

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 51611

2: Name of authorisation holder ROCIALLE HEALTHCARE LIMITED

3: Address(es) of manufacturing site(s) ROCIALLE HEALTHCARE LIMITED, CWM CYNON BUSINESS PARK (NORTH), MOUNTAIN ASH, CF45 4ER, UNITED KINGDOM

4: Legally registered address of authorisation holder ROCIALLE HEALTHCARE LIMITED, CWM CYNON BUSINESS PARK (NORTH), MOUNTAIN ASH, CF45 4ER, 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 06/12/2023

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

ROCIALLE HEALTHCARE LIMITED, CWM CYNON BUSINESS PARK (NORTH), MOUNTAIN ASH, CF45 4ER, 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