**December 3, 2020** **COM-2020-090**

# RECALL NOTIFICATION

**FDA PUBLICATION DATE:**

**December 2, 2020**

**DRUG NAME: Regenecare HA Topical Hydrogel - OTC**

**COMPANY: MPM Medical, LLC**

**REASON: Contamination with *Burkholderia cepecia***

**Dear provider of pharmaceutical services,**

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate you with the latest up-to-date information on drug safety. For this reason, we are notifying you that on December 2, 2020, the U.S. Food and Drug Administration (FDA) published a voluntary recall for one lot of **Regenecare HA Topical Anesthetic Hydrogel** manufactured by MPM Medical, LLC.

| NDC | Product description | Lot # | Expiration Date |
|---|---|---|---|
| 66977-0107-03 | Regenecare HA Topical Anesthetic Hydrogel | 41262 | 01-2021 |

The voluntary recall is due to product contamination with the bacteria *Burkholderia cepecia*. The utilization of the contaminated product may result in serious skin infections leading to life-threatening sepsis in the immunocompromised patient population. Up to date, no adverse events have been reported to the manufacturer.

**Pharmacy required actions(s):**

- Identify if the product is in inventory and immediately stop dispensing it.
- Advise patients to stop using the product and contact their physician or healthcare provider if they have experienced any problems that may be related to using this drug product



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**Contact information**:

- Contact MPM Medical by phone at 1-800-232-5512 (toll-free) Monday through Friday between 7AM and 5PM CST.

Remember, you can report adverse events or side effects at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

- Complete and submit the MedWatch Online Voluntary Reporting Form online.
- Download FDA Form 3500 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.

Additional information can be found at:

- FDA Recall for MPM Medical LLC Regenecare HA Topical Hydrogel

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

Reference(s):

U.S. Food and Drug Administration. (2020). MPM Medical LLC Issues Voluntary Nationwide Recall of Regenecare HA Hydrogel Due to Burkholderia cepecia Contamination. Retrieved on December 2, 2020 from: 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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