

# MPM Medical Issues Voluntary Nationwide Recall of Regenecare<sup>®</sup> HA Hydrogel Due to *Burkholderia cepacia* Contamination

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MPM Medical is voluntarily recalling one (1) lot of Regenecare<sup>®</sup> HA Hydrogel to the consumer level. Following two customer complaints of visible contamination, the product was found to be contaminated with the bacteria *Burkholderia cepacia*.

**Risk Statement:** Topical application of Regenecare HA Hydrogel contaminated with *B. cepacia* may result in local skin infections. For immunocompromised patients, including patients receiving chemotherapy and patients with cystic fibrosis, the skin infection is more likely to spread into the blood stream leading to life-threatening sepsis which can include symptoms such as fever, difficulty breathing, low blood pressure, rapid heart rate, mental confusion, and possibly death. To date, MPM Medical has not received any reports of adverse events related to this recall.

Regenecare HA Hydrogel is an over-the-counter (OTC) product that contains 2% lidocaine and is used topically for temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites, or minor skin irritations. It is packaged in 3 oz. plastic tubes and distributed in boxes of 12. The product can be identified by NDC 66977-107-03 and the lot number 41262 with an expiration date 2021-01 debossed on the tube crimp as shown in the images provided at the below hyperlink. The recalled Regenecare HA Hydrogel lot (#41262) was distributed nationwide to wholesalers and healthcare facilities.

MPM Medical is notifying its distributors and customers by first class mail, electronic mail, and phone call and is arranging for return of all recalled product. Patients and healthcare facilities in possession of this product which is being recalled should stop using and dispensing.

Consumers with questions regarding this recall can contact MPM Medical by phone at 1-800-232-5512 (toll-free) Monday through Friday between 7 AM and 5 PM CST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit the report [Online](#)
- Regular Mail or Fax: [Download form](#) or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

MPM Medical is committed to delivering safe, fully compliant products of the highest quality and is taking necessary steps to prevent future occurrence of this issue.

This recall is being conducted with the knowledge of the United States (US) Food and Drug Administration.

Link to FDA website: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/mpm-medical-llc-issues-voluntary-nationwide-recall-regenecare-ha-hydrogel-due-burkholderia-cepecia>

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## Company Contact Information

### Consumers:

MPM Medical, LLC  
1-800-232-5512

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## Product Photos

To view product photos, use link to FDA website: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/mpm-medical-llc-issues-voluntary-nationwide-recall-regenecare-ha-hydrogel-due-burkholderia-cepecia>