

Date
April 25, 2018

URGENT – FIELD SAFETY NOTICE

Field Safety Corrective Action (FSCA): Product Recall

- **Askina Gel**
- **Askina Calgitrol Paste**

To whom it may concern,

On behalf of B. Braun Hospicare Ltd. we hereby recall the following products in the context of a FIELD SAFETY CORRECTIVE ACTION from the market:

| Article Number | Article Name | Batch |
|----------------|--------------------------------|-------|
| 14291 | ASKINA® GEL 100 G | all |
| 001419N | ASKINA GEL 15G | all |
| 001419NRU | ASKINA GEL 15G | all |
| 001419S | ASKINA GEL 15G | all |
| 001419SBR | ASKINA GEL 15G | all |
| 001419SES | ASKINA GEL 15G | all |
| 001419SESCP | ASKINA GEL 15 GR PHARMACY | all |
| 001419SF | ASKINA GEL 15G | all |
| 001419SFR | ASKINA GEL 15G | all |
| 001419SRU | ASKINA GEL 15G | all |
| 6241001 | ASKINA® CALGITROL® PASTE 100 G | all |
| 6241505 | ASKINA CALGITROL PASTE 15 G | all |
| 6241505F | ASKINA CALGITROL PASTE 15 G | all |
| 6241510 | ASKINA CALGITROL PASTE 15 G | all |
| 6242501 | ASKINA® CALGITROL® PASTE 250 G | all |
| 6242501FR | ASKINA® CALGITROL® PASTE 250 G | all |
| 6245001 | ASKINA® CALGITROL® PASTE 500 G | all |

Reason for the Recall

In our manufacturing site it was determined that the irradiation dose qualified for sterilization of the above mentioned products was too low. In consequence, the germ reduction through gamma irradiation may not have reached the requested sterility assurance level of 10^{-6} . The effect cannot be limited to specific batches.

Up to now we received no market feedback on any adverse patient outcome which could be associated to the above described observation. However, we have decided to recall the affected products from the market as a preventive measure.

Actions to be taken by the USER

Our records show that your facility has received one or more of the above listed products.

We kindly ask you to initiate the following activities immediately and with priority:

- Identify, quarantine and return affected devices.
- Do not use affected devices anymore.
- Patients with affected devices in use should be monitored carefully. If clinically uneventful, an exchange of the product is not indicated.
- Inform the responsible personnel in the affected facilities.
- Complete and sign the enclosed 'Recall Confirmation Form' and fax this back to us (fax no. 01-7091889) to confirm that you have received this notice and advise the quantity of affected product to be returned.

Please return the completed form by ***Tuesday 1st May***, or sooner if possible.

If you have any affected stock, B. Braun will organise collection of any quarantined units. Please enclose the Recall Confirmation Form with this collection. Credit will be provided for any affected product returned.

The Health Products Regulatory Authority (HPRA) has been informed of this Field Safety Corrective Action (FSCA).

If more information is needed, please contact:

Susan O'Connor
Business Unit Manager, OPM
B Braun Medical Ltd
Tel: 01 7091810
Email: susan.o'connor@bbraun.com

We appreciate your immediate attention and apologise for any inconvenience caused.

Yours sincerely,



Susan O'Connor
Business Unit Manager, OPM



Roberta Egan
Regulatory Affairs Manager

RECALL CONFIRMATION FORM
- Askina Gel
- Askina Calgitrol Paste

Please complete this form, even if you do not have any of the concerned product and fax this form back to Fax No. 01-7091889

- 1. We hereby confirm that we are aware of the Field Safety Notice from 25th April 2018 concerning the Askina Gel and Askina Calgitrol Paste.**
- 2. Please mark accordingly:**
 - We do not have any of the affected product in stock.
 - or
 - We will return the following products:

| Article Number | Article Name | Quantity to be Returned |
|----------------|--------------------------------|-------------------------|
| 14291 | ASKINA® GEL 100 G | |
| 001419N | ASKINA GEL 15G | |
| 001419NRU | ASKINA GEL 15G | |
| 001419S | ASKINA GEL 15G | |
| 001419SBR | ASKINA GEL 15G | |
| 001419SES | ASKINA GEL 15G | |
| 001419SESCP | ASKINA GEL 15 GR PHARMACY | |
| 001419SF | ASKINA GEL 15G | |
| 001419SFR | ASKINA GEL 15G | |
| 001419SRU | ASKINA GEL 15G | |
| 6241001 | ASKINA® CALGITROL® PASTE 100 G | |
| 6241505 | ASKINA CALGITROL PASTE 15 G | |
| 6241505F | ASKINA CALGITROL PASTE 15 G | |
| 6241510 | ASKINA CALGITROL PASTE 15 G | |
| 6242501 | ASKINA® CALGITROL® PASTE 250 G | |
| 6242501FR | ASKINA® CALGITROL® PASTE 250 G | |
| 6245001 | ASKINA® CALGITROL® PASTE 500 G | |

| | |
|-------------------------|--|
| Organisation: | |
| Address: | |
| Contact Name: | |
| Contact Phone Number: | |
| Contact e-mail address: | |
| Date and signature | |

