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 Orally Disintegrating Tablets 5 mg	33342-093-41	BRL2102A	04/2025
		BRL2103A	04/2025
Rizatriptan Benzoate Orally Disintegrating Tablets 10 mg	33342-094-41	BRM2111A	04/2025
		BRM2112A	04/2025
		BRM2113A	04/2025
		BRM2114A	04/2025
		BRM2115A	04/2025
		BRM2116A	04/2025

Macleods Pharmaceuticals Limited is initiating a Retailer / Pharmacy level recall on Rizatriptan Benzoate ODT 5mg & 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 Orally Disintegrating Tablets 5 mg & 10 mg.

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 Orally Disintegrating Tablets 5 mg & 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.