

Formato 3

RAPID ALERT NOTIFICATION OF A QUALITY DEFECT / RECALL

IMPORTAN -- DELIVER IMMEDIATELY

Reference Number: MX/02/2020

(add letter head of sender):

1. To : (see list attached, if more than one)

2. Product Recall Clas of Defect:

I II
(circle one)

3. Falsification / Fraud (specify):
Falsification

4. Product:
Prednefrin SF (Prednisolona)

5. Marketing Authorisation number:
69456 SSA IV

For use in **humans** / animals (Selete as required)

6. Brand / Trade name:
Prednefrin SF

7. INN o generic name:
Prednisolona

8. Dosage form:
Suspension

9. Strength:
1%

10. Batch number (and bulk , if different):
01743, 06824, 99122

11. Expiry date:
06 Nov 20, 01 Ene 21, 20 Sep 20

12. Pack size and presentation:
Box with 5 ml dropper bottle

13. Date manufactured:

14. Marketing Authorisation holder:
Allergan, S.A. DE C.V.

15. Manufacturer:
Not known because it's a counterfeit product

16. Recalling firm (if different)

Contact person:

Contact person:

Telephone:

Telephone:

17. Recall number assigned (if available):

18. Details of defect / Reason for recall:

Lot 01743, 06824, 99122 of the product Prednefrin SF, was identified as falsified by the company Allergan, S.A. de C.V., they indicate not having manufactured, conditioned, distributed and / or marketed.

19. Information on distribution including exports (type of costumers, e.g. hospitals):

There is no knowledge of exports, the original product is fabricated by ALLERGAN SALES, LLC. IN WACO TX.

20. Action taken by issuing Authority:

Alert publication on the web site, surveillance in market for to avoid the marketing and use of the lot 01743, and international notification

21. Proposed action:

Aplication of security measures like product assurance

22. From (issuing Authority):

FEDERAL COMMISSION FOR THE PROTECTION AGAINST SANITARY RISKS

23. Contact person:

alertas@cofepris.gob.mx

Telephone: + 52 55 5080 52 00 ext. 11256, 11257 y 11183

24. Signed

Norberto López Santos
Emergency Manager

25. Date:

May,13 2020

26. Time:

17:00 H