

Product Recall: D METFO HCL ER750MGVIA\*MST\*100/METFORMI HCL ER TB750MGVIA100

The Board of Pharmacy has received notice of the following product market withdrawal:

Description – D METFO HCL ER750MGVIA\*MST\*100 Lot Number – M915602 Exp Date – 10/31/2021 NDC – 72578003601 UPC – 37257803601 Econo Number – 1527613

Description – D METFO HCL ER750MGVIA\*MST\*100 Lot Number – M915601 Exp Date – 10/31/2021 NDC – 72578003601 UPC – 37257803601 Econo Number – 1527613

Description – METFORMI HCL ER TB750MGVIA100 Lot Number – M915602 Exp Date – 10/31/2021 NDC – 72578003601 UPC – 37257803601 Econo Number – 3461225

Description – METFORMI HCL ER TB750MGVIA100 Lot Number – M915601 Exp Date – 10/31/2021 NDC – 72578003601 UPC – 37257803601 Econo Number – 3461225

Viona is voluntarily recalling the above item/lots due to Out of Specification (OOS) results observed in “N-nitrosodimethylamine (NDMA) (By GC-MS/MS)” for the product Metformin Hydrochloride Extended Release Tablets USP 750 mg, Lot No.: M915601 and M915602, in Long Term stability condition at 18 months time point interval. This recall is to the customer level. Affected product started shipping June 5, 2020.

The Board of Pharmacy strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.