

Direct Healthcare Professional Communication

21 Jan 2024

**Important Prescribing Information: Notice to Healthcare Professionals Regarding Instructions for Use for Leqvio (inclisiran) injection, 284 mg/1.5 mL (189 mg/mL) in a single-dose pre-filled syringe**

**Dear Health Care Professionals,**

Novartis Saudi LTD, in agreement with the Saudi Food and Drug Authority (SFDA) would like to inform you of the following:

**Summary**

The purpose of this letter is to provide important new user handling instructions for the Leqvio (inclisiran) single-dose pre-filled syringe injection.

**Further information on the safety concern and the recommendations**

Leqvio is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet.

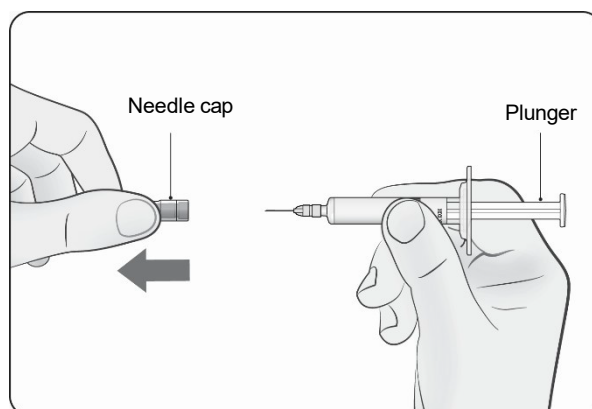
Novartis has received a small number of complaints associated with difficulty moving the syringe plunger that can result in the inability to inject Leqvio. This issue occurs infrequently globally (< 0.1%). The reviewed data confirms that there is no clinically relevant risk to patient safety.

To ensure optimal use of Leqvio for patients and healthcare professionals while technical solutions are investigated to alleviate the issue, Novartis is sharing with you important information for you to be aware of before injecting Leqvio (please see Prescriber Actions below).

**Prescriber Actions:**

Do not remove the needle cap until you are ready to inject (see Figure 1 below). In rare cases, early removal of the needle cap prior to injection can lead to drying of the drug product within the needle, which can result in needle clogging.

Figure 1: Removal of needle cap on a pre-filled syringe:



If following insertion of the needle you cannot depress the plunger, use a new pre-filled syringe. Novartis will provide a replacement for any impacted Leqvio syringes. For product replacement, please contact Novartis at Toll Free Number: 8001240078 or [adverse.events@novartis.com](mailto:adverse.events@novartis.com).

### Call for reporting

Please report any suspected adverse reactions associated with the use of Leqvio in accordance with the national requirements to:

Novartis Saudi Ltd  
Toll Free Number: 8001240078 Phone:  
+966112658100  
Fax: +966112658107  
Email: [adverse.events@novartis.com](mailto:adverse.events@novartis.com) Or by  
online: <https://report.novartis.com/>



Saudi Food and Drug Authority National  
Pharmacovigilance Center  
Unified Contact Center: 19999 Email:  
[npc.drug@sfda.gov.sa](mailto:npc.drug@sfda.gov.sa)  
Or by online: <https://ade.sfda.gov.sa>

We sincerely apologize for any inconvenience this may have caused and thank you for your continued support.

Sincerely,

**Hajer Mohammed Alsaleh**  
**Patient safety manager/ QPPV**  
**Novartis Saudi**