

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 12862

2: Name of authorisation holder RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED

3: Address(es) of manufacturing site(s) KFM CO-PACKER LIMITED, EAGLE BUSINESS CENTRE, 49 CLEVELAND STREET, HULL, HU8 7AU, UNITED KINGDOM
PHARMAPAC (UK) LIMITED, UNITS 20 TO 24 AND 29 AND 30, VALLEY ROAD BUSINESS PARK, BIRKENHEAD, CH41 7EL, UNITED KINGDOM
RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED, NOTTINGHAM SITE, THANE ROAD, NOTTINGHAM, NG90 2DB, UNITED KINGDOM

4: Legally registered address of authorisation holder RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED, NOTTINGHAM SITE, THANE ROAD, NOTTINGHAM, NG90 2DB, 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 22/05/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

KFM CO-PACKER LIMITED, EAGLE BUSINESS CENTRE, 49 CLEVELAND STREET, HULL, HU8 7AU, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.5] Packaging [1.5.2] Secondary packaging

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

PHARMAPAC (UK) LIMITED, UNITS 20 TO 24 AND 29 AND 30, VALLEY ROAD BUSINESS PARK, BIRKENHEAD, CH41 7EL,
UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.5] Packaging [1.5.1] Primary packaging [1.5.1.2] Capsules, soft shell [1.5.1.8] Other solid dosage forms [1.5.2] Secondary packaging

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED, NOTTINGHAM SITE, THANE ROAD, NOTTINGHAM, NG90 2DB,
UNITED KINGDOM

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 [1.1.1] Aseptically prepared (processing operations for the following dosage forms) [1.1.1.1] Large volume liquids [1.1.1.4] Small volume liquids [1.1.3] Batch certification [1.2] Non-sterile products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.8] Other solid dosage forms [1.2.1.13] Tablets

[1.2.1.17] Other non-sterile medicinal products

Medicated Lozenges

[1.2.2] Batch certification

[1.4] Other products or manufacturing activity

[1.4.2] Sterilisation of active substances/excipients/finished products:

[1.4.2.1] Filtration

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.2] Capsules, soft shell

[1.5.1.17] Other non-sterile medicinal products

Solid non-sterile unit dosage forms: capsules. Medicated Lozenges

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.1] Microbiological: sterility

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.2] Microbiological: non-sterility

[2.1.3] Chemical/Physical

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.2] Non-sterile products