

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, THE HEWETT BUILDING, 14 HEWETT STREET, LONDON, EC2A 3NP, 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 | 20/01/2025 |

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

3rd Country Manufacturer

3rd Country Distributor

EZETIMIBE (1000000757)

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

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

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| LEVODOPA (1000007908) | SHANDONG XINHUA PHARMACEUTICAL CO , EAST CHEMICAL ZONE OF ZIBO HIGH & NEW TECHNOLOGY DEVELOPMENT ZONE, ZHANGDIAN DISTRICT, ZIBO, SHANDONG, CN-255 075, CHINA |
| HYDROCHLOROTHIAZIDE (1000008764) | IPCA LABORATORIES LIMITED , P.O. SEJAVTA, RATLAM, MADHYA PRADESH, IN-457001, INDIA |
| 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 |
| CARBIDOPA (1000006709) | MERCK & CO ELKTON , MERCK MANUFACTURING DIVISION, 2778 SOUTH EAST SIDE HIGHWAY, ELKTON, 22827, UNITED STATES |
| ENALAPRIL MALEATE (2000007672) | DIVI'S LABORATORIES LIMITED , UNIT 2, CHIPPADA VILLAGE, ANNAVARAM POST, BHEEMUNIPATNAM MANDAL, VISAKHAPATNAM, ANDHRA PRADESH, IN-531 162, INDIA |
| LOSARTAN POTASSIUM (2000007877) | SIEGFRIED EVIONNAZ SA , ROUTE DU SIMPLON 1,36, EVIONNAZ, CH-1902, SWITZERLAND |
| SITAGLIPTIN PHOSPHATE (2000010308) | DIVI'S LABORATORIES LIMITED , UNIT 2, CHIPPADA VILLAGE, ANNAVARAM POST, BHEEMUNIPATNAM MANDAL, VISAKHAPATNAM, ANDHRA PRADESH, IN-531 162, INDIA |
| | MSD INTERNATIONAL GMBH, SINGAPORE BRANCH , 50 TUAS WEST DRIVE, SINGAPORE, SG-638408, SINGAPORE |