



## Drug Withdrawal

**DATE OF WITHDRAWAL:** April 6, 2020

**DRUG NAME:** Ranitidine 25mg Injection

**MANUFACTURER:** Zydus Pharmaceuticals, Inc.

**REASON FOR WITHDRAWAL:** This withdrawal is being initiated, because the FDA has announced that it is requesting manufacturers to withdraw all prescription and over-the-counter (OTC) ranitidine drugs from the market immediately. The Agency has determined that the impurity in some ranitidine products increases over time and when stored at higher than room temperatures it may result in consumer exposure to unacceptable levels of this impurity. Though all currently distributed lots of Zydus' Ranitidine Injection meet specifications of product, Zydus is withdrawing this product keeping in view of the FDA's request.

**FDA LINK:** N/A

### WITHDRAWN PRODUCT:

Product Description	NDC Number	Affected Lots/Expire Date
Ranitidine Injection, 25 mg/mL, 2 mL	68382-0422-02	M812490 exp. 07/31/2020 M808367 exp. 04/30/2020 M808368 exp. 04/30/2020 M808376 exp. 04/30/2020 M809235 exp. 05/31/2020 M809238 exp. 05/31/2020 M812489 exp. 07/31/2020 M812491 exp. 07/31/2020 M812492 exp. 07/31/2020 M812933 exp. 07/31/2020 M813476 exp. 07/31/2020 M813770 exp. 07/31/2020 M906333 exp. 03/31/2020 M906334 exp. 03/31/2021 M809243 exp. 05/31/2020 M812742 exp. 07/31/2020
Ranitidine Injection, 25 mg/mL, 6 mL	68382-0423-06	M818853 exp. 10/31/2020 M904264 exp. 02/28/2021 M904265 exp. 02/28/2021 M813773 exp. 07/31/2020
Ranitidine Injection, 25 mg/mL, 40 mL	70710-1550-01	L900007 exp. 02/28/2021 L900005 exp. 02/28/2021 L900006 exp. 02/28/2021