



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Guidance on prevention of medication errors with diabetes medicines containing insulin and a non-insulin active substance

Recently, diabetes medicines that contain insulin in combination with a non-insulin active substance have been approved in the EU. These types of combination medicines are advantageous to patients since they reduce the number of injections they need to have and may help them keep to their treatment. However, there is a potential risk of patients receiving too little or too much of their medicine because of confusion that may arise over the way the doses are expressed for the individual components – the dose of the insulin is expressed in units while the dose of the non-insulin medicine may be expressed in other units such as mg.

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

### Recommendations for patients and carers

- Read the instructions in your package leaflet carefully before using your medicine.
- One dose step contains a set number of units of insulin plus a fixed amount of the non-insulin medicine. Before you use your medicine be clear on how many dose steps you require. Your healthcare professional will give you this information.
- Your healthcare professional will explain the design and features of your pen, including how the dose counter of the pen device shows the number of dose steps to be injected.
- During the switch to this type of combination medicine and in the weeks after the switch you should measure your blood sugar levels more frequently.
- If you have any questions about your treatment speak to your healthcare professional.

### Recommendations for healthcare professionals

- Ensure that your patients are adequately informed on how to use their medicine.
- Explain to your patient that the dose counter of the pen device shows the number of dose steps to be injected. Always prescribe the dose of insulin and the dose of non-insulin to be injected as well as the dose frequency.



- If the patient has been transferred from another pen device, highlight the differences in design between the two devices.
- 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.
- Tell patients to closely monitor their blood sugar levels when starting a medicine containing insulin and a non-insulin active substance and in the weeks after.
- Pharmacists are encouraged to check that patients and carers are able to read 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.

In addition, healthcare professionals are encouraged to take the following precautions when storing, prescribing and dispensing diabetes medicines that contain insulin in combination with a non-insulin active substance:

- 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.

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#### **Further information**

An example of a diabetes medicine that contains insulin in combination with a non-insulin active substance is [Xultophy](#) (100 units/ml insulin degludec and 3.6 mg/ml liraglutide) which was authorised in the EU on.

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