

### RAPID ALERT

**DRAP ALERT No:** N° I/S/12-25-122

CRACKDOWN AGAINST FALSIFIED / SPURIOUS/ UNREGISTERED TRAMADOL TABLETS

Date: 18th December, 2025

### **Target Audience:**

- Regulatory Field Force of DRAP and Provincial Drug Control departments.
- Healthcare Professionals
- Consumers

#### **Problem Statement:**

Central Drugs Laboratory (CDL), Karachi informed that the samples of following drug products sent by National Task Force (NTF), have been declared 'spurious/falsified/unregistered' as under:

S#	Product Name	Batch No.	Manufacturer	Remarks
1.	Tablet TAMOL-X 225 mg Each tablet contains: Tramadol HCl 225 mg	TM004	M/s Ciba Pharmaceuticals (Pvt) Ltd. A-371 Nooriabad Main Super Highway Karachi (DML # 000825)	'Unregistered (Falsified)' Tablet Tamol X 225 mg is not registered with DRAP.
2.	Tramaking 250 mg Tablets Each tablet contains: Tramadol HCl 250 mg	TRD379	M/s Ciba Pharmaceuticals (Pvt) Ltd. A-371 Nooriabad Main Super Highway Karachi (DML # 000825)	'Unregistered (Falsified)' Tablet Tramaking 250mg is not registered with DRAP.
3.	Namadol – 225 mg Tablets Each tablet contains: Tramadol HCl 225 mg	TRD2025	M/s Ciba Pharmaceuticals (Pvt) Ltd. A-371 Nooriabad Main Super Highway Karachi (DML # 000825)	'Spurious & Falsified (unregistered)' Tablet Namadol 225mg is not registered with DRAP & does not contain the Active Pharmaceutical Ingredient (Tramadol HCl) as claimed on the label claim.









### PICTORIAL EVIDENCE FOR IDENTIFICATION OF THESE FALSIFIED PRODUCTS



























#### **Risk Statement:**

The above-mentioned products, namely Tablet TAMOL-X 225 mg, Tramaking 250 mg Tablets, and Namadol 225 mg Tablets, have been identified as unregistered, spurious, and falsified therapeutic goods and are therefore not evaluated or approved by DRAP for safety, quality, or efficacy. Laboratory findings indicate that Namadol 225 mg Tablets do not contain the declared Active Pharmaceutical Ingredient (Tramadol HCl), while the remaining products are unregistered and illegally manufactured/marketed, posing a serious public-health risk. Consumption of such products may result in therapeutic failure, uncontrolled pain, withdrawal symptoms, unexpected toxicity, overdose, respiratory depression, or other serious adverse drug reactions, particularly due to uncertain composition, strength, and quality.

The population most likely to be affected includes patients suffering from moderate to severe pain, individuals with chronic pain conditions, post-operative patients, and persons misusing or dependent on opioid analgesics, as well as elderly patients and those with comorbidities (hepatic, renal, or respiratory disorders). Healthcare professionals, pharmacies, and distributors handling these products are also at risk of legal and regulatory consequences. Immediate removal of the products from the supply chain is essential to prevent potential harm to public health.

#### **Action Initiated: -**

The Regulatory Field Force of DRAP and Provincial Drug Control Departments has been directed to conduct surveillance activities throughout the supply chain to confiscate the falsified products.

#### 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 <u>Adverse Event Reporting Form</u> or online through this <u>link</u>. Further information on reporting problems to DRAP is available on this <u>link</u>.









### **Advice for Consumers:**

Consumers should not use these products and should contact their physician or healthcare provider(s) if they have experienced any problem related to taking or using the above mentioned products 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.







