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Class 4 Caution in Use: EcoLab Klerpack BD Syringe Multi-Pack

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Alert type: [Drug alert](#)

Ecolab are recalling batches of Klerpack BD Syringe Multi-Pack as the sterile packaging may contain small holes in the film of the pouch. (EL (16)A/13

Product description

- [Brief description of the problem](#)
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Class 4 Medicines Defect Information

Caution in Use

Distribute to Hospital Pharmacy Level

EL number

EL (16)A/13

MDR number

MDR 037-09/16

Company name

EcoLab

Product description

Klerpack BD Syringe Multi-Pack

Brief description of the problem

Ecolab are recalling batches of Klerpack BD Syringe Multi-Pack as the sterile packaging may contain small holes in the film of the pouch. If holes are present, the package integrity is compromised and there is a risk that the syringe may no longer be sterile. The affected syringe products and batches are listed in Appendix 1 (Ecolab Field Safety notice).

Advice for healthcare professionals

The objective of this Drug Alert is to make users of the syringes aware of the Field Safety Notice in order to:

- Quarantine affected stock of the syringes
- Perform a local risk assessment for unexpired medicinal products produced using the affected batches of syringes

The local risk assessment should take into account the following factors:

- Specific use of the syringe (such as use during the manufacturing/compounding process and/or the final closed container system)
- Nature of the medicinal product (such as expiry period; susceptibility to microbiological proliferation, or any inhibitory effect)

- Route of administration and patient population
- Likelihood of medicinal product shortage (is replacement stock or an alternative product available?); impact of shortage on patients
- Ecolab data indicates a high likelihood of syringe packaging being compromised. The holes cannot be detected visually.

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[Klerpack BD Syringe Multi-Pack EL16 A13](#)

[Appendix 1 - Ecolab Field Safety notice](#)

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

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