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**Urgent Field Safety Notice**

**Notification of a safety warning**

**regarding**

**LQD<sup>®</sup> Spray**

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30th September 2019

**Sender:**

  
Medoderm GmbH  
Robert-Koch-Str. 50D  
55129 Mainz  
Germany

**Attention:**

Users, patients, pharmacists, nurses, physicians, wholesalers, health care suppliers, hospitals, homecare services

**Details on affected devices:**

LQD<sup>®</sup> Spray is a primary wound dressing that is used for the external, local treatment of chronic wounds (such as leg ulcers), secondary wound healing disorders, acute wounds and epidermal and superficial partial thickness burns. This safety information applies to all batches of the medical device concerned:

- LQD<sup>®</sup> Spray 7 mL
- LQD<sup>®</sup> Spray 12 mL
- LQD<sup>®</sup> Spray 20 mL (marketed in Germany only)

**Description of the problem:**

For the first time, a single case report has become known in which the accidental inhalation of a spray of LQD<sup>®</sup> may have caused a severe allergic reaction in a person with a known allergy to shellfish.

LQD<sup>®</sup> Spray contains an aqueous chitosan-acetate solution that forms a thin, elastic and transparent film after application on the cleaned wound and which is removed as part of standard wound cleaning or remains on the wound until removal during natural skin renewal. The biopolymer chitosan is a derivative of chitin which is obtained from the exoskeleton of the Northern shrimp *Pandalus borealis*. LQD<sup>®</sup> Spray is manufactured by a stringent process which results in the removal of virtually all potential allergens. The chitosan used in LQD<sup>®</sup> Spray has

the highest degree of purity and is analysed in two independent investigations for potential impurities of proteins which may evoke an allergic reaction. However, the presence of shellfish allergens or allergen epitopes cannot be excluded with absolute certainty. When applied as intended according to the indication, no allergic reactions have been reported in connection with LQD<sup>®</sup> Spray so far.

Based on this first assumed allergic reaction towards LQD<sup>®</sup> Spray after accidental inhalational exposure in a person with known shellfish allergy, the following safety warning is given in connection with the use of LQD<sup>®</sup> Spray:

*Inhalation or ingestion of the spray should always be avoided. Special caution is recommended in any user, including those applying or in the immediate vicinity of the treatment being applied, where there is a history or suspicion of shellfish allergy.*

So far, this is the only case report of an allergic reaction in connection with LQD<sup>®</sup> Spray that the manufacturer has become aware of. Despite the new safety warning, the benefit-risk profile of LQD<sup>®</sup> Spray continues to be evaluated as positive.

**Advice for Healthcare Professionals and patients wishing to use LQD<sup>®</sup> Spray:**

The safety warning given above will be included in the instructions for use of LQD<sup>®</sup> Spray. Users, patients, pharmacists, nurses, physicians, wholesalers, health care suppliers, hospitals and homecare services are herewith informed by this Field Safety Notice. Since there is no product defect, LQD<sup>®</sup> Spray packs containing the old instructions for use still in circulation can continue to be used. However, the safety warning itself must be taken into account with immediate effect.

**Transmission of this Field Safety Notice:**

Please ensure that all people who order, distribute or handle LQD<sup>®</sup> Spray, and any other relevant people, are aware of this **Field Safety Notice**. It will also be published on the LQD<sup>®</sup> Spray website. If you have provided the product to third parties, please forward a copy of this information.

Please keep this information at least until the procedure has been completed, i.e. until the instructions for use have been updated.

**Contact reference person:**

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The undersigned confirm that the Medicines and Healthcare products Regulatory Agency (MHRA) has been notified of this notice.

Signature



Signature

