RAPID ALERT

DRAP ALERT NO. Nº I/S/03-24-15

FALSIFIED RISEK 40MG INJECTION

Date: 26th March 2024

Target Audience:

- Regulatory Field Force.
- Healthcare Professionals - Physicians, Pharmacists, and Nurses.
- Procurement Managers at Hospitals, Clinics, Pharmacies and other Healthcare Institutions
- General Public.

Problem Statement:

The Federal Inspector of Drugs Karachi identified suspected samples of Risek 40mg Injection co-packed with Sterile Water for Injection from the market and sent them to the Central Drug Laboratory (CDL), Karachi for testing/analysis. The Federal Government Analyst, CDL has declared the sample as falsified/spurious under section 3(z-b) (ii) of the Drugs Act 1976. The samples were also declared as substandard for not complying with the assay test.

The detail of the affected product is as under:-.

Product Name	Composition	Batch details (as per label)	Purported to be Manufactured by	Remarks
Risek 40mg injection Reg No. 024170	Omeprazole	Batch No. **059PA5** Mfg. Date: 11-22 Exp. Date: 05-25	Getz Pharma Pvt Limited Karachi. (as per label)	The sample has been disowned by Getz Pharma and is neither manufactured nor sold by them. Numerous differences were identified upon comparison with the original product.

Risk Statement:

Spurious or falsified pharmaceuticals may contain harmful levels of toxic substances, posing a significant risk of widespread poisoning. These substandard medications have the potential to undermine the efficacy of disease treatment and exacerbate preexisting medical conditions.

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During the investigation when the suspected samples were compared with the original product of Getz Pharma, Karachi, the following significant variations were revealed in various segments of the samples:-

RISEK UNIT CARTON	RISEK IV VIAL.	LEAFLET
• Font, font size and printing style, batch number, date of manufacturing and expiry are changed. • Getz logo not as per standard. • Printing style of sterile changed in Urdu text. • In subheading of infusion of instructions (Urdu text). Printed "**refrigerator**" instead of "**refrigerate**". • In heading of instructions "**moistutre**" print instead of "**moisture**".	• In subheading of injection instruction "**in stable**" is print instead of "**is stable**". • Getz logo and design is changed. • Font, font size and printing style of batch, date of manufacturing and expiry are changed. • In subheading "injection of instruction" (English text) printed "**in sterile**" instead of "**is sterile**". • In subheading of infusion of instruction (Urdu text) "**refriger**" is printed instead of "**refrigerate**".	• There are several spelling mistakes on leaflet. • Getz logo not as per standard. • N is missing from the chemical structure of Omeprazole. • In heading of therapeutic indication written "**Pepatic**" ulcer instead of "**peptic**" ulcer. • In sub heading, geriatrics of special population written "**elderely**" instead of "**elderly**".

The sealed samples contain water for injection (ampoule) of Bosch Pharmaceuticals (Pvt) Ltd., Karachi while Getz Pharma supplies the Risek 40mg Vial with the water for injection (ampoule) manufactured by NovaMed Pharmaceuticals (Pvt) Ltd. Lahore.

Falsified Product

Manufacturer Authorized Product

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Action Initiated: -

The Regulatory Field Force has been instructed to increase surveillance activities at health facilities (hospitals), as well as markets, and confiscate any falsified products. All pharmacists and chemists working at distributions and pharmacies should immediately check their stock and stop supplying any suspected products that differ from the original. Such stock should be quarantined immediately, and supplier information should be provided to the Regulatory Field Force (DRAP, provincial and state drug control administrations) to ensure the removal of these products.

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. 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 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
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