RAPID ALERT

DRAP ALERT NO. Nº I/S/02-23-13

FALSIFIED[1] (SPURIOUS) CILAPEN 500MG INJECTION

Date: 21st February, 2023

Target Audience:

- Regulatory Field Force
- Healthcare Professionals- Anesthesiologist, Surgeons, Pharmacists, and Nurses
- Pharmacists and Chemists at Distribution, Institutional suppliers
- General Public

Problem Statement:

Federal Inspector of Drugs Karachi took the sample of **Cilapen 500mg Injection** and sent to Central Drug Laboratory, Karachi for test/analysis. Federal Government Analyst has declared the sample as **Spurious** under section 3(z-b) (ii) of the Drugs Act 1976.
The product detail is as under: -

Product Name	**Purported to be Manufactured by (as stated on label)**	**Remarks by Laboratory**
Cilapen 500mg Injection Composition: Imipenem + Cilastatin Batch No. CP19014 Mfg. Date: 06-2022 Exp. date: 03-2024	Ms. Bosch Pharmaceuticals (Pvt.) Ltd., Karachi.	The sample was compared with authentic reference pack provided by the manufacturer to compare the original pack and the referred sample. Based on comparison, the sample is declared as Spurious.

Risk Statement:

Imipenem and Cilastatin injection is used to treat certain serious infections that are caused by bacteria, including endocarditis and infection of respiratory tract, urinary tract, abdominal, gynecological, blood, skin, bone, and joint. Wrongful use / misleading information as mentioned above may leads to adverse reactions including but not limited to following:

- Severe stomach pain, diarrhea that is watery or bloody.
- Upper stomach pain, loss of appetite.
- Jaundice and fever.
- Seizure; light-headed feeling, like you might pass out.

[1]The drug product was not manufactured and / or marketed by the authorized company / registration holder. Hence, it is declared as spurious / falsified product.

Consequences of use of Falsified/Spurious Drugs are:

- Falsified/Spurious drugs may contain toxic doses of dangerous ingredients and cause mass poisoning.
- Contributes to the progression of antimicrobial resistance and drug-resistant infections.
- Poor-quality medicines compromise the treatment of chronic and infectious diseases, causing disease progression, drug resistance, and death.

Action Initiated: -

The Regulatory Field Force has been directed to increase the surveillance activities in the market to confiscate this batch of product. All Pharmacists and chemists working at distributions and Pharmacies should **immediately check** the stock and stop supplying this batch product. The remaining stock should be quarantine immediately, and supplier(s) information should be provided to the Regulatory field force (DRAP, Provincial Health Departments and States) in order to ensure the removal of this products.

Following is the comparison of sample against the original pack of the product: -

S.No.	Description	Original pack of the manufacturer (Bosch)	Sample pack (Spurious/Falsified)
1	Batch number for vial	CP19014	CP19014
2	Manufacturing date	**11-2018**	**06-2022**
3	Expiry date	**10-2020**	**03-2024**
4	M.R.P	**Rs.810.90/=**	**Rs.1,140/=**
5	Batch number of WFI on the ampoule and carton	**Both same as WI19085**	**WI21042 on the ampoule where as WI19085 on the carton**
6	Color of WFI ampoule	**Blue**	**Orange**
7	Printing of descriptions of product	Over-printing batch no. manufacturing date and expiry date	Plain printing (pre-printing)
8	Font size and style	As per standard approved Bosch Artwork.	Different from the company.
9	Direction insert/leaflet	As per standard approved Bosch Artwork.	Paper size and quality, color, printing is totally different from that of the company.

DRAP, Islamabad | 92 51 9107404 | gsms@dra.gov.pk

Advice for Healthcare Professionals: -

DRAP requests increased vigilance at hospitals and within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by this product. Anesthesiologists and the supporting staff involved in surgical procedures where anesthetics are involved should remain vigilant about the suspected batches of said products.

Adverse reactions or quality problems experienced with the use of this product shall be reported to the National Pharmacovigilance Centre(NPC), DRAP using Adverse Event Reporting Form or online through this link. Further information of reporting problems to DRAP is available on this link.

Advice for Consumers / General public: -

Consumers should stop using this product and shall contact to their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product, and report the incident to Drug Regulatory Authority of Pakistan / National Pharmacovigilance Centre.

All therapeutic goods must be obtained from the licensed pharmacies, and other authorized / licensed retail outlets. The authenticity and condition of products should be carefully checked. Seek advice from your pharmacists or other healthcare professionals in case of any doubt.

Drug Regulatory Authority of Pakistan
محفوظ، موثر اور معیاری اشیائے علاج

DRAP, Islamabad | 92 51 9107404 | gsms@dra.gov.pk