

Header sheet with Logo of Manufacturer or the person responsible for the implementation of the corrective measure

Urgent Safety Information

Recall
concerning
HYALUBRIX

21.10.2022

Sender:

Fidia Farmaceutici S.p.A., Via Ponte della Fabbrica 3/A – 35031 Abano Terme (PD) – Italy

Addressee:

Users of HYALUBRIX syringes in their inventory.

Identification of the medical devices concerned:

The following Hyalubrix batch is affected by the recall: F21980

Please consider that the recall 06-Oct-2022 for batch F12150, F12160, F16670, F21680 and F22110 is still valid!

Description of the problem including the identified cause:

From monitoring the safety of the product on the market, we have received more reports of undesirable effects than previously observed. These undesirable effects are mainly represented by pain and swelling at the level of the knee joint subject to treatment for intra-articular infiltration with variable clinical intensity and, in any case, all defined as not serious events on basis of the information collected. In addition, the observed side effects are known for hyaluronic acid intra-articular injections and are already described in the Hyalubrix package insert.

What measures are to be taken by the addressee?

- Please check your inventory of HYALUBRIX syringes for one of the following batches: F21890 subject of this recall or F12150, F12160, F16670, F21680 or F22110 subject of the recall 06-Oct-2022.
- Please do not use the syringes of this batches.
- You will soon receive mail from us in which we announce the recall as well. The mail will contain a return form. Please fill in the form and forward it to the address on the form. We will take care of the return of the products. All returned units will of course be reimbursed.
- Please answer with the return form within 48h after receiving the mail.
- Syringes that have already been used do not pose a risk to your patients. The effect described above occurs within 24 hours after the injection.

If you have any questions, please call us at the following number: 02173 - 8954 - 444.

Passing on the information described here:

All affected users will be contacted separately by us.

Contact person:

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- Signature -