



Islamabad, the 10th November, 2020.

[Medical Product Alert]

“Torfen (Ibuprofen 200mg/5ml) Suspension”

M/s Kaizen Pharmaceuticals,
Plot No. E-127 E-128 & E-129
North Western Zone Port Qasim Authority

Karachi.

Subject: **DRUG RECALL OF SUBSTANDARD Sub-Standard Torfen Suspension,**
Reg. No. 073895, Batch No. 035, Mfg. date 06-20, Exp. Date 05-22,
Manufactured by M/s Kaizen Pharmaceuticals, (Pvt.) Ltd., Karachi

I am directed to refer to the subject cited above and CDL, Karachi report vide No.KQ.220/2020 dated 09th October, 2020 wherein your product “**Torfen (Ibuprofen 200mg/5ml) Suspension**”, Reg. No. 073895, Batch No. 035, Mfg. date 06-20, Exp. Date 05-22, has been declared of Substandard quality. Details of CDL reports are as under;

S.No.	Test	Specifications	Result	Reference
1	Description	Orange flavor orange color suspension	Complies	Mfg. Specs.
2	Identification	The identification test must identify Ibuprofen	Complies	USP 43
3	pH	3.6 to 4.6	4.6 Complies	USP 43
4	Assay Ibuprofen (label claim 200mg/5ml)	90.0% to 110.0%	311.6% Does not comply	USP 43

02. You are therefore directed to recall all the stock of above-mentioned batch of product “**Torfen (Ibuprofen 200mg/5ml) Suspension**” from market, alert your sales officers/suppliers/ distributors to issue instructions to the pharmacies/hospitals, point of sales/purchase/use for the return of suspected stocks of product in question. Furthermore, you are directed to submit a compliance report of recall to this division within seven (07) days positively.

-/sd-
(Shahid Nawaz)
Assistant Director (QC-II)

Copy for information and necessary action – with request to issue necessary directions to points of use/sale (Hospitals Pharmacies, Medical stores, Distributors, Whole sellers, etc) under administrative control/ fall under area of jurisdiction, please.

1. The Secretary (SHC&ME) Health Department (Government of Punjab).
2. The Secretary Primary and Secondary Health Department (Government of Punjab).
3. The Secretary Health Department (Government of Sindh).
4. The Secretary (SHC&ME) Health Department (Government of KPK).
5. The Secretary (SHC&ME) Health Department (Government of Baluchistan).
6. The Secretary (SHC&ME) Health Department (Government of AJ&K).
7. The Director General Health, M/o NHR&C, Islamabad.
8. The Director General Health, Government of Punjab.
9. The Director General Health, Government of Sindh.
10. The Director General Health, Government of KPK.
11. The Director General Health, Government of Baluchistan.
12. The Director General Health, Government of AJ&K.
13. The Additional Director / Office In-charge, DRAP, Lahore, Karachi, Islamabad, Peshawar, and Quetta.
14. The Chief Drug Controller / Inspector Punjab, Sindh, KPK, Baluchistan, AJ&K, GB and ICT.

Copy to:-

- i. The Director, QA<, DRAP, Islamabad.
- ii. The Additional Director MIS **with request to upload it on official website in the larger interest of public.**
- iii. FID-VII, DRAP, Karachi for information record and necessary action, if any, please.
- iv. PS to CEO, DRAP, Islamabad.
- v. Assistant Director QC-I, DRAP, Islamabad.
- vi. Office copy.


(Assistant Director QC-II)