Organon LLC is writing to inform you about a Recall of **ASMANEX® TWISTHALER®.** The Recall applies to **Wholesalers ONLY**.

This recall has been initiated due to the potential for a few numbers of units (*12 units or less*) that may be missing desiccant in the product assembly, arising from the manufacturing process in certain batches of **ASMANEX® TWISTHALER®**. Missing desiccant could reduce the moisture-ingress protection and increase the risk of exposure of the product to moisture, leading to clumping and lesser fine particles. This could result in administration below the required dose. In the unlikely event of patients being exposed to 'underweight' units, there are no immediate health consequence expected for administration below the required dose. There have been no reported adverse events attributable to 'underweight' units in the potentially impacted and distributed product batches. The long-range health consequences of underdosing could lead to inadequate therapeutic exposure or undertreatment.

All batches manufactured since investigation into the missing desiccant have been thoroughly monitored for quality in accordance with Organon's practices and industry standards, and all batches released were compliant with quality standards, site procedures, product specifications, and in accordance with their marketing authorizations.

These lots were distributed between February 12, 2024, and February 27, 2024.

Name of the preparation and package size	Lot Number	NDC Number	EXP
ASMANEX 220MCG 60DOSE INHALER USA	**X025346**	**78206-0114-02**	**3/3/2025**
ASMANEX 220MCG 14DOSE INHALER HOSP USA	**X024051**	**78206-0114-03**	**4/25/2025**
ASMANEX 220MCG 30DOSE INHALER USA	**Y000085**	**78206-0114-04**	**4/25/2025**