

DRAFT
Urgent Field Safety Notice



Voluntary Precautionary Recall of ZomaJet Injector Device for Zomacton

For the attention of: Patients as well as caregivers, parents and healthcare professionals to patients on a treatment with Zomacton from Ferring using the ZomaJet injector device

Contact details of local representative:

<Local Ferring contact>

<Address>

<Phone>

<E-mail>

Dear Valued Customer

This letter is to inform you that Ferring Pharmaceuticals is voluntarily recalling the following models of the **ZomaJet injector device** for administering the medicine, Zomacton 4 mg or Zomacton 10 mg/mL.

ZomaJet 4
ZomaJet 10
ZomaJet 2 Vision
ZomaJet Vision X

Ferring is recalling all ZomaJet 4 and ZomaJet 10 injector devices, as well as all ZomaJet 2 Vision and ZomaJet Vision X injector devices that were previously distributed by Antares Pharma.

This recall does not concern the medicine, Zomacton 4 mg or Zomacton 10 mg/mL.

Description of the product problem

The ZomaJet injector device is used to inject Zomacton, a medicine that contains the active substance somatotropin, also known as growth hormone (GH). Zomacton is used for the long-term treatment of:

- Growth problems due to a lack of GH in children
- Growth problems due to Turner's syndrome (a genetic disorder affecting females)
- Replacing GH in adults with severe GH deficiency

Ferring has received a small but recent increase in the number of complaints of "Injector disintegrating into pieces" events associated with the ZomaJet injector device, a few of which have resulted in minor/temporary injuries, which completely resolved, to the patient. This type of event may lead to forceful ejection of the device's components and have a potential for injury.

Potential risk associated with the use of ZomaJet injector device

Although considered unlikely that the ejection of components following "Injector disintegrating into pieces" may cause harm to the caregiver or patient, a possible risk still remains for minor/temporary injury or, in the worst-case scenario, for potential serious injury to caregivers or patients.

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To date, no serious injuries related to the use of a ZomaJet injector device have been reported to Ferring.

What action should you take?

- Immediately discontinue using your ZomaJet injector device.
- Immediately contact your doctor for further guidance on your treatment. This guidance may include injecting Zomacton with a conventional syringe and needle using correct injection technique or the use of alternative devices and GH medicines.
- You should return the device to the location where you received it, such as the clinic of your healthcare professional, pharmacy or other service that you used, where it will be disposed.

What may happen when you temporarily stop taking Zomacton?

Zomacton is used for long-term treatment. Considering this, temporary interruption of your treatment is unlikely to have an effect on long term efficacy and safety.

Yours faithfully,

Signature