

QD004/07 Appendix 01 Version01

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Drug Alert

CLASS 2 MEDICINES RECALL

Action within 48 hours

Date:30th December 2015

Our Ref: MDR 9-12/15

Cherubino Ltd. (MA holder: Hospira Ltd.)

Mitoxantrone Injection 2mg/ml Concentrate for Solution for Infusion

PL 04515/01247

Batch Number	Expiry Date	Pack Size	First Distributed
B024636AB	30/6/2016	1	N/A
B034636AA	31/12/2016	1	N/A

The Medicines Authority has been notified by Cherubino Ltd. – a local licensed wholesale dealer - that the above batches of the medicinal product Mitoxantrone Injection 2mg/ml Concentrate for Solution for Infusion have yielded atypical results for impurities during routine stability studies. The batches are still within their registered specifications but are being recalled as a precautionary measure.

This recall is being classified as a Class II recall up to pharmacy level and is being carried out by Cherubino Ltd. under the supervision of the Medicines Authority.

Yours faithfully

Eloise Buontempo Medicines Inspector Medicines Authority