



DRUG REGULATORY AUTHORITY OF PAKISTAN

Division of Quality Assurance and Laboratory Testing

RAPID ALERT

DRAP ALERT No: N° I/S/06-26-31

SPURIOUS / FALSIFIED BREXIN TABLETS 20 mg

Date: 02nd June, 2026

Target Audience:

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

Problem Statement:

Drug Testing Laboratory (DTL), Government of Punjab, has reported that under Section 3(z-b)(i) & (ii) of the Drugs Act, 1976, based on the laboratory findings and confirmation received from the Marketing Authorization Holder, the sample of the following drug product is considered a **Falsified/spurious**.

S#	Product Name	Batch	Manufacturer	Remarks
1	Brexin Tablets 20 mg (Piroxicam-β-Cyclodextrine) Reg. No. 010637	1207863	<i>Purportedly manufactured under license of</i> Chiesi Farmaceutici S.p.A., Parma, Italy	Declared Spurious by DTL; Piroxicam not identified; Assay 0%; Marketing Authorization Holder has confirmed that the sample is not a genuine Chiesi product and has disowned the batch.

M/s Chiesi Pharmaceuticals (Pvt.) Ltd., Pakistan, the authorized marketer of Brexin in Pakistan, has formally communicated to the regulatory authorities that the seized sample was **neither manufactured under license of Chiesi Farmaceutici S.p.A., Italy, nor marketed or distributed through its authorized supply chain**. The company has also identified multiple packaging discrepancies between the seized sample and authentic Brexin tablets and has categorically disowned the product as counterfeit/spurious.

Brexin (Chiesi)	Brexin (Spurious/Counterfeit)
Unit carton is sealed with transparent tape on both closure sides	Unit carton is not sealed with tape of Chiesi specifications
Font (Size & Style) is specific for Chiesi	Font (Size & Style) is different
Variable data is printed through Inkjet printer	Variable data is pre-printed
Tablet color is pale yellow	Tablet color is dark yellow or pigmented at some spots
Aluminum foil is specific for Chiesi	Aluminum foil is shiny which is not Chiesi specifications
Blister color is off white	Blister color is white
Printing of variable data on blister is Chiesi specific	Stamping of variable data is different than Chiesi printed
Leaflet color is white printed on imported paper	Leaflet color is pale yellow local paper



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Risk Statement:

Laboratory analysis conducted by Drug Testing Laboratory, Punjab, revealed that the declared active pharmaceutical ingredient (**Piroxicam**) could not be identified in the sample. Assay results demonstrated **0.0% content of Piroxicam** against the labeled claim of 20 mg per tablet, indicating complete absence of the declared active ingredient. Use of this counterfeit/spurious product may result in:

- Complete therapeutic failure in patients requiring anti-inflammatory and analgesic treatment.
- Delay in appropriate medical management due to false reliance on ineffective therapy.
- Potential exposure to unknown or undeclared ingredients of uncertain quality, safety, and efficacy.
- Increased risk of adverse health outcomes, particularly in patients suffering from painful inflammatory conditions.

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 [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 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.



Drug Regulatory Authority of Pakistan

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