



F. No.03-23/2021-QC
Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services,
Regulation & Coordination

MOST IMMEDIATE
THROUGH COURRIER

Islamabad, the 09th July 2021.

[Medical Product Alert]

“Tempramine Suspension”

M/s W.Woodward Pakistan Ltd.,
F-275 SITE Karachi., Sindh
Karachi.

Subject: **Manufacture & Sale of Sub-Standard Tempramine Suspension, Reg. No. 011432, Batch No. 5TR131 Manufactured by M/s. W.Woodward Pakistan (Pvt.) Ltd., Karachi.**

I am directed to refer to the subject cited above and CDL, Karachi report vide R.KQ.143/2021 dated 25-06-2021 wherein your following product has been declared as of Sub-Standard quality. Details of CDL reports are as under;

Name of Product	Manufactured by	Reg. no.	Batch no.	Mfg. Date	Exp. Date	Report No. & Date
Tempramine Suspension	W.Woodwards (Pvt.) Ltd., Karachi	011432	5TR131	11- 2020	11- 2022	R.KQ.143/2021 dated 25-06- 2021

02. You are therefore directed to recall all the stock of above-mentioned batch of product “**Tempramine 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/-
(Mehwish Tanveer)
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 Additional Director, QA<, DRAP, Islamabad.
- ✓ ii. Additional Director MIS **with request to upload it on official website in the larger interest of public.**
- iii. Area FID, 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)