D R U G A L E R T

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Hospital and Clinic Level

Date: 29 October 2015 EL (15)A/09 Our Ref: MDR 44-10/15

Dear Healthcare Professional,

AstraZeneca UK Limited

Marcain Polyamp Steripack 0.5% PL 17901/0145
(Bupivacaine Hydrochloride)

AstraZeneca has notified us of an error on the carton and ampoule label of all batches of Marcain Polyamps 0.5% released to the UK market since December 2012. The text on the carton and label states that this product may be administered by intra-articular administration. This route of administration is not appropriate for the 0.5% presentation, however. The correct information is presented in the SMPC for Marcain Polyamps, see link below:

https://www.medicines.org.uk/emc/medicine/9367

To ensure continuity of supply, distribution of affected stock will continue whilst the error is being corrected. Corrected stock is expected to be available for distribution by the end of January 2016.

For further information on this matter, please contact AstraZeneca Medical Information on 01582 836836

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

Yours faithfully

Alison Bunce

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