

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): MED-2022-166

Date: 30/06/2022

Time:

Initials:

Please complete sections 1 to 5 providing as much information as possible.

1. REPORTING PERSON

Name:

Position:

Organisation:

Address:

Telephone No:

Ext:

e-mail address:

2. PRODUCT DETAILS

Product name: CURACNE (Active ingredient : isotretinoïne)

Manufacturer: Pierre Fabre Dermatologie

Supplier: Pierre Fabre Dermatologie

Legal status: Banned ☐ Falsified ☐ Unlicensed ☐ Stolen ☒

Dosage form: soft capsules

Strength: 5 mg, 20 mg, 40 mg

Batch / lot no: CURACNE 5 batch HR309400, CURACNE 20 HR343203 ;

CURACNE 40 HR381712 Is batch number genuine: Yes ☒ No ☐

If yes to the above, advise batch destination country: Tunisia (Curacne 5, 20 and 40) and others countries (Curacne 20 and 40) , these batches having been distributed in part to wholesale distributors for export in France and will also be distributed for the remaining stock

Expiry date: CURACNE 5 batch HR309400 per 02/2024

CURACNE 20 HR343203 per 06/2024

CURACNE 40 HR381712 per 01/2025

Language of packaging: French

Date of discovery: 07 may 2022

Details of discovery: CURACNE 5 batch HR309400 : 640 medicine boxes stolen

CURACNE 20 HR343203 : 1280 medicine boxes stolen

CURACNE 40 HR381712 : 1600 medicine boxes stolen

Theft during transport between Vitrolles (France, loading 4 may 2022) and Tunis

(Tunisia) via Marseille (4 may 2022 loading on a boat).Discovery of the theft upon the arrival at Central Pharmacy of Tunis (7 may 2022)

Analysed: YES ☐ NO ☒

If yes, result of analysis:

3. DISTRIBUTION METHOD

Internet: YES ☐ NO ☐

Internet:

Non internet, advise full details:

URL:

Website address:

Other details:

Currency of payment:

Has product reached patients/consumers?

4. RISK TO PUBLIC HEALTH

Adverse reactions: YES ☒ NO ☐

If yes, please advise details: if the product is not used under strict medical supervision (many side effects and teratogenic product)

Medical assessment details:

5. NEED FOR PUBLICITY

Are you making a public statement? YES ☒ NO ☐

Are you issuing a press release? YES ☐ NO ☒

Are you recalling product? YES ☐ NO ☒

If yes to any of the above, when do you intend to take action?

Information on wholesale distributors in France

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 _____

7. PHOTOGRAPH

If possible, please attach a photograph of the product.



Lactone-Gel
lactonine

20mg

120

CIP: 3400935813688
LOT: HR343203
EXP: 06 2024



30
CAPSULES MOLLES

Curacné® Gé
Isotrétinoïne

Voie orale

Composition par boîte (30 capsules) : Huile de soja

5mg



CIP: 3400935812568
LOT: HR309400
EXP: 02 2024



30
CAPSULES MOLLES

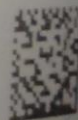
Curacné® Gé
Isotrétinoïne

5mg



5812568

CIP: 3400935812568
LOT: HR309400
EXP: 02 2024



5812568
LOT: HR309400
EXP: 02 2024

CIP: 3400935812568
LOT: HR309400
EXP: 02 2024



30
CAPSULES

5812568
LOT: HR309400
EXP: 02 2024

5812568
LOT: HR309400
EXP: 02 2024

40mg



Clozapine
sulfate

30
CAPSULES MOLLES

CIP: 3400936760349
LOT: HR381712
EXP: 01 2025



CIP: 3400936760349
LOT: HR381712
EXP: 01 2025



CIP: 3400936760349
LOT: HR381712
EXP: 01 2025



CIP: 3400936760349
LOT: HR381712
EXP: 01 2025



40mg



349

349
381712
01 2025

349
381712
01 2025

349
381712
01 2025

