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

Product Name	NDC(s)	Lot(s)/Batches	Exp
Rizatriptan Benzoate Film Coated Tablets 10mg	33342-088-45	BRJ2112A	04/2024
		BRJ2113A	04/2024
		BRJ2114A	04/2024
	33342-088-41	BRJ2114B	04/2024

Macleods Pharmaceuticals Limited is initiating a Retailer / Pharmacy level recall on Rizatriptan Benzoate Film Coated Tablets 10mg. This recall is being conducted with the knowledge of the Unites States Food and Drug Administration.

This recall is based upon out of Specification result for Rizatriptan N-Oxide impurity obtained in Organic Impurities test against the specification limit (NMT 0.5%) during stability study and control sample analysis of above batches of the product Rizatriptan Benzoate Film Coated Tablets 10 mg.

Investigation revealed the root cause of higher impurity result as usage of one of excipient i.e. Microcrystalline Cellulose USP-NF/ Ph. Eur (Avicel PH 102) having batch number K2711220 (Item code: RM003143, A.R. no. GRM2100151) having higher H_2O_2 value. Health hazard assessment indicates Rizatriptan N-oxide is non carcinogenic and non-mutagenic. Therefore increase in Rizatriptan N-oxide impurity will not affect systemic bioavailability and efficacy of Rizatriptan Benzoate Film Coated Tablets 10 mg but as an abundance precaution, recall of these batches is initiated.

The batch was distributed during the period of 22 Jul 2021 until 01 Oct 2021.