



DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy Level

Date: 14th December 2016

EL(16)A/17

Our Ref: MDR 099-11/16

Dear Healthcare Professional,

Medreich

Amoxicillin Sugar Free Suspension 250mg/5ml

PL 21880/0124

Amoxicillin Sugar Free Suspension 125mg/5ml

PL 21880/0123

Medreich has received several complaints that the child-resistant caps on the above mentioned products are difficult to open. This follows the introduction of a new child-resistant cap with a red tamper-evident ring earlier this year. A very small number of packs have an incompatibility between the cap and the bottle.

Additionally, the new child-resistant caps with a red tamper-evident ring require more pressure to open for the first time compared to child-resistant caps with an induction seal.

Please follow the handling instructions below to avoid difficulty in opening the child-resistant cap, and see photos on page 2 for illustration.

- 1) Place the bottle on a flat, firm surface.
- 2) To break the tamper-evident ring, apply a moderate force to push down on the top of the cap and turn the cap anti-clockwise. **Take care to ensure that the force is uniform**, as a non-uniform force may cause incomplete breakage of the tamper-evident ring, preventing opening of the closure. The red tamper-evident ring is not visible on the unopened bottle.
- 3) After reconstitution, **press the cap down** from the top and turn the cap clockwise while **continuing to press down**. This will ensure the child-resistant cap is properly closed, and eliminate any issue related to leakage.
- 4) To re-open the cap, turn the cap anti-clockwise **whilst pressing down on the cap**.
- 5) If the correct opening technique is not used, the cap will rotate and will not open.

If the bottle cannot be opened using the handling instructions, please contact Medreich by email gagroup@medreich.co.uk or by phone on 020 8831 1580.

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

Yours faithfully

Sandra Bax

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Unopened Bottle - 01



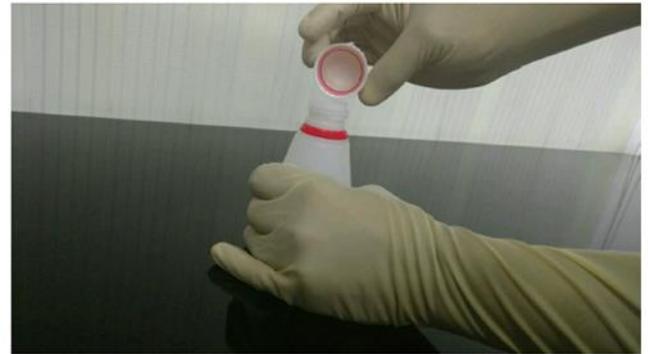
Press the Cap from Top - 02



Rotate the Cap Anti-Clockwise While Pressing - 03



Breaking of Ring on Opening - 04



Reconstituted Product - 01



Placing of Cap on Bottle - 02



Rotate the Cap Clockwise while pressing from top - 03

