

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 2021

2: Name of authorisation holder FUCHS LUBRICANTS (UK) PLC

3: Address(es) of manufacturing site(s) FUCHS LUBRICANTS (UK) PLC, HANLEY PLANT, NEW CENTURY STREET, HANLEY, STOKE-ON-TRENT, ST1 5HU, UNITED KINGDOM

4: Legally registered address of authorisation holder FUCHS LUBRICANTS (UK) PLC, HANLEY PLANT, NEW CENTURY STREET, HANLEY, STOKE-ON-TRENT, ST1 5HU, 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 10/04/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

FUCHS LUBRICANTS (UK) PLC, HANLEY PLANT, NEW CENTURY STREET, HANLEY, STOKE-ON-TRENT, ST1 5HU, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.2] Non-sterile products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.6] Liquids for internal use [1.2.1.11] Semi-solids [1.2.1.17] Other non-sterile medicinal products Liquid Mineral hydrocarbon SI 1073 1966. Soft paraffin - BP/EP: used as excipients, Liquid & Light Liquid paraffin - BP/EP: used as emollients and laxatives by pharmaceutical companies, hospitals and pharmacists

