



DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy Level

Date: 18 February 2019

EL (19)A/05

Our Ref: MDR 18-01/19

Dear Healthcare Professional,

Laboratoire Aguettant

Atropine Sulfate 3mg/10ml Solution for injection in pre-filled syringe. PL 14434/0016

Batch Number	Expiry Date	Pack Size	First Distributed
6501622*A	04/2020	1 x pre-filled syringe	08/11/2018
6502640	10/2021	10 x pre-filled syringes	07/01/2019
6502785	12/2021	10 x pre-filled syringes	Not applicable
9901362	12/2021	10 x pre-filled syringes	Not applicable

Brief description of the problem

Aguettant Limited has informed the MHRA that there is an error in the Patient Information Leaflet (PIL) for batches of the above product listed above. In Section 6 of the Leaflet included in these batches, the equivalent content of Atropine base is expressed incorrectly as 0.17mg per ml and 0.83mg in 10ml.

The corrected PIL will state the following:

Each ml of solution for injection contains 0.3mg atropine sulfate monohydrate equivalent to 0.25mg atropine

Each 10ml syringe contains atropine sulfate monohydrate equivalent to 2.5mg atropine

In addition to this, minor errors on the Summary of Product Characteristics (SPC) and the carton are also being corrected. In the current versions of both, the equivalent content of Atropine base is expressed as 0.26mg per ml and 2.49mg in 10ml. This is being corrected to give equivalent contents of 0.25mg per ml and 2.5mg in 10ml

Steps have already been taken to correct the PIL, the SPC and the carton. Distribution of the above batches will cease once corrected stock is available. It is anticipated that new batches will be available in June 2019.



Contact Information

For all enquiries, including medical information enquiries, please contact info@aguettant.co.uk, or telephone 01275 463691

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS regional teams are asked to forward this to relevant clinics, general practitioners and community pharmacists for information.

Yours faithfully

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