



MEDICAL PRODUCT ALERT

DRAP ALERT NO. N° I/S/8-21-01

PRESENCE OF SPURIOUS MERONEM INJECTION, BATCH NO. 4B20E273 PURPORTED TO BE MANUFACTURED BY M/S PFIZER PAKISTAN LIMITED IN THE MARKET

Date: 02nd August, 2021.

Target Audience:

- Healthcare Professionals- Physicians, Pharmacists, and Nurses.
- General Public

Alert Summary:

DTL Faisalabad declared the batch No. 4B20E273 of product “Meronem Injection” as spurious drug product. Details of the product are given as under:

Sr.	Product Name	Active Ingredient	Strength and Dosage form	Batch No.	Test/Analysis result of DTL
1	Meronem	Meropenem trihydrate	500mg / Injection	4B20E273	Spurious

Identification of product:

White color powder contained in transparent glass vial with rubber stopper, aluminum sealing and blue color plastic flip-off cap, packed in outer hard carton with insertion of leaflet.





Following are the differences of spurious sample with the original retention sample provided by the manufacturer as observed by DTL Faisalabad

Label of	QC retention sample (Original Product) from manufacturer, Pfizer Pakistan Limited.	Spurious Sample / Sample received from Narowal (B. No. 4820E273)
Outer carton	<ul style="list-style-type: none">• Font style of batch No., manufacturing and expiry, MRP Rs. and SN is different when compared with given sample• SN 011784 is printed on outer unit carton	<ul style="list-style-type: none">• Font style of batch No., manufacturing and expiry, MRP Rs. and SN is different when compared with manufacturer's provided QC retention sample.• SN 005117 is printed on outer unit carton
Inner Vial	<ul style="list-style-type: none">• Font style of MRP Rs., B. No., Mfg and Exp is found different when compared with given sample• H05Z401 E02 1019 is printed on the label on QC retention sample.• Address is written as "Packed and Marketed By: Pfizer Pakistan Limited B-2, S.I.T.E., Karachi, Pakistan"	<ul style="list-style-type: none">• Font style of MRP Rs., B. No., Mfg and Exp is found different when compared with manufacturer's provide QC retention sample.• H05Z401 E01.0319 is printed on the label of given sample.• Address is written as "Marketed By: Pfizer Pakistan Limited 12 Dockyard Road, West wharf, Karachi, Pakistan"





Action to be taken/ Advice for Healthcare Professionals and general public: -

DRAP requests increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by this spurious products batch.

If anyone is in possession of the above stated product batch, please do not use. If anyone has used this spurious product batch, or if anyone suffer an adverse reaction/event having used this product batch, it is advised to seek immediate medical advice from a qualified healthcare professional, and to report the incident to Drug Regulatory Authority of Pakistan/National Pharmacovigilance Centre.

All medical products must be obtained from licensed, authentic and reliable sources. Their authenticity and condition should be carefully checked. Seek advice from a healthcare professional in case of any doubt.



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