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IMMEDIATE MESSAGE TO:

Medical Directors NHS Boards
Directors of Pharmacy

8 December 2023

Dear Healthcare Professional,

NATIONAL PATIENT SAFETY ALERT /2023/016/DHSC – POTENTIAL FOR INAPPROPRIATE DOSING OF INSULIN WHEN SWITCHING INSULIN DEGLUDEC (TRESIBA®) PRODUCTS

Please see attached National Patient Safety alert. Following the Medicine Supply Notification issued on 24 May 2023, detailing a shortage of Tresiba® (insulin degludec) FlexTouch® 100units/ml solution for injection 3ml pre-filled pens.The Medication Safety Officer (MSO) network has highlighted that in response to this shortage, some patients may have been switched to Tresiba® (insulin degludec) FlexTouch® 200units/ml solution for injection 3ml pre-filled pens. Tresiba® FlexTouch® pen delivery devices dial up in unit increments rather than volume resulting in a small number of patients being incorrectly advised to administer half the number of units for onward transmission as below :

Please could all Directors of Pharmacy please forward this alert to:-

- Chief Pharmacists
- Hospital Pharmacists
- Community Pharmacists

Please could Medical Directors arrange to forward this alert on to:-

- Clinical Leads Diabetes
- General Practitoners
- Dispensing Doctors
- Relevant Clinics Private Healthcare providers

Thank you for your co-operation.
Yours sincerely

IRENE FAZAKERLEY
Medicines Policy Team

National Patient Safety Alert

Department of Health & Social Care

NHS England

Potential for inappropriate dosing of insulin when switching insulin degludec (Tresiba®) products

Date of issue:	8-Dec-23	Reference no:	NatPSA/2023/016/DHSC

This alert is for action by: All organisations involved in prescribing, dispensing and administering Tresiba® products.

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards) and supported by clinical leaders in diabetes, GP practices, pharmacy services in all sectors, private healthcare providers, those working in the Health and Justice sector.

Explanation of identified safety issue:

A Medicine Supply Notification issued on 24 May 2023, detailed a shortage of Tresiba® (insulin degludec) FlexTouch® 100units/ml solution for injection 3ml pre-filled pens. Advice on how to manage this supply issue can be found on the Medicine Supply Tool.

The Medication Safety Officer (MSO) network has highlighted that in response to this shortage, some patients may have been switched to Tresiba® (insulin degludec) FlexTouch® 200units/ml solution for injection 3ml pre-filled pens. Tresiba® FlexTouch® pen delivery devices dial up in unit increments rather than volume.

However, a small number of patients have been **incorrectly** advised to administer half the number of units.

MSOs have highlighted five reports of patients being **incorrectly** advised to reduce the number of units of insulin to be administered. These reports suggest that errors have occurred at the prescribing, dispensing and administration stages of the medicine journey. One case described a patient requiring treatment in hospital for diabetic ketoacidosis because of a reduced insulin dose.

Actions required

Actions to be completed as soon as possible and no later than 22nd December 2023

All providers MUST ensure that patients who have been switched to Tresiba® (insulin degludec) FlexTouch® 200units/ml solution for injection 3ml pre-filled pens are:

1. Made aware that Tresiba® FlexTouch® pen delivery devices dial up in unit increments rather than volume and no dose change is necessary.

Primary care providers should:

2. Continue to follow the advice in the Medicine Supply Notification.
3. When prescribing Tresiba® 100units/ml Penfill® **cartridges**, ensure the patient is also supplied with a compatible Novo Nordisk insulin delivery system and appropriate needles.
4. For a small cohort of patients unable to use Tresiba® 100units/ml Penfill® cartridges a switch to Tresiba® FlexTouch® **200units/ml** prefilled pens may be necessary, clinicians should not adjust the dose of insulin.
5. Ensure all patients initiated on a new device are counselled on the change and provided with training on their use, including signposting to training videos, and the potential need for closer monitoring of blood glucose levels.

Secondary care providers should:

6. Avoid initiating patients on Tresiba® (insulin degludec) FlexTouch® 200units/ml prefilled pens due to supply constraints.
7. If unable to switch to Tresiba 100units/ml Penfill® cartridges, consider initiating a patient on an alternative long-acting insulin.

For further detail, resources and supporting materials see: Enter specific webpage provided by alert issuer

For any enquiries about this alert contact: dhscmedicinesupplyteam@dhsc.gov.uk

Additional information:

Clinical information

Insulin degludec is a basal insulin for once-daily subcutaneous administration at any time of the day, preferably at the same time every day. In people with type 2 diabetes mellitus, it can be administered alone, in combination with oral antidiabetic drugs as well as in combination with bolus insulin. It is dosed in accordance with the individual patient's needs. On occasions when administration at the same time of the day is not possible, insulin degludec allows for flexibility in the timing of insulin administration. A minimum of 8 hours between injections should always be ensured.

Insulin degludec is available in 2 strengths: 100 units/ml and 200 units/ml. The dose-counter window of the pen device shows the number of units that will be injected, irrespective of strength. Therefore, no dose conversion is needed when transferring a person from one strength of insulin degludec to another.

NICE guidance suggests the use of twice daily insulin detemir as long-acting basal insulin therapy for adults with type 1 diabetes. Insulin degludec is an alternative once-daily basal insulin therapy where there is a particular concern about nocturnal hypoglycaemia, or if people need help from a carer or healthcare professional to administer injections. Insulin glargine is another alternative once-daily basal insulin therapy if insulin detemir is not tolerated or the person has a strong preference for once-daily basal injections.

Healthcare professionals are reminded of the significant risk and fatal overdosing incidents have arisen from staff extracting insulin directly from the pen or cartridge. Further information can be found in the Enduring Standards document (here) under the section on 'Selecting medication presentations for safety'

Supply Summary

Tresiba® FlexTouch® 100units/ml pre-filled pens are out of stock until December 2024. Prescribers should not initiate new patients on Tresiba® FlexTouch® 100units/ml pens during this time and should consider prescribing Tresiba® Penfill® cartridges with a NovoPen® 6 or Echo® Plus, which can support increased demand. Tresiba® FlexTouch® 200units/ml pre-filled pens are not able to support increased demand during the affected period and should not be prescribed as an alternative to Tresiba® FlexTouch® 100units/ml pens. Where switching to Tresiba® Penfill® cartridges is not considered suitable, due to a patient's dexterity or ability to use the new device, seek advice from specialist diabetes teams on the use of an alternative insulin.

References:

1. Tresiba® (insulin degludec) SmPC
2. BNF insulin degludec
3. BNF insulin preparations
4. Novo Nordisk quick guide to using NovoPen® 6 or NovoPen Echo® Plus
5. NICE guidance: Type 1 diabetes in adults (insulin therapy)
6. Smart insulin pens - JDRF, the type 1 diabetes charity
7. Novo Nordisk 'Connected Pens'
8. NovoPen® 6 and NovoPen Echo® Plus resources
9. NHS England » Purchasing for safety

Stakeholder engagement:

The following stakeholders have been engaged in the management and consulted in the drafting of this alert: NHS Specialist Pharmacy Service, National MSO network, Medicine Shortage Response Group and NHS England.

Advice for Central Alerting System (CAS) officers and risk managers

This is a safety critical and straightforward National Patient Safety Alert. In response to CHT/2019/001 and CHT/2023/002 your organisation should have developed new processes to ensure appropriate oversight and co-ordination of all National Patient Safety Alerts. CAS officers should send this Alert to executive lead nominated in their new process to coordinate implementation of safety critical and complex National Patient Safety Alerts, copying in the leads identified on page 1.