

Formato 3

**RAPID ALERT NOTIFICATION OF A QUALITY DEFECT / RECALL**

IMPORTAN -- DELIVER IMMEDIATELY

Reference Number: MX/01/2020

(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 / Adulterated

4. Product:  
Atripla (Efavirenz / Tenofovir / Emtricitabina)

5. Marketing Authorisation number:  
073M2010 SSA IV  
For use in **humans** / animals (Selete as required)

6. Brand / Trade name:  
Atripla

7. INN o generic name:  
Efavirenz / Tenofovir / Emtricitabine

8. Dosage form:  
Tablet

9. Strength:  
Efavirenz 600 mg / Emtricitabine 200 mg / Tenofovir disoproxil fumarate 300

10. Batch number (and bulk , if different):  
M370810A

11. Expiry date:  
23 Ene 21

12. Pack size and presentation:  
Cardboard box with bottle labeled with 30 tablets, with an envelope or bottle of desiccant (silica gel), and attached instructions.

13. Date manufactured:

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

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

16. Recalling firm (if different)  
Contact person:  
Telephone:

17. Recall number assigned (if available):

18. Details of defect / Reason for recall:  
The product with batch number M370810A was identified as counterfeit by the company ESPECIFICOS STENDHAL, S.A. DE C.V., after analysis it was found that it does not contain the active ingredients Efavirenz and Emtricitabine, in addition of differences between the primary and secondary packaging, as well as in the tablets.

19. Information on distribution including exports (type of costumers, e.g. hospitals):  
There is no knowledge of exports.

20. Action taken by issuing Authority:  
Alert publication on the web site, surveillance in market for to avoid the marketing and use, and international notification

21. Proposed action:  
Aplication of security measures like product assurance

22. From (issuing Authority):  
Federal Commission for the Protection from Sanitary Risk.

23. Contact person:  
[alertas@cofepris.gob.mx](mailto: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