MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/02-22-06

SUBSTANDARD AND SPURIOUS CEFIM DS SUSPENSION

(MANUFACTURED BY M/S. HILTON PHARMA (PVT.) LTD., KARACHI)

Date: 09th February 2022.

Target Audience:

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

Alert Summary:

CDL Karachi has declared the batch No. 141865 of product "Cefim DS Suspension" as substandard and spurious. Details of the product are given as under:

Sr.	Product Name	Active Ingredient	Mfg. & Exp. date	Batch No.	Test/Analysis result of CDL
1	Cefim DS Suspension	Cefixime 200mg/5ml	Mfg: 01-2022 Exp: 01-2024	141865	Substandard and Spurious

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 **substandard and spurious product** batch.

If anyone is in possession of the above stated product batch, please do not use. If anyone has used this **substandard and 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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Remarks of CDL:

1) The Federal Inspector of Drugs/Assistant Director vide memorandum No.DHB-001 to 007/2022-FID-III (K), dated 19 January 2022 has communicated that the sample is taken from Mr. Muhammad Zeeshan Lasani Buliding Meznine Floor Ramsami Ranchore Line, Karachi and suspected as "Spurious".
2) The sample was compared with the original pack (authentic specimen provided by the manufacturer) and a number of significant variations were found which include:
a) The specification for description of authentic product is off white to cream powder upon reconstitution off white to cream coloured suspension whereas the sample received is white to off white powder upon reconstitution becomes pink coloured suspension
b) 2D barcode has same serial number on all four received bottles i.e. FTB2UOQBYL, which be different for each pack of the batch.
c) Colour of Cefim (Brand name) is lighter in sample received from reference pack,
d) Colour of Cefixime (Generic Name) is darker in sample received from reference pack.
e) Instructions on side panel are printed with different font style than reference pack
f) “TO BREAK SEAL AND TO OPEN → UNSCREW → THIS WAY→” is printed on cap of reference pack whereas, "AND" is missing on the sample received.
g) "To be sold on the prescription of registered medical practitioner only is printed with bold fonts on reference pack whereas the sample received has normal fonts.
h) The printing colour is different on cap of sample received than reference pack
i) The sample received has graduations of 2.5ml. 5.0ml, 7.5ml & 100ml on measuring cup, whereas measuring cup of reference pack contain only 2.5m & 5.0ml graduation
3) The firm vide letter number SA-004/2022, dated 27-01-2022 has disowned the sample by stating 'based on above facts this is not our product and it is spurious/ counterfeit product"
4) Therefore, the sample is declared as **"Sub-Standard"** quality under the Drugs Act 1976 & **“Spurious"** under section 3 (z-b) (ii) of the Drugs Act 1976.