

HMA WGEO Rapid Alert Form

Falsified or illegal product found in the illegal supply chain

Unique Reference N0 (to be filled by Member State issuing alert): 2022-MED-226		
Date: 19/01/23	Time: 20h46	Initials: MCA
Please complete sections 1 to 5 providing as much information as possible.		
1. REPORTING PERSON		
Name:	Position:	
Organisation:		
Address:		
Telephone No:	Ext: NA	
e-mail address:		
2. PRODUCT DETAILS		
Product name: FLUOCARIL BI FLUORE 250 mg MENTHE		
Manufacturer: Delpharm, Orléans France		
Supplier: U-Labs 20, rue des Deux Gares 92500 RUEIL MALMAISON, FRANCE		
Legal status: Banned <input type="checkbox"/> Falsified <input checked="" type="checkbox"/> Unlicensed <input type="checkbox"/> Stolen <input type="checkbox"/>		
Dosage form: toothpaste 125 ml Fluorure de sodium (0.3315 g = 250 mg of active fluoride per 100g), Monofluorophosphate de sodium 0.7600 g per 100 g		
Strength:		
Batch / lot no: 25311/R		
Is batch number genuine: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
If yes to the above, advise batch destination country:		
Date of manufacture : 04/2020 Expiry date: 04/2024		
Language of packaging: French, English		
Date of discovery: 22/09/2022		
Details of discovery. The distributor in Africa PIEX informed U labs of parallel circuits on the African market on the Fluocaril brand, including counterfeit products FLUOCARIL BI-FLUORE 250 mg drug. Case of FLUOCARIL BI-FLUORE 250 mg counterfeit product reported from Congo Brazzaville (under the Sanofi brand) subject of this AR This is a falsified product which partly reproduces the presentation of Fluocaril Bi-Fluorinated Toothpaste 250 mg. This counterfeit claims to be manufactured by Sanofi-		

Winthrop Industrie and operated by Sanofi-Synthelabo (pharmaceutical group no longer holding the marketing authorization since 2006) Additional information dated October 12, 2022 circulation of counterfeit product in Mauritania whose graphics are exactly the same, the wording and the batch number are also the same, only the date of manufacture differs (01/20 versus 04/20 in Congo Brazzaville).
Analysed: YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>
If yes, result of analysis: The results of the physico-chemical and microbiological analyzes do not comply with the registered specifications of the product with a high microbial load.

3. DISTRIBUTION METHOD	
Internet: YES <input type="checkbox"/> NO <input type="checkbox"/>	
Internet: na	Non internet, advise full details:
URL: na	na
Website address: na	
Other details:.	
Currency of payment: na	
Has product reached patients/consumers? Yes	
4. RISK TO PUBLIC HEALTH	
Adverse reactions: YES NO <input type="checkbox"/>	
If yes, please advise details: patients would have reported to prescribers the creation of canker sores, without specifying whether the product used was counterfeit or not The patient risk in the event of the use of a falsified/counterfeit Fluocaril bifluoride 250 mg product is mainly linked to its toxicity by the presence of impurities in the product, the lack of efficacy of the treatment and its microbiological contamination.	
Medical assessment details: na	
5. NEED FOR PUBLICITY	
Are you making a public statement? YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>	
Are you issuing a press release? YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>	
Are you recalling product? YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>	
If yes to any of the above, when do you intend to take action? na	

6. DISSEMINATION

Are you content for this Rapid Alert to be shared outside WGEO membership?

YES ☒ NO (please see below)

If yes, please specify which of the below you are content for this to be shared with (you may tick more than 1 box)

Law Enforcement ☒ Industry Security ☒ Trade Associations ☒

Traders ☒ Customs (nominal data) Other

Please specify ____na____

7. PHOTOGRAPH

See appendix 1



Composition : Monofluorophosphate de sodium 0,7660 g - Fluorure de sodium 0,3315 g (250 mg de fluor actif pour 100 g - 2500 Ppm) -
Excipients q.s.p. 100 g. **Excipients ayant un effet notoire :** Parahydroxybenzoate de méthyle (E 218), benzoate de sodium (E 211).

Mode et voie d'administration : Usage local bucco-dentaire. En brossage.

Indications : Ce dentifrice contient du fluor. Il facilite la prévention de la carie dentaire en brossages quotidiens chez l'adulte et l'enfant de plus de 10 ans.
Brossages quotidiens 3 fois par jour, après chaque repas.

Mises en garde spéciales : Prendre en compte les autres apports fluorés par voie générale (eaux de boissons, sel fluoré, comprimés et gouttes de fluor...).
NE PAS AVALER. Lire attentivement la notice avant toute utilisation. NE PAS LAISSER À LA PORTEE DES ENFANTS.

Exploitant : SANOFI-SYNTHELABO OTC - 9, rue du Président Aillende - 94258 Gentilly Cedex (F)

Fabricant : SANOFI WINTHROP INDUSTRIE - 196, rue du Maréchal Juin - 45200 Amilly (F)

Made in France - Médicament Autorisé n° 350 086.1

125 ml

Composition : Sodium monofluorophosphate 0,7660 g - Sodiumfluoride 0,3315 g (250 mg of active Fluoride
per 100 g - 2500 ppm) - Excipients to make 100 g.

Excipients with a known significant effect: Methyl parahydroxybenzoate (E 218), sodium benzoate (E 211).

Method and route of administration: Oral use. By brushing.

Indications: This toothpaste contains fluoride. It makes the prevention of tooth decay easier by daily brushings in adults
and children over 10 years old. Daily brushing 3 times a day after each meal.

Special warnings: Take into account other sources of ingested fluoride (such as drinking water, fluoridated salt,
fluoride drops or tablets, etc).

DO NOT SWALLOW. Read the leaflet carefully before use. **KEEP OUT OF THE REACH OF CHILDREN.**



125 ml





