



MEDICAL PRODUCT ALERT

DRAP ALERT NO. N° I/S/06-25-48

RECALL OF PRODUCTS CONTAINING HYDROXYPROGESTERONE CAPROATE

Date: 16th June, 2025

Target Audience:

- National Regulatory Field Force of DRAP and Provincial Drug Control Departments.
- Healthcare Professionals (Physicians, Pharmacists & Nurses).
- General Public.

Alert Summary:

The Registration Board, in its 346th meeting held on 22nd April 2025, decided to **‘suspend’** registrations of products containing 17-Hydroxyprogesterone caproate, in light of the decision made by the Coordination Group for Mutual Recognition and Decentralized Procedures – Human (CMDh) of the European Medicine Agency (EMA). The details of the marketing authorization holders of the said molecule are provided below:

S#	Product Name	Reg. No.	Manufacturers
1.	GLOBINAN INJECTION 1ML & 2ML Each ampoule contains: Hydroxyprogesterone caproate250mg	030525 & 030526	M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle Kahuta Road, Islamabad.
2.	HYDROXYPROGESTERONE INJECTION Each ampoule contains: Hydroxyprogesterone caproate250mg	003746	M/s Haji Medicines Co, Haji Yasin Block, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad
3.	NANDROSOL 250MG INJECTION Each ampoule contains: Hydroxyprogesterone caproate250mg	096479	M/s Pharmasol (Pvt.) Ltd, Plot No. 549, Sundar Industrial Estate, Lahore



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4.	HYGEST INJECTION Each ampoule contains: Hydroxyprogesterone caproate250mg	094205	M/s Shaigan Pharmaceuticals (Pvt.) Ltd, 14 Km, Adyala Road Post Office Daghal, Rawalpindi.
5.	VIO-DEPOT INJECTION Each ampoule contains: Hydroxyprogesterone caproate250mg	013624	M/s. Venus Pharma, 23Km Multan Road Lahore, Lahore.
6.	HYDROXYPROGESTERONE INJECTION Each ampoule contains: Hydroxyprogesterone caproate250mg	003531	M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd., L-4/1, A&8, Block 21, F.B Industrial Area, Karachi.

Risk Statement:

A review by EMA's safety committee, Pharmacovigilance Risk Assessment Committee (PRAC) concluded that there is a possible but unconfirmed risk of cancer in people exposed to 17-Hydroxyprogesterone Caproate in the womb. In addition, the review considered new studies which showed that the said product is not effective in preventing premature birth; there are also limited data on its effectiveness in other authorized uses.

Action initiated: -

The field force of DRAP and Provincial Drug Control departments have been directed to immediately conduct market surveys for detection of presence and removal of mentioned batches from the market.

Advice for Pharmacies/Medical stores: -

All pharmacists and chemist working at distributions and pharmacies should **immediately check** their stocks and stop supplying mentioned products. The remaining stocks should be quarantined and returned to the supplier/company. Regulatory field force of all federating units (DRAP and Provincial Health Departments) should also increase surveillance in the market to ensure the effective recall of defective products(s).





Advice for Healthcare Professionals: -

DRAP requests increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by batches of the mentioned products. Adverse reactions or quality problems experienced with the use of above mentioned product are to 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 above mentioned products and shall contact to their physician or healthcare provider if they have experienced any problems that may be related to taking or using these drug products, and report the incident to Drug Regulatory Authority of Pakistan/ National Pharmacovigilance Centre.



Drug Regulatory Authority of Pakistan

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