

Medicines and Healthcare products Regulatory Agency

REGISTRATION OF MANUFACTURER, IMPORTER OR DISTRIBUTOR OF ACTIVE SUBSTANCES TO BE USED AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE

Registrant Details

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| 1. Registration Number | UK API 25 |
| 2. Name or corporate name of registrant | ORGANON PHARMA (UK) LIMITED |
| 3. Permanent or legal address of registrant | ORGANON PHARMA (UK) LIMITED, SHOTTON LANE,
CRAMLINGTON, NE23 3JU, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | ORGANON PHARMA (UK) LIMITED, SHOTTON LANE,
CRAMLINGTON, NE23 3JU, UNITED KINGDOM |
| 5. National legal basis of registration | Regulation 327 of The Human Medicines Regulations 2012 (SI
2012/1916) |
| 6. Name of responsible officer of the competent authority of the
member state validating the registration | Confidential |
| 7. Date | 29/09/2025 |

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in MHRA-GMDP.

The registration holder referred to in section 2 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in this registration form. Any changes that may have an impact on the quality or safety of the listed active substances must be notified immediately.

SCOPE OF REGISTRATION

Name and address of the site

ORGANON PHARMA (UK) LIMITED, SHOTTON LANE, CRAMLINGTON, NE23 3JU, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance

HYDROCHLOROTHIAZIDE
(1000008764)

3rd Country Manufacturer

IPCA LABORATORIES LIMITED, P.O. SEJAVTA, RATLAM, MADHYA
PRADESH, IN-457001, INDIA

3rd Country Distributor

LOSARTAN POTASSIUM
(2000007877)

DIVI'S LABORATORIES LIMITED, UNIT 2, CHIPPADA VILLAGE,
ANNAVARAM POST, BHEEMUNIPATNAM MANDAL, VISAKHAPATNAM,
ANDHRA PRADESH, IN-531 162, INDIA

ENALAPRIL MALEATE
(2000007672)

SIEGFRIED EVIONNAZ SA, ROUTE DU SIMPLON 1,36, EVIONNAZ, CH-1902,
SWITZERLAND

SITAGLIPTIN PHOSPHATE
(2000010308)

MSD INTERNATIONAL GMBH, SINGAPORE BRANCH, 50 TUAS WEST
DRIVE, SINGAPORE, SG-638408, SINGAPORE

EZETIMIBE (1000000757)

ZHEJIANG TIANYU PHARMACEUTICAL CO., LTD., NO. 15 DONGHAI 5TH
AVENUE, ZHEJIANG PROVINCIAL CHEMICAL AND MEDICAL RAW
MATERIALS BASE, LINHAI ZONE, TAIZHOU CITY, ZHEJIANG PROVINCE,
CN-317016, CHINA

MSD INTERNATIONAL GMBH, SINGAPORE BRANCH, 50 TUAS WEST
DRIVE, SINGAPORE, SG-638408, SINGAPORE

MONTELUKAST SODIUM
(2000007158)

ZHEJIANG TIANYU PHARMACEUTICAL CO., LTD., NO. 15 DONGHAI 5TH
AVENUE, ZHEJIANG PROVINCIAL CHEMICAL AND MEDICAL RAW
MATERIALS BASE, LINHAI ZONE, TAIZHOU CITY, ZHEJIANG PROVINCE,
CN-317016, CHINA

ATORVASTATIN (1000008348)

TEVA API INDIA PRIVATE LIMITED, PLOT NOS Q1 TO Q4, INDUSTRIAL
AREA, GHIRONGI, MALANPUR, BHIND, MADHYA PRADESH, IN-477 117,
INDIA