

Risk of mix-ups between insulin Fiasp[®]▼ (fast-acting insulin aspart) and Tresiba[®] (basal insulin degludec)

Direct Healthcare Professional Communication

16 April 2018

Dear Healthcare Professional,

Novo Nordisk A/S in agreement with the European Medicines Agency and the Medicines and Healthcare Products Regulatory Agency (MHRA) would like to inform you of the following:

Summary

- Cases have been reported where patients have mistakenly administered the mealtime insulin Fiasp[®] (currently available as yellow pens) instead of the basal insulin Tresiba[®] (available as light green pens) or vice versa.
- Such mix-ups can have serious clinical consequences, specifically hypo- or hyperglycaemia.
- Advise patients using both products to be extra vigilant and always check the name of the insulin before each injection to make sure that they administer the correct insulin.
- To strengthen the differentiation between the products, from 01 June 2018 Fiasp[®] will be available as red and yellow cartridges, pre-filled pens and vials (see Figure 1 below).

What to be aware of while dispensing existing products

- Check if the patient also uses Tresiba[®].
- If so, remind the patient of the risk of mix-ups and the need for extra vigilance.
- Advise them to check the name of the insulin before each injection and to take extra care if preparing injections in poor light.
- Advise patients to contact their diabetes nurse or doctor or their GP immediately if they do mix up injections

Background information

A new colour for Fiasp[®] products will be introduced from 01 June 2018 in order to increase differentiation (see illustrations). Until the colour change of Fiasp[®] products has been fully implemented patients should be extra vigilant.

Figure 1. New Fiasp[®] presentation:



Cases have been reported where patients have mistakenly administered mealtime Fiasp[®] instead of basal insulin Tresiba[®] mainly due to similarity in colour between the products. Poor lighting conditions have contributed to some of the mix-ups.

Figure 2. Current Fiasp[®] and Tresiba[®] presentation:



Call for reporting

Adverse reactions relating to Fiasp[®] or Tresiba[®], including medication errors should be reported to Novo Nordisk [Customer Care Centre 0845 6005055] or to local authorities: MHRA Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Company contact point

Further information can be obtained at novonordisk.com or by contacting Novo Nordisk Limited Customer Care Centre 0845 6005055.

Kind regards,

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