

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 11724

2: Name of authorisation holder ANDERSONBRECON (UK) LIMITED
ANDERSONBRECON (UK) LIMITED, UNIT 1, TALGARTH BUSINESS PARK, TREFECCA ROAD, TALGARTH, BRECON, LD3 0PQ, UNITED KINGDOM

3: Address(es) of manufacturing site(s) ANDERSONBRECON (UK) LIMITED, UNITS 2-7, WYE VALLEY BUSINESS PARK, BRECON ROAD, HAY-ON-WYE, HEREFORD, HR3 5PG, UNITED KINGDOM
ANDERSONBRECON (UK) LIMITED, FOREST ROAD, HAY-ON-WYE, HEREFORD, HR3 5EH, UNITED KINGDOM

4: Legally registered address of authorisation holder ANDERSONBRECON (UK) LIMITED, PHAROS HOUSE, WYE VALLEY BUSINESS PARK, BRECON PARK, BRECON ROAD, HAY-ON-WYE, HEREFORD, HR3 5PG, 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 12/02/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

ANDERSONBRECON (UK) LIMITED, UNIT 1, TALGARTH BUSINESS PARK, TREFECCA ROAD, TALGARTH, BRECON, LD3 0PQ, UNITED KINGDOM

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| Human Medicinal Products |
| Authorised Operations |
| MANUFACTURING OPERATIONS (according to part 1) |
| Part 1 - MANUFACTURING OPERATIONS [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
 - [1.5.1.13] Tablets
- [1.5.2] Secondary packaging

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

ANDERSONBRECON (UK) LIMITED, UNITS 2-7, WYE VALLEY BUSINESS PARK, BRECON ROAD, HAY-ON-WYE, HEREFORD, HR3 5PG, UNITED KINGDOM

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| Human 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 Products <ul style="list-style-type: none"> [1.1.3] Batch certification [1.2] Non-sterile products <ul style="list-style-type: none"> [1.2.2] Batch certification [1.3] Biological medicinal products <ul style="list-style-type: none"> [1.3.2] Batch certification <ul style="list-style-type: none"> [1.3.2.2] Immunological products [1.3.2.5] Biotechnology products [1.5] Packaging <ul style="list-style-type: none"> [1.5.1] Primary packaging <ul style="list-style-type: none"> [1.5.1.1] Capsules, hard shell [1.5.1.2] Capsules, soft shell [1.5.1.8] Other solid dosage forms [1.5.1.13] Tablets [1.5.2] Secondary packaging [1.6] Quality control testing <ul style="list-style-type: none"> [1.6.3] Chemical/Physical |
| Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [2.1] Quality control testing of imported medicinal products <ul style="list-style-type: none"> [2.1.3] Chemical/Physical [2.2] Batch certification of imported medicinal products <ul style="list-style-type: none"> [2.2.1] Sterile Products <ul style="list-style-type: none"> [2.2.1.1] Aseptically prepared |

- [2.2.1.2] Terminally sterilised
- [2.2.2] Non-sterile products
- [2.2.3] Biological medicinal products
 - [2.2.3.2] Immunological products
 - [2.2.3.5] Biotechnology products
- [2.3] Other Importation Activities**
 - [2.3.1] Site of Physical Importation

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

ANDERSONBRECON (UK) LIMITED, FOREST ROAD, HAY-ON-WYE, HEREFORD, HR3 5EH, UNITED KINGDOM

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| Human Medicinal Products |
| Authorised Operations |
| MANUFACTURING OPERATIONS (according to part 1) |
| Part 1 - MANUFACTURING OPERATIONS [1.5] Packaging <ul style="list-style-type: none">[1.5.1] Primary packaging<ul style="list-style-type: none">[1.5.1.1] Capsules, hard shell[1.5.1.2] Capsules, soft shell[1.5.1.8] Other solid dosage forms[1.5.1.13] Tablets[1.5.2] Secondary packaging |