

Recall of Regenecare[®] HA Hydrogel

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At Magellan Rx Management, we want to help you get the best possible care. We have created a site to share drug recall information.

MPM Medical LLC has posted a lot recall of Regenecare[®] HA Hydrogel.

About this Recall:

MPM Medical is voluntarily recalling one (1) lot of Regenecare 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*.

What this means to you:

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, fast 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 expiration date 2021-01 debossed on the tube crimp as shown in the images provided at the hyperlink below. The recalled Regenecare HA Hydrogel lot (#41262) was distributed nationwide to wholesalers and healthcare facilities.

Patients in possession of the product which is being recalled should stop using. 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.

For more information regarding this FDA Recall Notification, please refer to the 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>

FDA contact information for reporting adverse events/quality complaints can be reached online at

<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home> or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then select prompt #2.