PRODUCT RECALL ALERT

DRAP ALERT NO. Nº II/S/03-24-13

RECALL OF BARPON 100MG/5ML SUSPENSION (BATCH NO. 202)

(MANUFACTURED BY M/S JASM PHARMACEUTICAL (PVT.) LTD. RISALPUR KPK.)

Date: 13th March, 2024.

Target Audience:

- National Regulatory Field Force.
- Pharmacists and Chemists at Distribution, Pharmacies and Medical Stores
- Healthcare Professionals- Physicians, Pharmacists, and Nurses at hospital and clinics etc c.

Alert Summary:

Federal Government Analyst, CDL Karachi vide test report No. KQ-11-23-000155 dated 12-12-2023 has declared the subject mentioned product namely Barpon 100mg/5mL (Batch No. 202) as of substandard quality. Details of CDL test report are as under:

Product	Composition	Batch Details	Manufacturer	Lab Remarks
Barpon 100mg/5mL Suspension Reg No.114785	Ibuprofen	Batch No. 202 Mfg Dt: 07-2023 Exp.Dt: 06-2025	M/s. JASM Pharmaceutical (Pvt.) Ltd., Risalpur.	Product declared sub-standard for non-complying assay of Ibuprofen. Test/Analysis Result: 72.6% -

Risk Statement:

Barpon Infusion contains Ibuprofen, a medicine used to treat mild to moderate pain and fever (high temperature). Administration of substandard products may lead to complications, as well as an increased risk of failure of therapy. The age-profile of patients is important and young patients especially are at risk.

Action initiated: -

The manufacturer has been directed to immediately recall the defective batch of above mentioned product from the market. All pharmacists and chemists working at distributions and pharmacies are hereby advised to **immediately check** their stocks and stop supplying this batch of product. The remaining stock should be quarantined and returned to the supplier/ company. The regulatory field force of DRAP and Provincial Health Departments are also informed regarding the matter and are directed to increase surveillance in the market to ensure the effective recall of defective products(s).

-Distributors and pharmacies are advised to be vigilant and report any suspected batch of the product(s) in the supply chain to the DRAP using the online form, or through phone at +92 51 910 73 17, or by Email at gsms@dra.gov.pk.

Advice for Healthcare Professionals: -

DRAP requests increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by this affected batch of product. Adverse reactions or quality problems experienced with the use of this product may 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 bearing the affected batch number(s) 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 retail outlets. The authenticity and condition of products should be carefully checked. Seek advice from your pharmacists or other healthcare professional in case of any doubt.

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

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