher than 100 units/ml**, you are using high-strength insulin. Read the instructions in your package leaflet carefully before using this medicine.
- If you are using other types of insulin alongside your high-strength insulin, always check the strength on the packaging and the label of each type of insulin before every injection to avoid mixing them up.
- The high-strength insulin is supplied in a pre-filled pen and it should only be used with this device. The dose counter of the pen device displays the number of units of insulin irrespective of strength.
- If you are being transferred from standard-strength insulin to a high-strength insulin you will usually be using the same number of units that you were when using the standard-strength insulin.¹ This also applies if you are being transferred from a high-strength to a standard-strength insulin. Always follow the instructions of your healthcare professional.
- If you are being transferred from standard strength insulin to high-strength insulin, your healthcare professional will highlight any differences in design between your high-strength insulin pen and other standard-strength insulin pens.
- You must never use a syringe to withdraw insulin from a pre-filled pen otherwise severe overdose may result.

¹ In exceptional cases your dose may need to be changed because of differences in the way the high-strength and standard strength solutions are taken up into the body – your doctor will advise you if this is needed.



- During the switch to high-strength insulin and in the weeks after the switch you should measure your blood sugar levels more frequently.
- If you have any questions speak to your healthcare professional.

Recommendations for healthcare professionals

- Ensure that your patients are adequately informed on how to use their high-strength insulin.
- The insulin is supplied in a pre-filled pen and it should only be used with this device. Healthcare professionals must never use a syringe to withdraw insulin from a pre-filled pen otherwise severe overdose can result.
- When switching patients from standard-strength insulin to an insulin formulation that is **not bioequivalent** (such as Toujeo, insulin glargine 300 units/ml), switching can be done on a unit to unit basis, but the dose may need to be adjusted to achieve target ranges for plasma glucose level. More detailed information on such dose adjustment is provided in the product information.
- Tell patients to closely monitor their blood sugar levels when starting high-strength insulin and in the weeks after.
- Always prescribe the insulin dose in units (“units” to be spelled out and stated in lower case) and include the dose frequency. The strength of the insulin formulation should also be always included in the prescription.
- Explain differences in the design of the package and the pre-filled pen for high-strength insulins and standard-strength insulins, especially if the patient has been transferred from standard-strength insulin to high-strength insulin. Focus on colour differentiation, warning statements on carton/label and other safety design features (such as tactile elements on the pre-filled pen).
- If different short- and long-acting insulins are being prescribed together, the differences in appearance and use between the two pen devices must be highlighted.
- Pharmacists should be aware that insulins are now available in different strengths.
- Pharmacists are encouraged to check that patients and carers are able to read the strength of insulin and the dose counter of the pen device before dispensing the medicine. Pharmacists should also check that patients have been trained on how to use the new pen.
- Patients who are blind or with poor vision must be instructed to always get assistance from another person who has good vision and is trained in using the insulin pen device.

In addition, healthcare professionals are encouraged to take the following precautions when storing and dispensing high strength insulins:

- Ensure that electronic and paper systems used to prescribe and dispense these medicines facilitate correct selection of the medicine and avoid confusion with other medicines.
- Always carefully check the product selected in electronic prescribing or dispensing systems.
- Ensure that storage arrangements for combination insulin medicines facilitate correct selection of the medicine and avoid confusion with other medicines.

More information

Examples of high-strength insulin formulations are [Tresiba](#) (200 units/ml insulin degludec) and [Humalog](#) (insulin lispro 200 units/ml).

[Toujeo](#) (insulin glargine 300 units/ml), although it is also a high-strength insulin, is not bioequivalent to insulin glargine 100 units/ml (such as Lantus) which means that these insulins are not interchangeable. Therefore, when switching from insulin glargine 100 units/ml to Toujeo, this can be done on a unit to unit basis, but a higher Toujeo dose (approx. 10-18%) may be needed to achieve target ranges for plasma glucose level.

Further information on the safe use of these medicines and other ways to minimise the possible risk of medication errors with these medicines can be found in the [guidance on risk minimisation strategies for high-strength and fixed-combination insulin products](#).