

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 10947

2: Name of authorisation holder TEVA NI LIMITED

3: Address(es) of manufacturing site(s) TEVA NI LIMITED, OLD BELFAST ROAD,
MILLBROOK, LARNE, BT40 2SH, UNITED KINGDOM

4: Legally registered address of authorisation holder TEVA NI LIMITED, OLD BELFAST ROAD,
MILLBROOK, LARNE, BT40 2SH, 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 30/01/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

TEVA NI LIMITED, OLD BELFAST ROAD, MILLBROOK, LARNE, BT40 2SH, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [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 [1.2.1.2] Capsules, soft shell [1.2.1.8] Other solid dosage forms [1.2.1.11] Semi-solids [1.2.1.13] Tablets [1.2.1.15] Other non-sterile medicinal products Hormonal Products [1.2.2] Batch certification

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.2] Capsules, soft shell

[1.5.1.8] Other solid dosage forms

[1.5.1.11] Semi-solids

[1.5.1.13] Tablets

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical