### URGENT VOLUNTARY DRUG RECALL



Event 6579 May 14, 2025

### Dear Pharmacist:

### **PRODUCT**

**Product**: AIRSUPRA® (albuterol/budesonide) 90 mcg/80 mcg Inhalation Aerosol, for oral inhalation use

### **Product Label:**



**Package:** One (1) AIRSUPRA® 90 mcg/80 mcg Inhalation Aerosol canister contains 120-inhalation doses and a net weight of 10.7 grams.

NDC: 0310-9080-12

Lot	Expiry	Dates Distributed		
6270044C00	10/2026	4/9/2024 - 11/14/2024		
6270053C00	11/2026	9/12/2024 - 2/20/2025		
6270045C00	11/2026	7/25/2024 – 3/3/2025		
6270047C00	11/2026	8/12/2024 - 2/14/2025		
6270056C00	11/2026	10/7/2024 - 2/28/2025		
6270040D00	10/2026	7/1/2024 - 9/25/2024		
6270064C00	12/2026	2/17/2025 - 4/25/2025		
6270052C00	11/2026	8/8/2024 - 12/11/2024		
6270034E00	10/2026	5/2/2024 - 10/31/2024		
6270063E00	11/2026	1/27/2025 - 4/25/2025		
6270071D00	12/2026	1/30/2025 - 4/17/2025		
6270075D00	12/2026	3/24/2025 - 4/29/2025		
6270107C00	9/2027	4/10/2025 - 4/29/2025		
6270075F00	12/2026	3/31/2025 - 4/29/2025		

### **REASON**

In line with our commitment to ensuring quality supply of medicines and devices to patients and in an abundance of caution, we are initiating a limited, voluntary recall of a limited quantity of sample lots (listed above) in which no more than 0.005% of the lot may contain units of AIRSUPRA in which the actuator mouthpiece is in the incorrect orientation resulting in non-delivery of dose.

### HEALTH EFFECTS

This voluntary recall to the retail pharmacy level is being conducted with the full approval and knowledge of the US FDA and does not impact any lots not listed above nor the AIRSUPRA aerosol formulation, nor the availability or supply of the medicine in the US.

Based on the low number of potentially defective units and the very low likelihood of a patient receiving a defective unit, as well as the high detectability of the defect (when following the patient insert instructions), the potential risk to patients from the manufacturing defect of the AIRSUPRA mouthpiece appears to be medium for the vast majority of patients. However, in very rare circumstances, e.g. a defective device has been dispensed and not used until a patient experiences an acute severe asthma attack, the potential risk would be high if an alternative rescue treatment was not readily available.

## REQUIRED ACTION

- 1. STOP: Stop distributing and quarantine units from these fourteen (14) lots immediately.
- COUNT: Please carry out a physical count of the number of units of these lots in your inventory and record this data on the Business Reply Card and the Packing Slip that are included with this letter.
- 3. REPLY RETURN: Submit the completed Business Reply Card even if you do not have units from these fourteen (14) lots.

The Business Reply Card can be submitted by any of these methods:

• Fax: 1-866-201-9067 or

• Email: AZ6579@sedgwick.com or

• Mail: 2670 Executive Dr., Ste. A, Indianapolis, IN 46241

4. **RETURN:** If you have units from these (14) lots, return them with the Packing Slip using the prepaid UPS Return Service shipping label to:

Sedgwick Claims Management Services

Event: 6579

ATTN: PROCESSING CENTER 2670 EXECUTIVE DRIVE, SUITE A

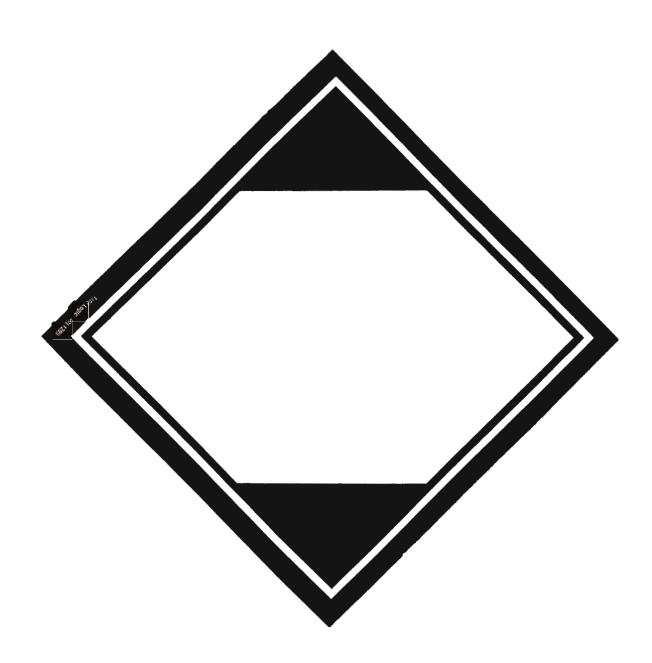
INDIANAPOLIS, IN 46241

## OTHER INFORMATION

- No other lots of AIRSUPRA are being recalled or credited for this voluntary recall.
- Medical Inquiries: 1-800-492-4319
- Sedgwick Claims Management Services: Please call 1-866-201-9064 for shipping assistance, additional shipping labels or questions about the recall process.
- Credit: Credit will be issued to pharmacies through their representative
   AstraZeneca authorized wholesalers for recalled product returned to the Sedgwick
   Claims Management Services Indianapolis location. Please provide your
   pharmacy DEA number and the Name, wholesaler account number and City, State
   and Zip Code of your AstraZeneca authorized wholesaler on the Business Reply
   Card provided.
- AstraZeneca has provided recall communication directly to potentially affected wholesalers.
- Visit AIRSUPRAHCP.com to see full prescribing information

## **Packaging Instructions:**

- 1. Cut out the Limited Quantity diamond below and tape to the outside of the return shipping container.
- 2. Place the enclosed Return Label on outside of the return shipping container.
- 3. Complete enclosed Packing Slip with quantities being returned, place inside the return shipping container with the product.
- 4. Seal container and take to the nearest UPS Drop off Facility (www.ups.com/dropoff) or call toll free: 1-800-742-5877 to arrange a pickup.



# AIRSUPRA® (albuterol/budesonide) 90 mcg/80 mcg Inhalation Aerosol, for oral inhalation use

Lot	Expiry	Units on Hand	Lot	Expiry	Units on Hand
6270044C00	10/2026		6270034E00	10/2026	
6270053C00	11/2026		6270063E00	11/2026	
6270045C00	11/2026		6270071D00	12/2026	
6270047C00	11/2026		6270075D00	12/2026	
6270056C00	11/2026		6270107C00	9/2027	
6270040D00	10/2026		6270075F00	12/2026	
6270064C00	12/2026				
6270052C00	11/2026		1		

within five (5) business days, even if you do not have any product on hand. Thank you.

6270052C00 11/2026

Your timely response to this recall notification is requested. Please fill out, tear off, and mail this reply card

We have the affected product on hand:	Yes No
Signature:	_ Title:
Contact Name:	Phone Number:
AIRSUPRA® (albuterol/budesonide) 90 mcg/80	mcg Inhalation Aerosol, for oral

### inhalation use

Lot	Expiry	Units Returned	Lot	Expiry	Units Returned
6270044C00	102026		6270034E00	10/2026	
6270053C00	11/2026		6270063E00	11/2026	
6270045C00	11/2026		6270071D00	12/2026	
6270047C00	11/2026		6270075D00	12/2026	
6270056C00	11/2026		6270107C00	9/2027	
6270040D00	10/2026		6270075F00	12/2026	
6270064C00	12/2026				
6270052000	11/2026		7		

We have the affected product on hand:	Yes No
Pharmacy Name:	Contact:
Phone Number:	DEA #:
Crediting Information:	
Name of Wholesaler:	Wholesaler City:
Debit Memo #/ Account Number:	

The below shipping label is not intended for multiple shipments. Please DO NOT duplicate or redistribute.

### **BUSINESS REPLY CARD**



AIRSUPRA®
(albuterol/budesonide) 90
mcg/80 mcg Inhalation Aerosol

EVENT 6579 ID 82040707

PHARMACY MANAGEMENT CO LLC

B82040707-50885

**PACKING LIST** 



AIRSUPRA®
(albuterol/budesonide) 90
mcg/80 mcg Inhalation Aerosol

EVENT 6579

ID 82040707

PHARMACY MANAGEMENT CO LLC



Ship To:	Sedgwick-Exec		RS	
	2670 EXECUTIVE	DRIVE SUITE A	ID: 82040707 Event: 6579 Seq: 50885	
		IN 462	8-01	
UPS GROUND TRACKING #: 1ZE380109026379377				

#### PACKING INSTRUCTIONS:

- Fill out this packing slip and photocopy it for your records. Return this
  original packing slip with your product shipment.
- Affix prepaid UPS RS shipping label to shipping container (if reusing a shipping container, remove or mark out all labels, stickers, hazmat and ORM markings). Give directly to any UPS driver or deliver to UPS. (Do not enter this shipment in a UPS log book or apply any other UPS shipping label or bar code.)
- Keep this for your records. All follow-up will be based on this shipping information.

Note: Please contact Sedgwick at 1-866-201-9064 or UPS directly to generate additional labels, as needed.

TRACKING #: 1ZE380109026379377

ID 82040707 EVENT 6579 PHARMACY MANAGEMENT CO LLC