

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 18515

2: Name of authorisation holder IBSA PHARMA LIMITED

3: Address(es) of manufacturing site(s) IBSA PHARMA LIMITED, UNITS 4-6 COLONIAL BUSINESS PARK, COLONIAL WAY, WATFORD, WD24 4PR, UNITED KINGDOM

4: Legally registered address of authorisation holder IBSA PHARMA LIMITED, UNITS 4-6 COLONIAL BUSINESS PARK, COLONIAL WAY, WATFORD, WD24 4PR, 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 25/03/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

IBSA PHARMA LIMITED, UNITS 4-6 COLONIAL BUSINESS PARK, COLONIAL WAY, WATFORD, WD24 4PR, 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 [1.1.3] Batch certification [1.3] Biological medicinal products [1.3.2] Batch certification [1.3.2.8] Other biological medicinal products Merional (Menotrophin BP) human menopausal gonadotrophin Fostimon (urofollitropin) 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

[2.2.3] Biological medicinal products

[2.2.3.8] Other biological medicinal products

Merional (Menotrophin BP) human menopausal gonadotrophin Fostimon (urofollitropin)