

HMA WGEO Rapid Alert Form
Falsified or illegal product found in the illegal supply chain

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| Unique Reference NO (to be filled by Member State issuing alert): | |
| Date: 31/03/2022 | 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: LIPOVON cápsulas | |
| Manufacturer: Unknown | |
| Supplier: LIPOVON LTD, Mexico | |
| Legal status: Banned <input type="checkbox"/> Falsified <input type="checkbox"/> Unlicensed <input checked="" type="checkbox"/> Stolen <input type="checkbox"/> | |
| Dosage form: capsules | |
| Strength: as per the labelling. | |
| Batch / lot no: 2848 Is batch number genuine: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> | |
| If yes to the above, advise batch destination country: Not applicable | |
| Expiry date: 29/02/2024 | |
| Language of packaging: English | |
| Date of discovery: 24.03.2022 | |
| Details of discovery: After the investigations carried out by Spanish National Police, these samples were analyzed by the Official Medicines Control Laboratory (OMCL) of the AEMPS and found to contain undeclared pharmacologically active substance. | |
| Analysed: YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> | |

If yes, result of analysis: The results of the analysis indicated that this product contained the following undeclared active substance: sibutramine

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| 3. DISTRIBUTION METHOD | |
| Internet: YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> | |
| Internet: | Sold on other websites herbalist's shops and health food shops |
| URL: https://lipovon.mx/ | |
| Website address: Mexico | |
| Other details: | |
| Currency of payment: | |
| Has product reached patients/consumers? Yes | |
| 4. RISK TO PUBLIC HEALTH | |
| Adverse reactions: YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> | |
| If yes, please advise details: No adverse reactions have been notified; however the presence of the undeclared active substance sibutramine is considered to pose a risk to public health. Medicines containing sibutramine have been withdrawn from the EU market due to safety concerns. | |
| Medical assessment details: | |
| 5. NEED FOR PUBLICITY | |
| Are you making a public statement? YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> | |
| Are you issuing a press release? YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> | |
| Are you recalling product? YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> | |
| If yes to any of the above, when do you intend to take action? | |
| Action was taken on 30.03.2022 (note published on the AEMPS website ¹) | |
| 6. DISSEMINATION | |
| Are you content for this Rapid Alert to be shared outside WGEO membership? YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> (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 <input checked="" type="checkbox"/> Industry Security <input type="checkbox"/> Trade Associations <input type="checkbox"/> | |
| Traders <input type="checkbox"/> Customs (nominal data) <input type="checkbox"/> Other <input type="checkbox"/> | |
| Please specify _____ | |

7. PHOTOGRAPH

If possible, please attach a photograph of the product.



(1) <https://www.aemps.gob.es/informa/notasinformativas/medicamentosusohumano-3/medillegales/2021-8/la-aemps-retira-el-producto-lipovon-capsulas/>