

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 49445

2: Name of authorisation holder AMAROX LIMITED

3: Address(es) of manufacturing site(s) AMAROX LIMITED, CONGRESS HOUSE, 14 LYON ROAD, HARROW, HA1 2EN, UNITED KINGDOM

4: Legally registered address of authorisation holder AMAROX LIMITED, CONGRESS HOUSE, 14 LYON ROAD, HARROW, HA1 2EN, 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 21/11/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

AMAROX LIMITED, CONGRESS HOUSE, 14 LYON ROAD, HARROW, HA1 2EN, UNITED KINGDOM

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| Human Medicinal Products |
| Authorised Operations |
| IMPORTATION OF MEDICINAL PRODUCTS (according to part 2) |
| Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [2.2] Batch certification of imported medicinal products [2.2.1] Sterile Products [2.2.1.1] Aseptically prepared [2.2.1.2] Terminally sterilised [2.2.2] Non-sterile products |