

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 242

2: Name of authorisation holder JANSSEN-CILAG LIMITED

3: Address(es) of manufacturing site(s) JANSSEN-CILAG LIMITED, 50-100 HOLMERS FARM WAY, HIGH WYCOMBE, HP12 4EG, UNITED KINGDOM

4: Legally registered address of authorisation holder JANSSEN-CILAG LIMITED, 50-100 HOLMERS FARM WAY, HIGH WYCOMBE, HP12 4EG, 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 28/04/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

JANSSEN-CILAG LIMITED, 50-100 HOLMERS FARM WAY, HIGH WYCOMBE, HP12 4EG, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [2.3] Other Importation Activities [2.3.4] Other Importation of QP-certified IMPs from a country on the approved country for import list