06.04.2018

Direct Healthcare Professional Communication

▼Inhixa (enoxaparin sodium) solution for injection: rare cases of self-activation of safety device in unopened, unused pre-filled syringes.

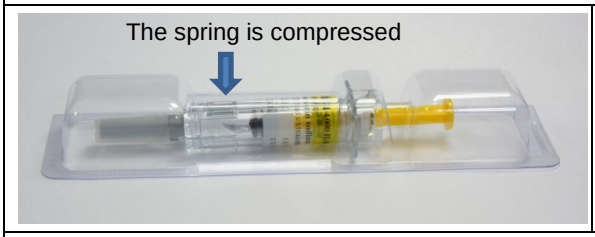
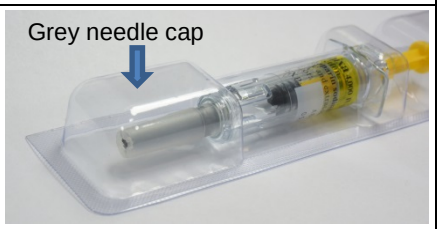
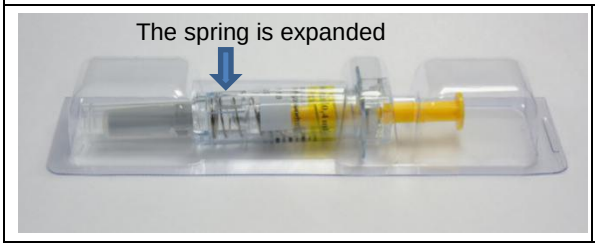
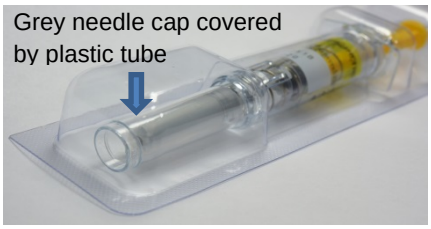
Dear Healthcare professional,

Techdow Europe AB in agreement with the European Medicines Agency and relevant local Competent Authorities would like to inform you of the following:

Summary

- In very rare cases, premature self-activation of the safety device has been observed in unused, unopened pre-filled Inhixa syringes (see Figure 1 below); when premature activation has occurred, medicine administration is not possible.
- **Pharmacists should visually check all devices before dispensing Inhixa and make sure they have sufficient stock of Inhixa available as replacements.**
- There is negligible risk of needle stick injury when handling these pre-filled syringes, since the safety device ensures full coverage of the needle; the risk of a patient missing a dose can be minimised by the above checks and advice to patients.

Figure 1. Pre-activation is easily detectable:

<table>
<tr><th colspan="2">Normal pre-filled syringes</th></tr>
<tr><td> 
</td><td> 
</td></tr>
<tr><th colspan="2">Pre-activated pre-filled syringes</th></tr>
<tr><td> 
</td><td> 
</td></tr>
</table>

Activated safety device effectively covers the needle


Background on the safety concern

Self-activation of the safety device has been observed rarely in unused, unopened blisters containing Inhixa pre-filled syringes. An analysis has shown that the incidence of self-activation is 0.001%. To date, the issue has not been associated with any adverse event or risk to public health.

The possibility of needle stick injury is negligible as the safety device ensures full coverage of the needle. With regard to the potential risk of missing a dose, this is easily manageable: as the product is presented in transparent blisters, self-activation is visually apparent and easily detectable before dispensing and use. Moreover it is not necessary for pharmacists to open the blister packs to perform a visual check of syringes blisters before dispensing.

Detailed investigation by the manufacturer has pinpointed the root cause, corrective and preventive actions have been implemented to prevent recurrence of the issue.

Call for reporting

We kindly ask you to notify the manufacturer or local representative of the Marketing Authorization Holder of any pre-activation events. In your notification, we would be grateful if you could provide your contact details (specifically your name, postal address, phone number, email address). Please do not forget to include the product name, strength and batch details (e.g., batch number and expiry date).

Inhixa is subject to additional monitoring. Please report any suspected adverse reactions.

Company contact point

To access to further information, please contact:

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Communication Plan for Direct Healthcare Professional Communication

DHPC Communication Plan	
Medicinal product/ Active substance	Inhixa with safety device Preventis, solution for injection Enoxaparin sodium
Marketing Authorization Holder (MAH)	Techdow Europe AB Kåbovägen 32 75236 Uppsala Sveden
Safety concern and purpose of the communication	Very rare cases of self-activation of safety device in unopened, unused pre-filled syringes of Inhixa (Enoxaparin sodium, solution for injection)
DHPC recipients	**Germany**: pharmacists (retail and procurement) **Italy**: hospital (only to the concerned hospitals which received the lot AB01831A) **United Kingdom:** pharmacists (retail, hospital and procurement)
Member States where the DHPC will be distributed	Germany, Italy, United Kingdom
Timetable	**Date**
DHPC and communication plan (in English) agreed by CHMP/CMDh	09 April 2018
Submission of translated DHPCs to the national competent authorities for review	11 April 2018
Agreement of translations by national competent authorities	13 April 2018
Dissemination of DHPC	18 April 2018