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Class 2 medicines recall: Respointin Nebules 250micrograms/1ml & Respointin Nebules 500micrograms/2ml (Ipratropium Bromide)

From: Medicines and Healthcare products Regulatory Agency (<https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>)

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Alert type: Drug alert (https://www.gov.uk/drug-device-alerts?alert_type%5B%5D=drugs)

Action within 48 hours: Glaxo Wellcome UK Ltd is recalling 4 batches of Respointin Nebules due to out of specification results for impurities obtained during routine stability testing (EL (16)A/10)

- Product information
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Product information

EL number

EL (16)A/10

MDR number

MDR 23-08/16

Company name

Glaxo Wellcome UK Limited

Product description

Batch Number	Expiry Date	Pack Size	First distributed
B76315BA	28/02/2017	20 x 1ml	30 Mar 2015
B85515J	31/10/2017	20 x 1ml	27 Jan 2016
B76315BA	28/02/2017	4 x 5 x 2ml	29 May 2015

B85515J	31/10/2017	4 x 5 x 2ml	18 Dec 2015
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Brief description of the problem

GlaxoSmithKline on behalf of the licence holder, Glaxo Wellcome UK Limited, is recalling the above batches because out of specification results for impurities were obtained during routine stability testing. No complaints or adverse reactions relating to this issue have been received by the company to date.

Remaining stocks of these batches should be quarantined and returned to the original supplier for credit. Please note, these products are being discontinued so no alternative batches are available however we understand that alternative versions of both presentations are available from a number of suppliers.

For returns and credit enquiries, please contact your local branch of AAH or Alliance Healthcare.

For medical information enquiries, please contact GlaxoSmithKline UK Medical Information Department on 0800 221 441 and choose Option 2

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(https://assets.publishing.service.gov.uk/media/57ab27ceed915d096e000060/160810EL__16_A_10_Final.pdf)

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS Regional teams: please cascade to relevant clinics, general practitioners and community pharmacies.