

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 530 |
| 2. Name or corporate name of registrant | NORTON HEALTHCARE LIMITED |
| 3. Permanent or legal address of registrant | NORTON HEALTHCARE LIMITED, RIDINGS POINT, WHISTLER DRIVE, CASTLEFORD, WF10 5HX, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | NORTON HEALTHCARE LIMITED T/A IVAX PHARMACEUTICALS UK, ASTON LANE NORTH, WHITEHOUSE VALE INDUSTRIAL ESTATE, RUNCORN, WA7 3FA, 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 | 18/10/2024 |

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

NORTON HEALTHCARE LIMITED T/A IVAX PHARMACEUTICALS UK, ASTON LANE NORTH, WHITEHOUSE VALE INDUSTRIAL ESTATE, RUNCORN, WA7 3FA, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance

BUDESONIDE (1000007214)

3rd Country Manufacturer

SICOR DE MEXICO S A DE C V, AVENIDA SAN RAFAEL NO. 35, PARQUE INDUSTRIAL LERMA, LERMA, MEXICO STATE, MX-CP 52000, MEXICO

3rd Country Distributor

LEVALBUTEROL
HYDROCHLORIDE
(4000002312)

AARTI INDUSTRIES LIMITED, UNIT IV, PLOT NO E-50, MIDC, TALUKA
PALGHAR, DISTRICT PALGHAR, TARAPUR, MAHARASHTRA, IN-401 506,
INDIA

ARFORMOTEROL
TARTRATE (2000016936)

MSN LABORATORIES PRIVATE LIMITED, SURVEY NOS 317, 320, 321, 322,
323, 604 & 605, RUDRARAM VILLAGE, PATANCHERU MANDAL,
SANGAREDDY DISTRICT, TELANGANA, IN-502329, INDIA

FREMANEZUMAB
(1000018900)

CELLTRION, INC, 20 ACADEMY-RO 51 BEON-GIL, YEONSU-GU, INCHEON,
KR-22014, SOUTH KOREA

LONZA BIOLOGICS INC., 101 INTERNATIONAL DRIVE, PORTSMOUTH,
03801-2846, UNITED STATES