Direct Healthcare Professional Communication Letter (DHPC)

Date: 18TH May, 2026

Subject: Lutrate 1 month Depot 3.75 mg (Leuprorelin acetate): Importance Safety Reminders and Clinical Management Guidelines

Dear Healthcare Provider,
As this product is currently unregistered and supplied only to specific HCPs.

GP-PHARM, S.A, in agreement with the Saudi Food and Drug Authority (SFDA), we are providing this letter to address the unavailability of the English leaflet. This letter serves to clarify the specific safety information required regarding the use of Lutrate 1 month 3.75 mg.

Summary

Lutrate 1 month Depot is a luteinizing hormone releasing hormone (LHRH) agonist used in the treatment of prostate cancer, breast cancer, endometriosis, uterine fibroids, and central precocious puberty. To ensure patient safety, please note:

- **Risk of Initial Flare:** Existing symptoms may temporarily worsen at the start of treatment due to an initial rise in sex steroids.
- **Serious Skin Reactions:** Rare but severe cases of Steven-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) have been reported.
- **Cardiovascular and Metabolic Monitoring:** Treatment may increase the risk of heart rhythm problem (QT prolongation), diabetes and changes in blood lipids.
- **Neurological Concerns:** Seizures and idiopathic intracranial hypertension have been reported in patients with or without a history of these conditions.

Further Information on Safety Concerns

1. Cardiovascular and Metabolic Risk
    - Diabetes: Monitor blood glucose levels more frequently in diabetic patients, as lutrate may alter glucose control.
    - Heart Rhythm: Caution is advised when used with medicines that prolong the QT interval (e.g., quinidine, amiodarone, methadone).
    - Bone Density: Long-term use may cause thinning of the bones (osteoporosis). Bone density monitoring is recommended, especially for patients with risk factors.
2. Specific Populations
    - Men with Prostate Cancer: Patients with spinal cord compression or urinary obstruction must be surprised closely during the first few weeks of therapy.
    - Women with Breast Cancer: If used with an aromatase inhibitor, lutrate must be started 6-8 weeks prior the inhibitor and continued throughout the treatment.

- Pediatrics: In girls with central precocious puberty, vaginal bleeding beyond the first month of treatment should be investigated as a potential sign of underdosage.

3. Administration and Storage:
    - Preparation: The product must be reconstituted using an aseptic technique and administered immediately after mixing.
    - Dosing: Ensure the injection is given intramuscularly once a month (every 28 to 33 days).
    - Storage: Store in the original package to protect from light at temperature not exceeding 25 °C. Do not freeze.

Call for Reporting

Saudi Arabia

Healthcare professionals are encouraged to report any suspected adverse reactions associated with Lutrate 1 month Depot through National Pharmacovigilance Center (NPC):

- SFDA Call Center: 19999.
- E-mail: npc.drug@sfda.gov.sa
- Website: https://ade.sfda.gov.sa/

Other GCC States:

Please contact the relevant competent authority.

Salehiya Trading Company :

- **Customer Service: 920020053**
- **General Phone: +966 11 4646 955**

Annex: Product Information Leaflet

Please find the full Patient leaflet information attached to this communication for detailed contraindications and side effects.

Sincerely,

Medical Department

Salehiya QPPV

Nejood M. Alsohaibani

nejood alsohaibani