Field Notice

Date issued: 21. Dec. 2017

CONTURA INTERNATIONAL A/S
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www.contura.com

Reg. no. 27 05 08 32

Affected product:

Bulkamid VUR, item no. 50047, lot number 16F0606.

Description of the situation

Dear valued Bulkamid VUR user,

Following a detailed clinical evaluation by Contura and with effect from 21 October 2016, the indication for use of Bulkamid was extended to include the treatment of vesicoureteral reflux ("VUR") in addition to stress urinary incontinence (SUI). Our Notified Body, Presafe, recently completed a review of our extended claim for VUR and determined that, whilst 3 year follow up data existed for the Bulkamid's use for VUR, further supportive data was required. This does not affect the indication of Bulkamid for SUI. We are consequently writing to you to inform you of the following actions that we have now agreed to take.

No risk to health

In raising this matter, Presafe has not identified any safety issues with Bulkamid for VUR. Patients with the implant are therefore not at risk.

Please note that we will be pursuing Presafe's complaint and appeal processes and until these are exhausted, we need to communicate to users of Bulkamid for VUR in all European CE-Mark territories that this extended claim for VUR is under review. Whilst this review takes place, we have voluntarily agreed to only release Bulkamid to customers under the original SUI indication for use.

Description of the temporary change

Contura will temporarily be removing the VUR indication for Bulkamid in all European CE-mark territories. This action will have no effect on Bulkamid for the treatment of SUI.

Required actions regarding the use of the Product

- Patients who have been injected with Bulkamid for the VUR are not at harm and should keep the implant as originally intended.
- Distributors must return all Bulkamid packs with the lot number 16F0606 to Contura International A/S.
- Physicians must return unused Bulkamid packs intended for VUR to their local distributor.

Required actions regarding this Field Notice

• Please ensure that all those who need to be aware of this notice within your organisation receive a copy of this notice.

• Please transfer this notice to any additional people or organisations who also need to be notified.

• As soon as possible, and **no later than 14 days after receipt of this notice**, you should complete the attached form and return it to Contura International A/S, either by post or by email to the addresses stated on the form.

Contacts

Contura sincerely apologises for any inconvenience caused by this Field Notice. We assure you that we will contact you in a timely manner to communicate the outcome of the review once it is complete. In the meantime, please do not hesitate to call your local distributor or sales agent. Alternatively you may contact us by email registration@contura.com if you have any further questions regarding this notification.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agencies.

2017 DEC 21

Maibrit Søe

Quality Assurance/Regulatory Affairs Director

For and on behalf of Contura International A/S and Speciality European Pharma Ltd.

Field Notice: Confirmation of receipt form

Date issued: 21 December 2017

Affected product:

Bulkamid VUR, item no. 50047, lot number 16F0606.

Customer information:

I confirm receipt of this Field Notice and that the information has been communicated to all relevant parties.

Distributor Name and Address:

_____

Hospital/Location:

_____

Name and Position:

_____

Contact Email:

_____

Contact Number:

_____

Date/Signature:

_____

This form is to be returned **no later than 14 days after receipt of this notice.**

By post to: Contura International A/S, Sydmarken 23, 2860 Søborg Denmark. For the attention of: Maibrit Søe - Quality Assurance/Regulatory Affairs Director

By e-mail to: registration@contura.com