



F.No.13-45/2020-QC
Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services,
Regulations & Coordination
Islamabad

MOST IMMEDIATE
THROUGH COURRIER

Islamabad, the 15th October, 2020.

[Medical Product Alert]
“Zental Suspension”

M/s GSK Pakistan Limited,
F-268, S.I.T.E, Karachi.

Subject: **RECALL OF ZENTAL SUSPENSION MANUFACTURED BY M/S GSK PAKISTAN LIMITED, KARACHI.**

I am directed to refer to your letters vide No. Nil dated 23rd September, 2020 & ^{30th} 23rd September, 2020 on the subject cited above wherein you have informed regarding the mislabeling of various batches of your product “Zental Suspension” i.e. printing of “USP Specifications” instead of “GSK’s Specifications”. The detail of the mislabeled batches of the said product is as under;

Product Name: Zental Suspension.
Manufacturer: M/s GSK Pakistan Limited, Karachi.
Registration No. 006730
Batch Numbers: VH8Y, 2B6X, 3A2F, 3A2L, 4A7N, 4C2T, 576M, 5K2B, CM4R, DJ4U, G39M, HG5R, HZDBQ, K38N, MN3J, NL8H, P33E, RG8G, T58R, TJ4K, UE5J, UE5K, UX4D, UX4E, VP8A, W33U, WR7L, X47X, Y38V, 5D4E, 4L2R, IZDBS, L26AHG5R

02. You are therefore advised to recall all the stocks of suspected batch(s) of product, 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. It shall be ensured that compliance report to this effect should reach to this division within seven (07) days positively.


(MUHAMMAD ASHFAQ)
Assistant Director QC-I

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.

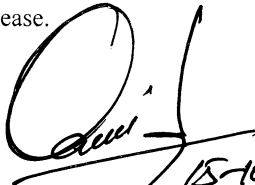
1. The Secretary (SHC&ME) Health Department (Government of Punjab).
2. The Secretary Primary and Secondary Health Department (Government of Punjab).

P.1/2

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 DRAP, Lahore.
14. The Additional Director DRAP, Karachi.
15. The Additional Director DRAP, Islamabad.
16. The Additional Director DRAP, Peshawar.
17. The Additional Director DRAP, Quetta.
18. The Chief Drug Inspector Baluchistan.
19. The Chief Drug Controller Punjab.
20. The Chief Drug Inspector Sindh.
21. The Chief Drug Inspector KPK.
22. The Chief Drug Inspector G.B.
23. The Chief Drug Inspector AJ&K.
24. Senior Drug Inspector, ICT, Islamabad.

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. The Area, FID, DRAP, Karachi for information, record and necessary action please.
- iv. PS to CEO, DRAP, Islamabad.
- v. Office copy.


15-10-2020
Assistant Director (QC-I)

P.242