

**Urgent Field Safety Notice**

Commercial name of the affected product: Emulsifying Ointment BP

FSCA-identifier: 15/02/17

Type of action: Device recall

Date: 17/02/17

Attention: Wholesalers, Pharmacies, End Users etc.

Details of affected devices:

Type of device: Class I Medical Device

Name: Emulsifying Ointment BP

BN: NR10041

Description of problem:

Emulsifying Ointment BP is a topical cream with emollient properties which is typically used for dry skin or as a soap substitute.

Testing of retain samples from batch number NR10041 generated OOS results for Sodium Lauryl Sulphate content from the approved specification. The product smell and the texture/feel of the product on the skin may be altered.

This defect is likely to diminish the effectiveness of Emulsifying Ointment BP to act as a moisturiser and soap substitute. The defect is unlikely to have any significant impact on the safety of the product.

Action to be taken by the user:

- Please immediately quarantine any units of this product which you have in your possession.
- Please contact Customer Services Pinewood Healthcare to arrange uplift of units of batch number BN NR10041.

Contact details are as follows:

Tel: 01 4569123

Email: CustomerServicem50@pinewood.ie

Fax: 01 4569125

- Last date for credit of returned stock: 4 weeks from date of issue of FSN

**Transmission of this Field Safety Notice:**

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

Name: Conor O'Brien

Organisation: Pinewood Healthcare

Address: Unit 1 and Unit 2, M50 Business Park, Ballymount, Dublin 12.

Contact details: Tel: 01 4569123

Email: CustomerServiceM50@pinewood.ie

Fax: 01 4569125

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.

Signed: Marita Kelly

Date: 17/02/17