



Urgent Field Safety Notice

NordiPen[®] medical device used with 5 mg and 10 mg Norditropin[®] SimpleXx[®] ("somatropin")

28062013

Advice on use of Novo Nordisk's NordiPen[®]

Date: 01 July 2013

Attention: Health Care Professionals

Details on affected devices:

NordiPen[®] 5 mg and NordiPen[®] 10 mg

The issue only concerns NordiPen[®] 5 mg and 10 mg products from specific lots (Lot Number beginning with A, B or C). However, not all patients using pens from these lots will experience problems.

How to Find the Lot Number?

The Lot Number is located on the mechanical section below the push button and can be exposed by turning the dose selector clockwise. The Lot Number in the example image begins with 'J'.



Description of the problem:

This letter is to bring to your attention that a few users have complained about challenges assembling the NordiPen[®] correctly. It is important to state that this is not drug related.

Novo Nordisk Limited

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**Novo Nordisk Customer
Care Centre 0845 600 5055**
*Calls may be monitored
for training purposes*

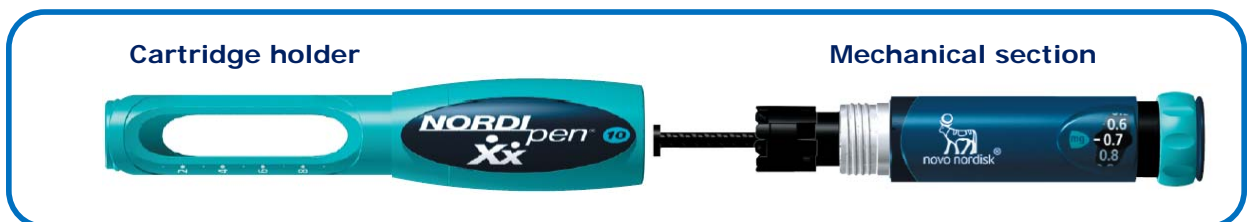
Internal investigations have concluded that a component supplier change led to a minor change in the shape of the metal threads which join the mechanical section to the cartridge holder. As a result, the metal threads on the mechanical section are more likely to cut into the plastic threads inside the cartridge holder resulting in increased resistance during assembly. Increased resistance during assembly can result in a patient assuming a pen is correctly assembled when it is not, which could result in under dosing.

Advice on action to be taken by the user:

It is important to note that a correctly assembled pen from lots beginning with A, B or C will deliver the correct dose. The information below will provide additional instructions to ensure correct assembly.

We kindly ask you to share the following instruction regarding proper pen assembly with your patients using the NordiPen®.

Additional information regarding assembly of NordiPen® 5 mg and NordiPen® 10 mg



Reference is made to the **Instruction Manual** that comes with NordiPen®, **page 4, step 5.**



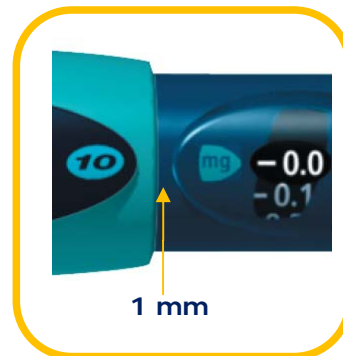
With the **starting position** shown in above illustration, it takes **3 complete turns** (3 times 360°) to screw the two parts tightly together.

If a **slight resistance** is felt **in the first turn**, **keep turning** until 3 complete turns are reached.

If a **strong resistance** is felt **before** 3 complete turns are reached, the threads inside the cartridge holder might be **misaligned**. In that case, **unscrew** the mechanical section from the cartridge holder, and **start over again**, ensuring the threads are correctly aligned.

The two parts are **correctly assembled** when

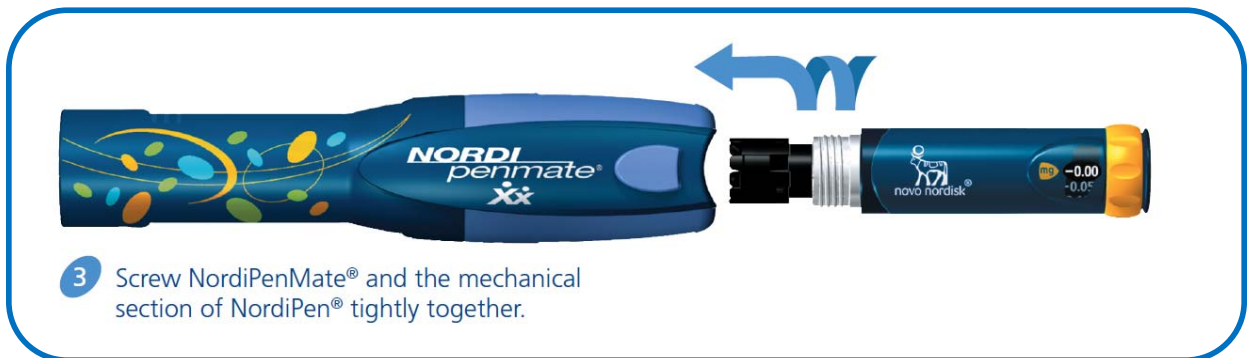
- **3 turns** are reached, and
- The **strength indicator** on the cartridge holder and the **mg pointer** on the mechanical section are **aligned**, and the **distance** between the edge of the cartridge holder and the raised dose indicator window is approximately **1 mm**, as shown in the illustration below.



Additional information regarding assembly of NordiPen® 5 mg and NordiPen® 10 mg when using NordiPenMate®



Reference is made to the **Instruction Manual** that comes with NordiPenMate®, **page 3, step 3.**



With the **starting position** shown in above illustration, it takes **4 complete turns** (4 times 360°) to screw the two parts tightly together.

If a **slight resistance** is felt **in the first turn**, **keep turning** until 4 complete turns are reached.

If a **strong resistance** is felt **before** 4 complete turns are reached, the threads inside NordiPenMate® might be **misaligned**. In that case, **unscrew** the mechanical section from NordiPenMate®, and **start over again**, ensuring the threads are correctly aligned.

The two parts are **correctly assembled** when

- **4 turns** are reached, and
- The **blue insertion button** on NordiPenMate® and the **mg pointer** on the mechanical section are **aligned**, and the **distance** between the edge of NordiPenMate® and the raised dose indicator window is approximately **3 mm**, as shown in the illustration below.



For your convenience, we have created a letter for patients (as shown on the MHRA website) explaining how to assemble the pen correctly along with:

- “Additional information regarding assembly of NordiPen® 5 mg and NordiPen® 10 mg”
- Additional information regarding assembly of NordiPen® 5 mg and NordiPen® 10 mg when using NordiPenMate®”

If you or any of your patients have questions or concerns, please contact Novo Nordisk Customer Service on 0845 600 5055.

Please can you complete the Field Safety Notice on page 6 to confirm receipt of the Field Safety Notice and send to Novo Nordisk within 3 working days.

The undersigned confirms that this notice has been notified to the MHRA.



Janet Penning
Regulatory & Safety Manager
Novo Nordisk Ltd.



Broadfield Park
Brighton Road
Crawley
West Sussex RH11 9RT
United Kingdom



Urgent Field Safety Notice

**NordiPen® medical device used with 5 mg and 10 mg Norditropin® SimpleXx®
("somatropin")**

28062013

Advice on use of Novo Nordisk's NordiPen®

Confirmation of Receipt of Field Safety Notice

Please can you complete the table below and send to Novo Nordisk Safety department via email or fax:

Contact name	
Contact title	
Contact address	
Contact phone no.	
Contact signature	
Date	

Email address: NNGB-Safety@novonordisk.com

Fax number: 01293 611819

Thank you very much for your help and understanding.

Additional information on how to assemble the NordiPen® medical device correctly

To:
Users of NordiPen®

From:
Novo Nordisk UK/IRE

July 1st, 2013

Subject: NordiPen® medical device used with 5 mg and 10 mg Norditropin® SimpleXx® (“somatropin”)

This letter is to bring to your attention that a few users have complained about challenges assembling the NordiPen® correctly. It is important to state that this is not drug related.

Please be aware that the issue described below only concerns NordiPen® products from specific lots (Lot Number beginning with A, B or C). However, not all patients using pens from these lots will experience problems.

How to Find the Lot Number?

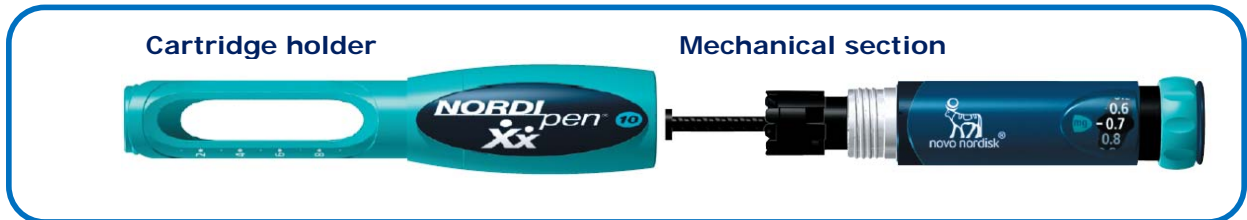
The Lot Number is located on the mechanical section below the push button and can be exposed by turning the dose selector clockwise. The Lot Number in the example image begins with 'J'.



We have in page 2 and 3 attached additional guidance on how to correctly assemble the NordiPen® and the NordiPenMate®, respectively.

If you have any questions or concerns, please contact your doctor or Novo Nordisk Customer Care on +44 (0)845 600 5055 in the country where you are situated.

Additional information regarding assembly of NordiPen® 5 mg and NordiPen® 10 mg



Reference is made to the **Instruction Manual** ([NordiPen user-guide](#)) that comes with NordiPen®, **page 4, step 5**.



With the **starting position** shown in above illustration, it takes **3 complete turns** (3 times 360°) to screw the two parts tightly together.

If a **slight resistance** is felt **in the first turn**, **keep turning** until 3 complete turns are reached.

If a **strong resistance** is felt **before** 3 complete turns are reached, the threads inside the cartridge holder might be **misaligned**. In that case, **unscrew** the mechanical section from the cartridge holder, and **start over again**, ensuring the threads are correctly aligned.

The two parts are **correctly assembled** when

- **3 turns** are reached, and
- The **strength indicator** on the cartridge holder and the **mg pointer** on the mechanical section are **aligned**, and the **distance** between the edge of the cartridge holder and the raised dose indicator window is approximately **1 mm**, as shown in the illustration below.



Additional information regarding assembly of NordiPen® 5 mg and NordiPen® 10 mg when using NordiPenMate®



Reference is made to the **Instruction Manual** ([NordiPenMate user-guide](#)) that comes with NordiPenMate®, **page 3, step 3**.



With the **starting position** shown in above illustration, it takes **4 complete turns** (4 times 360°) to screw the two parts tightly together.

If a **slight resistance** is felt **in the first turn**, **keep turning** until 4 complete turns are reached.

If a **strong resistance** is felt **before** 4 complete turns are reached, the threads inside NordiPenMate® might be **misaligned**. In that case, **unscrew** the mechanical section from NordiPenMate®, and **start over again**, ensuring the threads are correctly aligned.

The two parts are **correctly assembled** when

- **4 turns** are reached, and
- The **blue insertion button** on NordiPenMate® and the **mg pointer** on the mechanical section are **aligned**, and the **distance** between the edge of NordiPenMate® and the raised dose indicator window is approximately **3 mm**, as shown in the illustration below.



Urgent Field Safety Notice - Updated

**NordiPen® medical device used with 5 mg and 10 mg Norditropin® SimpleXx®
("somatropin")**

28062013

Advice on use of Novo Nordisk's NordiPen®

Date: 03 September 2013

Attention: Health Care Professionals

Details on affected devices and description of the problem:

NordiPen® 5 mg and NordiPen® 10 mg

This letter supplements the previous Field Safety Notice (01-Ju-2013, Ref: 2013/006/025/081/021) by including additional information regarding the urgency of communication with affected patients.

If you have already received communication regarding this matter and have communicated with your affected patients, then please disregard this notice. If you have not, then we request that you immediately share the following information, via a letter, email, telephone or in person, in case you have not already informed your patients affected by this Field Safety Notice regarding NordiPen® 5 mg and 10 mg.

The issue only concerns NordiPen® 5 mg and 10 mg products from specific lots (Lot Number beginning with A and B). However, not all patients using pens from these lots will experience problems.

How to Find the Lot Number?

The Lot Number is located on the mechanical section below the push button and can be exposed by turning the dose selector clockwise. The Lot Number in the example image begins with 'B'.



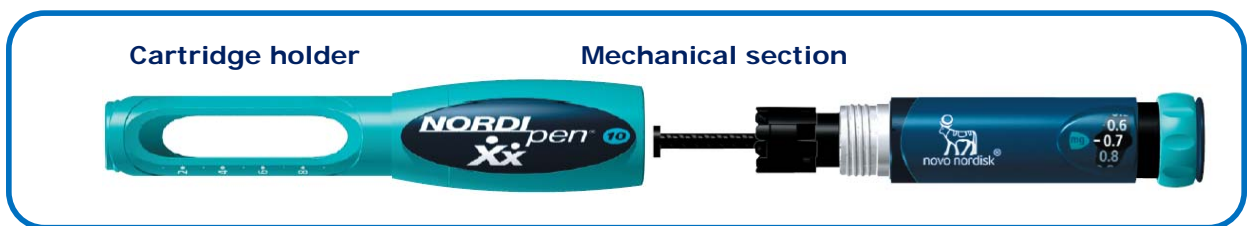
Advice on action to be taken by the user:

Incorrect assembly can lead to under dosing. It is important to emphasize that a correctly assembled pen from the affected batches will administer the correct dose. Please be aware that the issue described below only concerns NordiPen® products from specific lots (Lot Number beginning with A or B).

However, not all patients using pens from these lots will experience problems. It is important to note that a correctly assembled pen from lots beginning with A or B will deliver the correct dose.

We kindly ask you to share the following instructions regarding proper pen assembly with your patients using the NordiPen®:

Additional information regarding assembly of NordiPen® 5 mg and NordiPen® 10 mg



Reference is made to the **Instruction Manual** ([NordiPen user-guide](#)) that comes with NordiPen®, **page 4, step 5**.



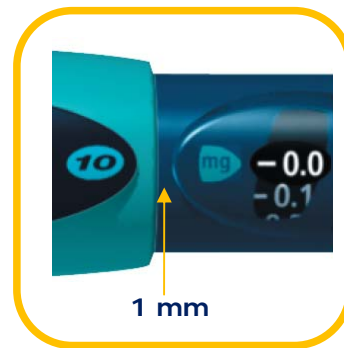
With the **starting position** shown in above illustration, it takes **3 complete turns** (3 times 360°) to screw the two parts tightly together.

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The two parts are **correctly assembled** when

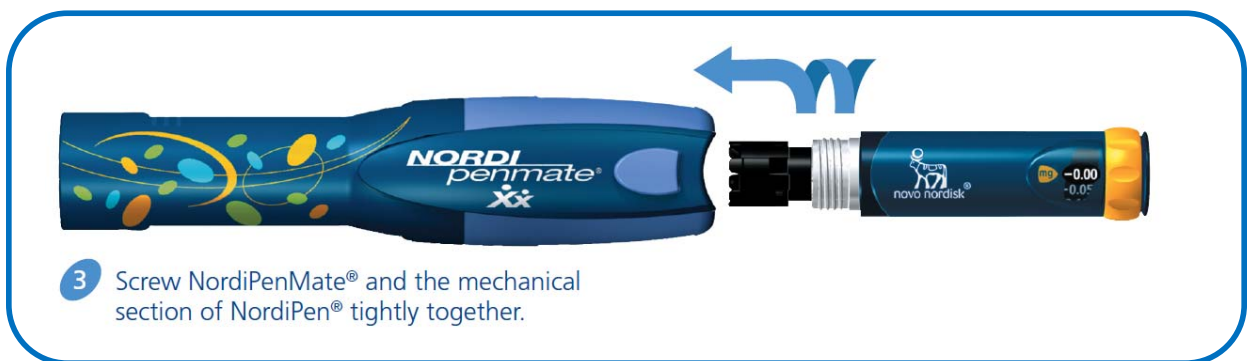
- **3 turns** are reached, and
- The **strength indicator** on the cartridge holder and the **mg pointer** on the mechanical section are **aligned**, and the **distance** between the edge of the cartridge holder and the raised dose indicator window is approximately **1 mm**, as shown in the illustration below.



Additional information regarding assembly of NordiPen® 5 mg and NordiPen® 10 mg when using NordiPenMate®



Reference is made to the **Instruction Manual** ([NordiPenMate user-guide](#)) that comes with NordiPenMate®, **page 3, step 3.**



With the **starting position** shown in above illustration, it takes **4 complete turns** (4 times 360°) to screw the two parts tightly together.

If a **slight resistance** is felt **in the first turn**, **keep turning** until 4 complete turns are reached.

If a **strong resistance** is felt **before** 4 complete turns are reached, the threads inside NordiPenMate® might be **misaligned**. In that case, **unscrew** the mechanical section from NordiPenMate®, and **start over again**, ensuring the threads are correctly aligned.

The two parts are **correctly assembled** when

- **4 turns** are reached, and
- The **blue insertion button** on NordiPenMate® and the **mg pointer** on the mechanical section are **aligned**, and the **distance** between the edge of

NordiPenMate® and the raised dose indicator window is approximately **3 mm**, as shown in the illustration below.



For your convenience, we have attached a letter for patients explaining how to correctly assemble the pen.

If you or any of your patients have questions or concerns, please contact Novo Nordisk Customer Service on 0845 600 5055.

Please can you complete the Field Safety Notice on page 6 to confirm receipt of the Field Safety Notice and send to Novo Nordisk within 3 working days.

The undersigned confirms that this notice has been notified to the MHRA.



Janet Penning
Regulatory & Safety Manager
Novo Nordisk Ltd.
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Urgent Field Safety Notice - Updated

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Date	

Email address: NNGB-Safety@novonordisk.com

Fax number: 01293 611819

Thank you very much for your help and understanding.



Additional information on how to assembly the NordiPen® medical device correctly

To:
Users of NordiPen®

From:
Novo Nordisk Ltd.

August 30th, 2013
Reference: 20130613

Subject: NordiPen® medical device used with 5 mg and 10 mg Norditropin® SimpleXx® (“somatropin”)

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Please be aware that the issue described below only concerns NordiPen® products from specific lots (Lot Number beginning with A or B). However, not all patients using pens from these lots will experience problems.

How to Find the Lot Number?

The Lot Number is located on the mechanical section below the push button and can be exposed by turning the dose selector clockwise. The Lot Number in the example image begins with 'B'.



We have in pages 2, 3 attached additional guidance on how to correctly assembly the NordiPen® and the NordiPenMate®, respectively.

If you have any questions or concerns, please contact your doctor or Novo Nordisk Customer Service on 0845 600 5055.

Thank you very much for your understanding.

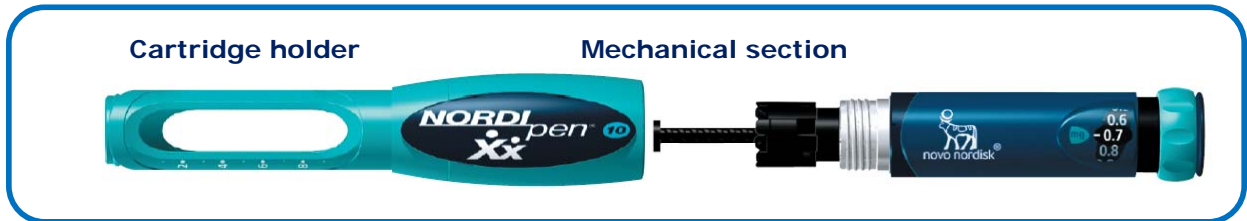
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Registered Office:
No: 1118740

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Care Centre 0845 600 5055**
*Calls may be monitored
for training purposes*

Additional information regarding assembly of NordiPen® 5 mg and NordiPen® 10 mg



Reference is made to the **Instruction Manual** ([NordiPen user-guide](#)) that comes with NordiPen®, **page 4, step 5**.



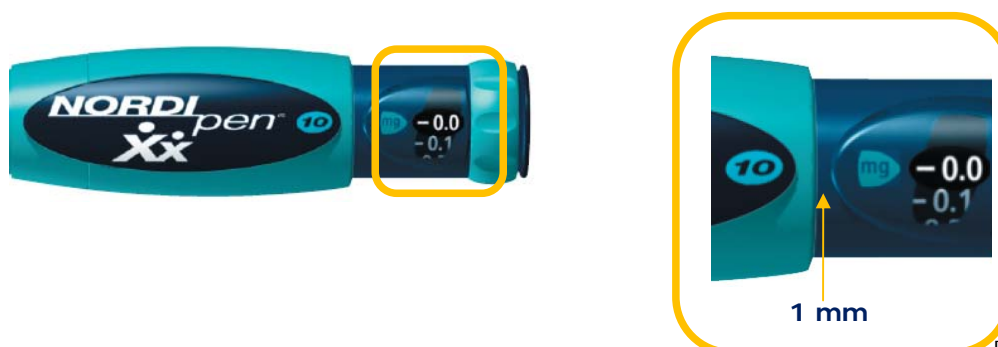
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Additional information regarding assembly of NordiPen® 5 mg and NordiPen® 10 mg when using NordiPenMate®



Reference is made to the **Instruction Manual** ([NordiPenMate user-guide](#)) that comes with NordiPenMate®, **page 3, step 3.**



With the **starting position** shown in above illustration, it takes **4 complete turns** (4 times 360°) to screw the two parts tightly together.

If a **slight resistance** is felt **in the first turn**, **keep turning** until 4 complete turns are reached.

If a **strong resistance** is felt **before** 4 complete turns are reached, the threads inside NordiPenMate® might be **misaligned**. In that case, **unscrew** the mechanical section from NordiPenMate®, and **start over again**, ensuring the threads are correctly aligned.

The two parts are **correctly assembled** when

- **4 turns** are reached, and
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