

Mylan Specialty L.P.

Morgantown, WV 26505 U.S.A.

[TOBI® PODHALER® \(tobramycin inhalation powder\) | HCP \(tobipodhalerhcp.com\)](#)

IMPORTANT PRESCRIBING INFORMATION: TOBI® PODHALER®

Subject: Temporary importation of TOBI® PODHALER® (tobramycin inhalation powder), with non-U.S. blister pack label, to address the potential drug shortage

August 2024

Dear Healthcare Professional/Customer:

We are writing to inform you of important new information concerning TOBI® PODHALER® (tobramycin inhalation powder). In order to alleviate a drug shortage of TOBI PODHALER in the United States (U.S.), expected to start in September 2024, Mylan Specialty L.P., a Viatrix Company, is coordinating with the U.S. Food and Drug Administration (FDA) to make available to U.S. patients during this period of shortage a TOBI PODHALER product that is packaged with capsule blister packs (28-day supply) originally intended for the United Kingdom (UK).

Since TOBI PODHALER is manufactured for the global market, the product which was intended for the UK market was made in the same manufacturing facilities as the currently available U.S. product. This UK product meets all currently registered and approved U.S. manufacturing controls and specifications.

The only difference between the product intended for the UK market and the product currently supplied to patients in the U.S. market is that the graphics printed on the outer surface of the capsule blister packs vary. Please see images comparing the original U.S. capsule blister pack graphics with the UK capsule blister pack graphics, and a list of the differences between these two graphics, in **Appendix 1**, below.

Viatrix will distribute the following batches of TOBI PODHALER, containing capsule blister packs originally intended for the UK, to U.S. patients.

Product Description	Strength	Pack Size	NDC #	Batch #	Expiration Date (mm/yr)
TOBI Podhaler (Tobramycin 28 MG inhalation powder 224 Monthly Pack)	28 mg	Box of 224 capsules*	49502-401-24	AKP0164R See Note 1	04/2025
TOBI Podhaler (Tobramycin 28 MG inhalation powder 224 Monthly Pack)	28 mg	Box of 224 capsules*	49502-401-24	AKP0179R See Note 1	04/2025
TOBI Podhaler (Tobramycin 28 MG inhalation powder 224 Monthly Pack)	28 mg	Box of 224 capsules*	49502-401-24	AKP0180R See Note 1	04/2025

*Each box contains 4 weekly packs (each with 56 capsules and 1 Podhaler device) and 1 reserve Podhaler device.

Note 1: Please note that the suffix ‘R’ is added to the batch numbers on the carton to ensure clear traceability.

As noted above, the only difference between these three batches of TOBI PODHALER (Batch # AKP0164R, AKP0179R and AKP0180R) and the product currently supplied to patients in the U.S. market is that the graphics printed on the outer surface of the capsule blister packs vary.

Of note, in contrast with the U.S. blister pack, the UK blister pack does not have a linear barcode. Institutions should therefore manually input the imported product information from the UK blister pack into their systems. Procedures should be followed to assure that the correct drug product is being used and administered to individual patients.

Other aspects of the modified TOBI PODHALER product, including the outer packaging, package insert and the Podhaler device, are the same as that currently supplied to U.S. patients.

To report an adverse event or quality problem concerning TOBI PODHALER, please contact Viatrix at 1-877-4-INFO-RX (1-877-446-3679).

Adverse events or quality problems experienced with the use of TOBI PODHALER may also be reported to the FDA’s MedWatch Adverse Event Reporting program either online or by regular mail or by fax:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular mail or Fax: Download form www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Please ensure that your staff and others in your institution who may be involved in the

administration of TOBI PODHALER receive a copy of this letter, review the information, and communicate this information to patients.

If you have any questions about the information in this letter, or need assistance with potentially locating your TOBI PODHALER, please contact Viatris Customer Relations at 1-800-796-9526 (Monday-Friday 8 a.m. - 5 p.m. ET).

This letter is not intended to provide a complete description of the benefits and risks related to the use of TOBI PODHALER. Please refer to the full U.S. prescribing information.

Thank you for your attention to this important update. Your role in understanding and communicating this information is critical to ensuring the safe and effective use of TOBI PODHALER in your patients.

Sincerely,

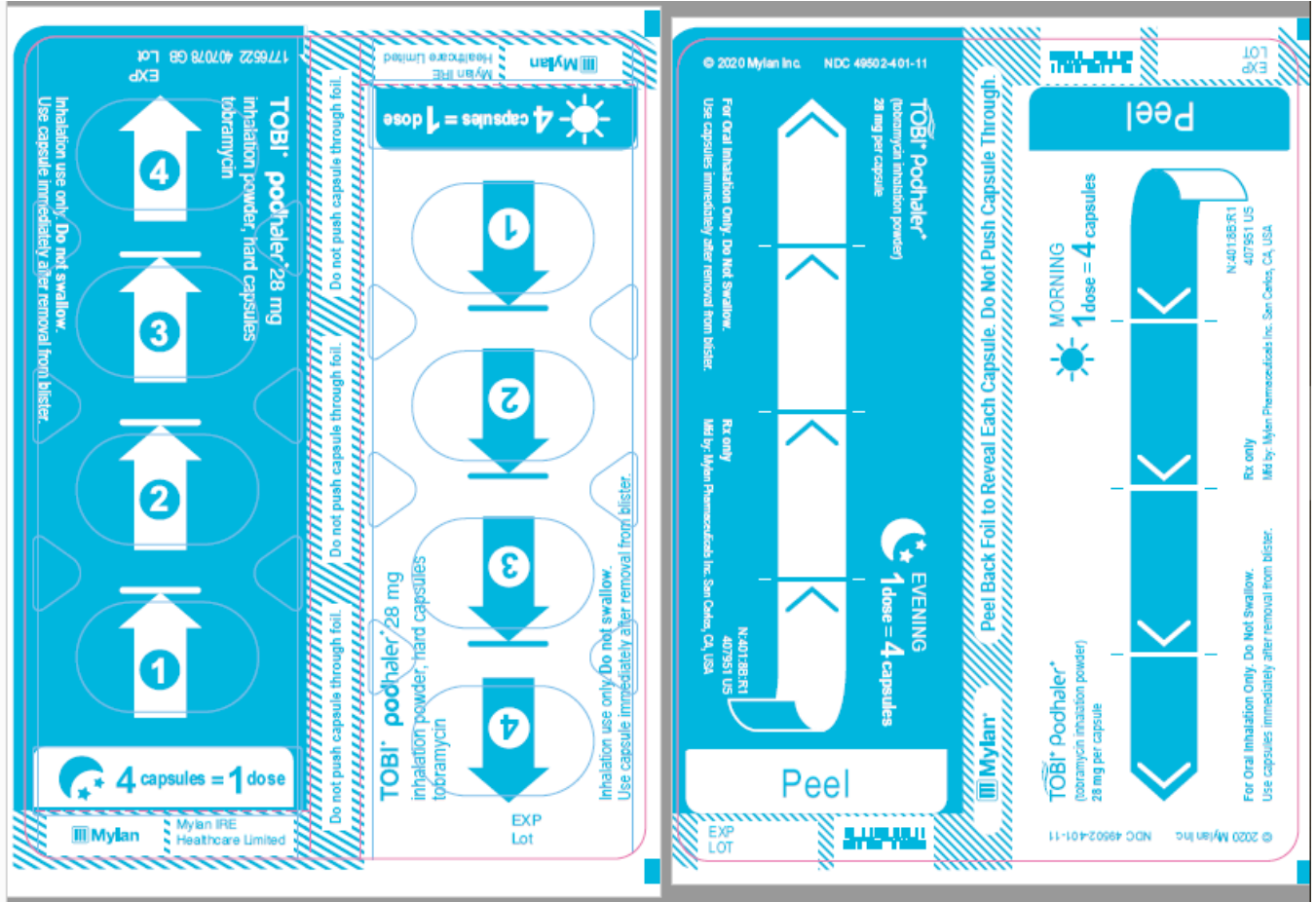
A handwritten signature in black ink, appearing to read "Seth Woodruff". The signature is written in a cursive style with a prominent flourish at the end.

Seth Woodruff, M.D.
Head of Medical Affairs – NA/US Brands Viatris

Appendix 1. - Images comparing the original U.S. capsule blister pack graphics with the UK capsule blister pack graphics and a list of the differences between these two graphics

UK Blister Pack

U.S. Blister Pack



Differences between UK and U.S. blister packs

UK Blister Pack	U.S. Blister Pack
BLUE BACKGROUND	
Missing	“2020 Mylan Inc” and NDC number
“TOBI Podhaler 28 mg, inhalation powder, hard capsules, tobramycin”	“TOBI Podhaler, (tobramycin inhalation powder), 28 mg per capsule”
“Inhalation use only. Do not swallow.”	“For Oral Inhalation Only. Do not swallow.”
4 white arrows	4 blue arrowhead symbols
Has numbers 1-4 within arrows	Missing
“4 capsules = 1 dose”, in different position	“Evening, 1 dose = 4 capsules”
Missing	“Rx only, Mfd by Mylan Pharmaceuticals Inc San Carlos, CA, USA”
Missing	“Peel”

Does not provide barcode – states “Mylan IRE Healthcare Limited”	Provides linear barcode
SHADED BACKGROUND	
“Do not push capsule through foil.” stated 3 times	“Peel Back Foil to Reveal Each Capsule. Do Not Push Capsule Through.” stated once
WHITE BACKGROUND	
Does not provide barcode – states “Mylan IRE Healthcare Limited”	Provides linear barcode
Missing	“Peel”
“4 capsules = 1 dose”, in different position	“Morning, 1 dose = 4 capsules”
4 blue arrows	4 white arrowhead symbols
Has numbers 1-4 within arrows	Missing
“TOBI Podhaler 28 mg, inhalation powder, hard capsules, tobramycin”	“TOBI Podhaler, (tobramycin inhalation powder), 28 mg per capsule”
“Inhalation use only. Do not swallow.”	“For Oral Inhalation Only. Do not swallow.”
Missing	“Rx only, Mfd by Mylan Pharmaceuticals Inc San Carlos, CA, USA”