

Drug Alert

MEDICINES DEFECT INFORMATION

Caution in Use

Date: 3rd May 2013

Our Ref: MDR 08-04/13

Dear Healthcare Professional,
Cherubino Ltd.

Zarzio pre-filled syringe 30 MU/0.5ml solution for injection (Filgrastim)

EU/1/08/495/001-004

Batch Number	Expiry Date	Pack Size	First Distributed
All batches	N/A	X 5 syringes	N/A

It has been brought to the attention of the Medicines Authority that there is an error in the product label contained in all batches of Zarzio pre-filled syringes 30 MU/0.5ml currently on the market. This is a centrally authorised product.

The pre-filled syringe was noted to have an add-on label in one specific area which is partially covering the 0.5ml dose rendering it legible as 5ml instead of 0.5 ml.

Correspondence is undergoing with the MAH through the local representative to rectify the situation. In the meantime, not to avoid stock disruption, distribution of affected stock will continue under caution in use.

Health Authorities are asked to bring this information to the attention of Hospital Doctors, Hospital Pharmacies and Ward Nurses by copy of this letter.

Yours faithfully

Muriel Giglio
Medicines Inspector
Medicines Authority