Direct Healthcare Professional Communication
31 January 2023

Norditropin (somatropin) NordiFlex® and Norditropin® FlexPro®: action needed from prescribers due to supply shortage

Dear Healthcare professional,

Novo Nordisk UK, in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA), would like to inform you of the following:

Summary:

- There is a shortage of Norditropin NordiFlex and Norditropin FlexPro due to supply constraints at our manufacturing site, which will affect the delivery of the medicines to the UK. The shortage is not a consequence of any safety or quality related issues.
- No new patients should be initiated on either Norditropin NordiFlex or Norditropin FlexPro as of the date of this letter, until Novo Nordisk UK advise otherwise. We will update you regularly when we have updates.
- Patients on Norditropin NordiFlex (5mg, 10mg and 15mg) should be transferred to another alternative growth hormone preparation as soon as possible and as per the prescribers' clinical discretion. We currently have very limited supply and expect to have no further supply from February 2023 to Quarter 1 2024 (at the earliest).
- Please do not switch any patients from one Norditropin product to another Norditropin product as the stock issues affect all products. Please be reminded that Norditropin SimpleXx was discontinued in the UK from September 2022.
- The supply situation could result in patients missing the required doses, which may in turn lead to suboptimal treatment of patients. Healthcare professionals are therefore urged to ensure that patients prescribed Norditropin NordiFlex and FlexPro (in case of prolonged supply challenge) are made aware and are transferred to an alternative growth hormone therapy.
- Novo Nordisk anticipates that these intermittent supply shortages for Norditropin FlexPro (5mg, 10mg and 15mg) will continue throughout 2023 with the situation potentially improving during the second half of the year.
- Transfer to an alternative growth hormone therapy should happen under supervision of a healthcare professional. Additional guidance and support should be provided to patients and caregivers until they are comfortable with the alternative product supplied to them
- A Medicines Shortage Notification (MSN) (MSN/2023/001) has been issued by the Department of Health and Social Care (DHSC) on 03/01/2023.

Background
Norditropin (somatropin) is a biosynthetic human growth hormone indicated to treat growth failure in children and as a growth hormone replacement in adults. See the Norditropin Summary of Product Characteristics (SmPC) for the detailed therapeutic indication at https://www.medicines.org.uk/emc/product/11756/smpc or search on the EMC website (https://www.medicines.org.uk/emc).

Current Status
Norditropin NordiFlex (5mg, 10mg and 15mg)
We currently have very limited supply and expect to have no further supply from February 2023 to Quarter 1 2024 (at the earliest).

Norditropin FlexPro (5mg, 10mg and 15mg)
We will have an intermittent supply of Norditropin FlexPro throughout 2023 with the situation potentially improving during the second half of the year. We are working with our homecare partners to adjust the frequency of deliveries appropriately to minimise the impact and enable continuity of supply to patients currently prescribed our medicines. We are working with the Department of Health and Social Care (DHSC), Medicines and Healthcare products Regulatory Agency (MHRA) and other relevant authorities to closely monitor our stock levels and act accordingly until a return to stable levels of supply has been achieved.

Mitigating actions
Healthcare professionals are advised to use locally approved alternatives for both Norditropin NordiFlex and Norditropin FlexPro (if they face prolonged FlexPro supply issues). Switching between types of medicines should only be done in consultation with a healthcare professional and requires strict medical supervision along with any prescribing requirements as stated in the relevant SmPC.

Substitution with locally approved alternative
Please do bear in mind that the available literature on possible consequences of switching brand during recombinant human growth hormone treatment includes concerns involving dosing errors and treatment lapses from having to learn how to use a new device and impaired adherence related to patient-family frustration and anxiety.[1]
To mitigate the above risks, additional guidance and support should be provided to patients and caregivers until they are comfortable with the alternative product supplied to them.

Call for reporting
Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme.
Please report:

- **all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason**

- **all suspected ADRs associated with new drugs and vaccines identified by the black triangle▼**

It is easiest and quickest to report ADRs online via the Yellow Card website https://yellowcard.mhra.gov.uk/ or via the Yellow Card app available from the Apple App Store or Google Play Store. Suspected side effects can also be reported by calling 0800 731 6789 for free.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

Adverse events should also be reported to Novo Nordisk Limited at 0800 023 2573. Calls may be monitored for training purposes.

Company contact:

If you have any questions about this letter, please contact Novo Nordisk customer care centre on 0800 023 2573.

I understand the uncertainty and concern this shortage may cause patients prescribed the products mentioned above. This is not something we are taking lightly, and we are working hard to solve these challenges.

Yours Sincerely

Avideh Nazeri

Avideh Nazeri MD MBA
Vice President
Clinical Development, Medical & Regulatory Affairs (CMR) UK

Annexes
Reference :

1. Grimberg A et al Endocr Pract. 2012 May-Jun;18(3):307-16. doi: 10.4158/EP11217.OR. PMID: 21940275.