

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 49594 |
| 2. Name or corporate name of registrant | ACI GROUP LTD |
| 3. Permanent or legal address of registrant | ACI GROUP LTD, MOOR HALL, THE MOOR, COOKHAM, MAIDENHEAD, SL6 9QH, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | MOVIANTO UK LIMITED, UNIT 1, BEDFORD LINK LOGISTICS PARK, BELL FARM WAY, KEMPSTON, BEDFORD, MK43 9SS, UNITED KINGDOM ACI GROUP LTD, MOOR HALL, THE MOOR, COOKHAM, MAIDENHEAD, SL6 9QH, 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 | 20/08/2024 |

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

MOVIANTO UK LIMITED, UNIT 1, BEDFORD LINK LOGISTICS PARK, BELL FARM WAY, KEMPSTON, BEDFORD, MK43 9SS, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

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|---|-------------------------------------|
| B | Distribution |
| | DOMIPHEN BROMIDE (2000007748) |
| | PARACETAMOL (1000009609) |
| | BENZOCAINE (1000009160) |
| | AMOBARBITAL SODIUM (4000006304) |
| | SECOBARBITAL SODIUM (4000007161) |
| | HYDROCORTISONE ACETATE (2000007338) |

PSEUDOEPHEDRINE HYDROCHLORIDE (2000007829)

Name and address of the site

ACI GROUP LTD, MOOR HALL, THE MOOR, COOKHAM, MAIDENHEAD, SL6 9QH, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

| Active Substance | 3rd Country Manufacturer | 3rd Country Distributor |
|--|---|-------------------------|
| PSEUDOEPHEDRINE HYDROCHLORIDE (2000007829) | MALLADI DRUGS AND PHARMACEUTICALS LIMITED, UNIT 3, 7B AND 7C, SIPCOT INDUSTRIAL COMPLEX, RANIPET, RANIPET, TAMIL NADU, IN-632403, INDIA | |
| CYCLIZINE HYDROCHLORIDE (2000007923) | SRIKEM LABORATORIES PVT, LIMITED, PLOT NO. 17/42 MIDC, TALOJA, PANVEL, NAVI MUMBAI, MAHARASHTRA, IN-410 208, INDIA | |
| CHLORPHENIRAMINE MALEATE (2000008095) | SUPRIYA LIFE SCIENCE LIMITED, A-5/2 LOTE PARSHURAM INDUSTRIAL AREA, MIDC, TALUKA KHED, RATNAGIRI, MAHARASHTRA, IN-415 722, INDIA | |
| BENZOCAINE (1000009160) | CHANGZHOU SUNLIGHT PHARMACEUTICAL CO., LIMITED., 216 YUNNAN WEST ROAD, BENNIU TOWN, XINBEI DISTRICT, CHANGZHOU CITY, JIANGSU PROVINCE, CN 213134, CHINA | |
| PARACETAMOL (1000009609) | ANQIU LUAN PHARMACEUTICAL, 35 WEIXU NORTH ROAD, ANQIU CITY, SHANDONG PROVINCE, CN-262 100, CHINA | |

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

AMOBARBITAL SODIUM (4000006304)
DOMIPHEN BROMIDE (2000007748)
CHLORAL HYDRATE (1000005193)
QUININE HYDROCHLORIDE (2000007815)
BARBITAL SODIUM (2000008438)
PSEUDOEPHEDRINE HYDROCHLORIDE (2000007829)
CYCLIZINE HYDROCHLORIDE (2000007923)
CHLORPHENIRAMINE MALEATE (2000008095)
BISMUTH SUBSALICYLATE (2000008291)
HYDROCORTISONE ACETATE (2000007338)
SECOBARBITAL SODIUM (4000007161)
QUININE SULPHATE (2000007814)
BENZOCAINE (1000009160)
GLYCERYL TRINITRATE (1000001637)
PARACETAMOL (1000009609)