

Accord Healthcare – Recall of daptomycin injection

- On December 27, 2022, the <u>FDA announced</u> a consumer level recall of a single lot of Accord Healthcare's <u>daptomycin</u> 500 mg/vial injection and a single lot of daptomycin 350 mg/vial injection due to a complaint report from a hospital pharmacy that vials labeled as "daptomycin for injection 500 mg/vial" were found in cartons labeled as "daptomycin for injection 350 mg/vial".
 - Other daptomycin injection vials that are not being recalled are available.
- This recalled lots were distributed nationwide to wholesalers.

Product Description	NDC#	Lot# (Expiration Date)
Daptomycin for injection 500 mg/vial	16729-435-05	R2200232 (1/2025)
Daptomycin for injection 350 mg/vial	16729-434-05	

- Daptomycin is used for the treatment of adult and pediatric patients with complicated skin and skin structure infections (cSSSI) caused by susceptible isolates of the following Gram-positive bacteria: Staphylococcus aureaus (including methicillin-resistant isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae subsp. equisimilis, and Enterococcus faecalis (vancomycin-susceptible isolates only).
- The lot and expiration date printed on the outer carton and inner vial are the same and correspond
 to "daptomycin for injection 500 mg/vial." Accordingly, Accord is voluntarily recalling all of lot
 R2200232, daptomycin for injection 500 mg/vial, which may be in outer cartons that read
 "daptomycin for injection 500 mg/vial" or "daptomycin for injection 350 mg/vial."
- To date, Accord has not received any reports of adverse events related to this recall.
- Patients who have the recalled daptomycin should contact their physician or health care provider
 if they have experienced any problems that may be related to using the recalled product.
- Anyone with an existing inventory of the recalled product should stop use, distribution and quarantine the product immediately.
- For any questions regarding this recall, contact Accord by phone at 1-855-869-1081, fax: 1-817-868-5362 or e-mail at rxrecalls@inmar.com.



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