



**Urgent Field Safety Notice**

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**Voluntary Precautionary Recall of ZomaJet Injector Device for Zomacton (somatropin)**

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:  
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Dear Zomajet User,

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

ZomaJet Vision X – ALL devices
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This recall does not concern the medicine 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 somatropin, 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)

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.

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



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**What action should you take?**

- Immediately discontinue using your ZomaJet injector device.
- Immediately contact your Growth Hormone specialist/doctor for further guidance on your treatment. This guidance may include the use of alternative Growth Hormone medicines.
- You should return the device to the location where you received it, where it will be disposed of. If received from Hibernian nursing service then Hibernian will be in contact shortly and you will be receiving a pre-paid return envelope for the return of the device.

Yours faithfully,

**Signature:**   
S.A. Davis (Feb 25, 2021 18:49 GMT)  
**Email:** sean.davis@ferring.com

Feb 25, 2021

Sean Davis  
General Manager, Ferring UK and Ireland