

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 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 Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

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 1

Name and address of the site:

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

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.2] Non-sterile products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.1] Capsules, hard shell [1.2.1.8] Other solid dosage forms [1.2.1.13] Tablets [1.2.2] Batch certification [1.5] Packaging [1.5.1] Primary packaging [1.5.1.1] Capsules, hard shell

[1.5.1.8] Other solid dosage forms

[1.5.1.13] Tablets

[1.5.1.17] Other non-sterile medicinal products

Including Powders, Labelling of Primary containers & secondary packaging of primary containers.

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical