

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 52842

2: Name of authorisation holder CAMBRIDGE ALLERGY LTD

3: Address(es) of manufacturing site(s) CAMBRIDGE ALLERGY LTD, CENTRAL BUILDING, HOEFORD POINT, BARWELL LANE, GOSPORT, PO13 0AU, UNITED KINGDOM

4: Legally registered address of authorisation holder CAMBRIDGE ALLERGY LTD, BEECH HOUSE, 4A NEWMARKET ROAD, CAMBRIDGE, CB5 8DT, 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 05/04/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

CAMBRIDGE ALLERGY LTD, CENTRAL BUILDING, HOEFORD POINT, BARWELL LANE, GOSPORT, PO13 0AU, UNITED KINGDOM

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| 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 [1.2.1.15] Other non-sterile medicinal products Multi-dose container [1.2.2] Batch certification [1.5] Packaging |

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.15] Other non-sterile medicinal products

Powder for oral use (Blend of peanut powder in excipients filled into either pull-apart hard HMPC capsules or multi-dose container)

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

[1.6.4] Biological