Know-X Rapid Alert

Administrative information

Type of reporting entity: Health

Name of the reporting entity: Swissmedic

Reporting country: Switzerland

Reporting date: 22/10/2021

Main contact: Medicrime National SPOC

Phone: +41 58 462 07 27

Email: medicrime@swissmedic.ch

Laboratory / Authority case number: 20210902-01 / A-022845

Other contact: Phone: Email:

Sample provider: Customs

Date of seizure: 27/08/2021

Sample origin: Parcel delivery 41 packs of product stopped at customs; parcel was addressed to a big Swiss online shop

Product description

Product type: Food supplements labelled as dietary supplement, classified as medicinal product for human use

Medical device group:

Medical device class:

Notified Body name and address for MD:

MD registered with competent authority:

Product name labelled: Boners Libido Performa

Dosage form: Capsules Blue capsules with brown powder

Active ingredient labelled: Scrophularia Strength: 12.5 Unit of measurement: mg Strength: 12.5 Active ingredient labelled: Rehmannia Glutinosa Unit of measurement: mg Active ingredient labelled: Cinnamomum Cassia Strength: 12.5 Unit of measurement: µg/mg Active ingredient labelled: Fallopia Multiflora Strength: 12.5 Unit of measurement: mg Active ingredient labelled: Eucommia Strength: 12.5 Unit of measurement: mg Active ingredient labelled: Schisandra Chinensis Strength: 12.5 Unit of measurement: µg/mg

Active ingredient labelled: Lonicera Japonica Strength: 25 Unit of measurement: mg

Active ingredient labelled: Cynomorium

Strength: 25

Unit of measurement: mg

Active ingredient labelled: Panax ginseng

Strength: 25

Unit of measurement: mg

Active ingredient labelled: Ophiocordyceps Sinensis

Strength: 25

Unit of measurement: mg

Active ingredient labelled: Rhodiola Strength: 50 Unit of measurement: mg

Active ingredient labelled: Maca extract

Strength: 60

Unit of measurement: mg

Therapeutic class labelled: Erectile dysfunction

Packaging type: Blister 5 caps per blister Primary/Secondary: primary

Batch number: 2126 Expiry date: 2026

Unique identifier (A list can be attached at the end):

Quantity (seized or received) and/or pack size: pack size: 5 caps per blister in a box

Language labelling: English

Manufacturer/Marketing authorisation holder: Unknown

Name: according to labelling: Manufactured for: ONE-DC Brands B.V., Phoenixweg 6, 9641 kS, Veendam - NL

Distribution path: Distributor parcel was shipped from the Netherlands

Legal status in the reporting country (from a regulatory perspective): Unlicensed

Product assessment

Analysed: Yes

Active ingredient identified: nortadalafil Strength: 46 Unit of measurement: mg

Analytical information:

Mass Information

Other analytical parameters:

Details for mass information:

Outcome

Analytical conclusion: Undeclared API

Criminal phenomenon: Falsified undeclared nortadalafil

Follow-up / Actions

Involved authorities: Local authority Kantonales Labor Zuerich / local cantonal law enforcement for foodstuff Zurich

Public health risk assessment: May cause side effects

Risk communication: Rapid alert WGEO, Warning on website published on list "Warning about supposedly herbal products":

https://www.swissmedic.ch/swissmedic/en/medicrime/news/warnings/warnung_pflanzlichen_produkten.html

Withdrawal / Recall information: Distribution stopped

Additional information / comments

Photos















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