

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 322

2: Name of authorisation holder NORGINE LIMITED

3: Address(es) of manufacturing site(s) NORGINE LIMITED, NEW ROAD, TIR-Y-BERTH, HENGOED, CF82 8SJ, UNITED KINGDOM

4: Legally registered address of authorisation holder NORGINE LIMITED, ARC UXBRIDGE, BUILDING 01, SANDERSON ROAD, UXBRIDGE, UB8 1DH, UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

6: Legal Basis of authorisation Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Confidential

8: Authorisation Date 24/10/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

NORGINE LIMITED, NEW ROAD, TIR-Y-BERTH, HENGOED, CF82 8SJ, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Investigational Medicinal Products [1.1.3] Batch certification [1.2] Non-sterile investigational medicinal products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.1] Capsules, hard shell [1.2.1.5] Liquids for external use [1.2.1.6] Liquids for internal use [1.2.1.8] Other solid dosage forms

[1.2.1.12] Suppositories

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.2] Capsules, soft shell

[1.5.1.5] Liquids for external use

[1.5.1.6] Liquids for internal use

[1.5.1.8] Other solid dosage forms

[1.5.1.11] Semi-solids

[1.5.1.13] Tablets

[1.5.1.15] Other non-sterile medicinal products

Pessaries, Powders

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.3] Chemical/Physical

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

[2.3] Other Importation Activities

[2.3.4] Other

Importation of QP-certified IMPs from a country on the approved country for import list