



DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Hospital Pharmacy Level

Date: 28 February 2019

EL (19)A/06

Our Ref: MDR 07-02/19

Dear Healthcare Professional,

Paracetamol 10mg/ml Solution for Infusion

Actavis Group PTC ehf, PL 30306/0391

Accord Healthcare Limited, PL 20075/0701

Brief description of the problem

Accord Healthcare Limited has informed us that there is an error on the portion of the Patient Information Leaflet (PIL) for the above product which is intended for Healthcare Professionals. The PIL for Paracetamol 10mg/ml Solution for Infusion is a joint PIL between the 50ml vial and the 100ml vial. The error applies to the 50ml vial, which is not currently marketed. The 100ml vial is restricted for use in adults, adolescents and children weighing more than 33kg but we cannot rule out the possibility that it is being used for the treatment of term newborn infants, infants, toddlers and children weighing 33kg or less. All unexpired batches of the product currently on the market supplied by both Marketing Authorisation holders listed above are within scope.

In the **incorrect** version of the PIL, the maximum volume of solution for administration to babies and infants weighing 10kg or less is given as 75ml on the dosage table intended for Healthcare professionals. **The correct maximum volume for administration to this group is 7.5ml, however.**

The PIL has already been corrected and can be accessed via the following link:

<https://www.medicines.org.uk/emc/product/2972/pil>.

Distribution of affected batches will cease once corrected stock is available. It is anticipated that new batches will be available during Q2 2019.



Contact Information

For stock control enquiries, please contact Accord Customer Services Team on 0800 373573

For medical Information enquiries, please contact Accord Medical Information Department on 01271 385257

Advice for healthcare professionals

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

Yours faithfully

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