

### 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. 5TE049 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.142/2021 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.	Batch no.	Mfg. Date	Exp. Date	Report No. & Date
Tempramine	W.Woodwards	011432	5TE049	11-	11-	R.KQ.142/2021
Suspension	(Pvt.) Ltd., Karachi			2020	2022	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 NHSR&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&LT, 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)