RAPID ALERT

DRAP ALERT No: I/S/01-25-08

PRESENCE OF COUNTERFEIT OCREVUS 300MG/10ML SOLUTION FOR INJECTION MANUFACTURED BY M/S. ROCHE DIAGNOSTICS GMBH, MANNHEIM, ALMANYA

Date: 14th January, 2025

Target Audience:

- Regulatory Field Force of DRAP and Provincial Drug Control departments.
- Healthcare Professionals
- Pharmacies and medical stores

Problem Statement:

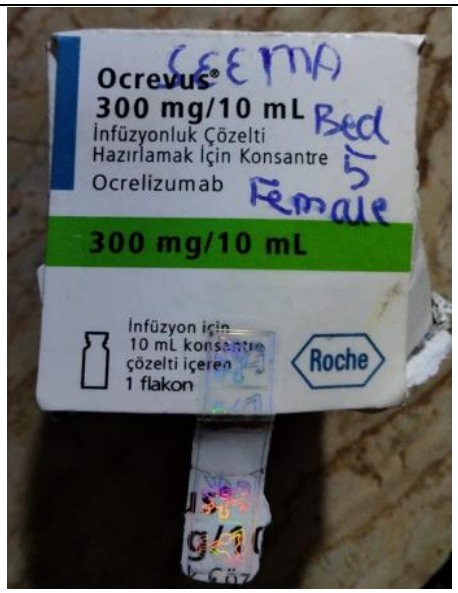
M/s Roche Pakistan Limited, Karachi, has notified DRAP, regarding the circulation of counterfeit Ocrevus 300mg/10ml Solution for Injection in the market across Pakistan. Investigation carried out by Roche Global revealed that the genuine product, batch H0041B27, was originally distributed to Turkey in August 2020 and expired on 07-02-2022, while the counterfeit sample displayed expiry date of 05-09-2025. These discrepancies confirmed the product as counterfeit. Details of counterfeit product are as follows:

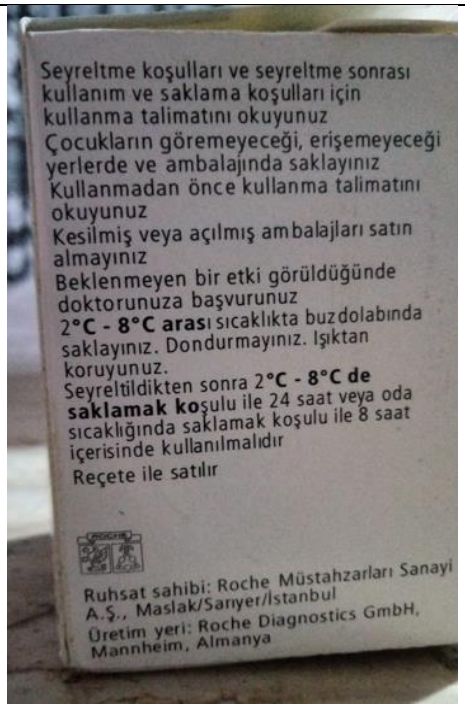
Product name	Batch/Lot No.	Stated Manufacturer	Mfg. date	Exp. date
Ocrevus Solution for Injection, 300mg/10ml (Ocrelizumab)	H0041B27	M/s Roche Diagnostics GmbH, Mannheim, Almanya.	Nil	05-09-2025

Risk Statement:

Ocrelizumab is a humanized monoclonal antibody used in the treatment of multiple sclerosis. The use of counterfeit product could result in treatment failure, worsening of the disease, or life threatening consequences.

Identification and details of counterfeit product:





Action Initiated: -

The Regulatory Field Force has been directed to increase surveillance throughout the supply chain to confiscate the mentioned product. All Pharmacists, chemists, and other healthcare professionals working at distributions, pharmacies, healthcare facilities, and other aspects of the supply chain system should immediately check the stock, and information related to the supplier of such product should be provided to the Regulatory field force (DRAP, Provincial Health Departments and States) to ensure the removal of this product from the circulation.

Advice for Healthcare Professionals: -

DRAP requests healthcare professionals to have increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by above mentioned product. Any adverse events or quality problems experienced with the use of these products should be reported to National or Provincial pharmacovigilance centers using Adverse Event Reporting Form or online through this link. Further information on reporting problems to DRAP is available on this link.

Advice for Consumers:

Consumers should not use this product and should contact their physician or healthcare provider(s) if they have experienced any problem related to taking or using the above mentioned product and should report the incident to the 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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