

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 39574 |
| 2. Name or corporate name of registrant | FAGRON UK LIMITED |
| 3. Permanent or legal address of registrant | FAGRON UK LIMITED, MEDIA EXCHANGE, 4B COQUET STREET,
NEWCASTLE UPON TYNE, NE1 2QB, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | FAGRON UK LIMITED, MEDIA EXCHANGE, 4B COQUET STREET,
NEWCASTLE UPON TYNE, NE1 2QB, 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 | 01/05/2025 |

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

FAGRON UK LIMITED, MEDIA EXCHANGE, 4B COQUET STREET, NEWCASTLE UPON TYNE, NE1 2QB, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
MINOCYCLINE HYDROCHLORIDE (2000008251)	KUMAR ORGANICS PRODUCTS LIMITED , TUSTIN, CALIFORNIA 92680, Data Not Available, Data Not Available, UNITED STATES	

DUTASTERIDE (1000007791)	SWATI SPENTOSE PRIVATE LIMITED , UNIT-I, PLOT NUMBER A-1/2102, 2103 AND A-2/2120, PHASE III, G.I.D.C., DISTRICT VALSAD, VAPI, GUJARAT, IN- 396195, INDIA	
CAPTOPRIL (1000006787)	CHANGZHOU PHARMACEUTICAL FACTORY , 518 LAODONG EAST ROAD, CHANGZHOU, JIANGSU PROVINCE, CN-213018, CHINA	FAGRON US INC , 2400 PILOT KNOB ROAD, ST PAUL, 55120, UNITED STATES
ADAPALENE (1000002293)	BAL PHARMA LIMITED , UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, INDIA	
L-ARGININE (3000004673)	SHANGHAI KYOWA AMINO ACID CO, LIMITED , NO.158, XINTUAN ROAD, QINGPU INDUSTRIAL ZONE, SHANGHAI, CN-201 707, CHINA	
IVERMECTIN (1000001158)	ZHEJIANG HUAHAI PHARMACEUTICAL CO.LTD , XUNQIAO, LINHAI CITY, ZHEJIANG PROVINCE, CN- 317024, CHINA	
FINASTERIDE (1000007415)	HUBEI GEDIAN HUMANWELL PHARMACEUTICAL CO, LIMITED. , NO. 199 JIANSHE AVENUE, GEDIAN ECONOMIC DEVELOPMENT DISTRICT, EZHOU, HUBEI, CN-436070, CHINA	HUBEI GEDIAN HUMANWELL PHARMACEUTICAL CO, LIMITED. , NO. 199 JIANSHE AVENUE, GEDIAN ECONOMIC DEVELOPMENT DISTRICT, EZHOU, HUBEI, CN-436070, CHINA
LOPERAMIDE HYDROCHLORIDE (2000008494)	VASUDHA PHARMA CHEM LIMITED , UNIT I, PLOT NO. 37/A, 38, 39 A & B , PHASE I, INDUSTRIAL DEVELOPMENT AREA, JEEDIMETLA, HYDERABAD, TELANGANA, IN 500055, INDIA	FAGRON US INC , 2400 PILOT KNOB ROAD, ST PAUL, 55120, UNITED STATES
SUCRALFATE (1000009411)	ZHEJIANG HAISEN PHARMACEUTICAL CO LIMITED , LIUSHI STREET, DONGYANG CITY, ZHEJIANG, CN- 322104, CHINA	
AZATHIOPRINE (1000009761)	RPG LIFE SCIENCES LIMITED , 25 MIDC LAND, THANE- BELAPUR ROAD, NAVI MUMBAI, MAHARASHTRA, IN- 400 703, INDIA	

TRANEXAMIC ACID (1000009308)	HUNAN DONGTING PHARMACUTICAL CO. LIMITED, NO.16 DONGYANG ROAD, CHENJIAGANG COMMUNITY, DESHAN SUB-DISTRICT OFFICE, CHANGDE ECONOMIC AND TECHNICAL DEVELOPMENT ZONE, CHANGDE CITY, HUNAN PROVINCE, CN-415001, CHINA	
PHENOL CRYSTALS (3000020190)	AVANTOR PERFORMANCE MATERIALS INCORPORATED, 7001 MARTIN LUTHER KING BOULEVARD, PARIS, 40361, UNITED STATES	FAGRON US INC, 2400 PILOT KNOB ROAD, ST PAUL, 55120, UNITED STATES
ATROPINE SULPHATE (2000008446)	SAURAV CHEMICALS LIMITED, UNIT 3, DERABASSI BARWALA ROAD, VILLAGE BHAGWANPURA, SAHIBZADA AJIT SINGH NAGAR, DERABASSI, PUNJAB, IN-140507, INDIA	
HYDROCORTISONE (1000008762)	TIANJIN JINJIN PHARMACEUTICAL CO LIMITED, 8 JINGFU ROAD, INDUSTRIAL ZONE OF ZHANGJIAWO TOWN, XIQING DISTRICT, TIANJIN, CN-300387, CHINA	
CLOTRIMAZOLE (1000003999)	AMOLI ORGANICS PVT. LIMITED., PLOT NO 322/4, 40 SHED AREA, GIDC, VAPI, GUJARAT, IN-396 195, INDIA	
TACROLIMUS (1000002882)	CONCORD BIOTECH LIMITED, 1482-1486 TRASAD ROAD, DHOLKA, AHMEDABAD DISTRICT, GUJARAT, IN-382 225, INDIA	FAGRON US INC, 2400 PILOT KNOB ROAD, ST PAUL, 55120, UNITED STATES
MINOXIDIL (1000000832)	KUMAR ORGANICS PRODUCTS LIMITED, TUSTIN, CALIFORNIA 92680, Data Not Available, Data Not Available, UNITED STATES	
TADALAFIL (1000000162)	ZHEJIANG HUAHAI PHARMACEUTICAL CO.LTD, XUNQIAO, LINHAI CITY, ZHEJIANG PROVINCE, CN- 317024, CHINA	
TESTOSTERONE MICRONISED (2000018723)	JIANGSU JIAERKE PHARMACEUTICALS GROUP CORP LIMITED, SANHUANGMIAO, WUJIN, CHANGZHOU, ZHENGLU, JIANGSU, CN-213 111, CHINA	FAGRON US INC, 2400 PILOT KNOB ROAD, ST PAUL, 55120, UNITED STATES

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B	Distribution
	THIAMINE HYDROCHLORIDE (4000010937)
	CALCIUM HYDROGEN PHOSPHATE (2000008265)

TOCOFERSOLAN (4000012967)
ESTRADIOL HEMIHYDRATE (2000016108)
TRYPTOPHAN (1000009274)
METHIMAZOLE (3000012191)
BUPIVACAINE HYDROCHLORIDE (2000008278)
METHACHOLINE BROMIDE POWDER (4000015286)
PREGNENOLONE ACETATE (2000009822)
OXYBUTYNIN HYDROCHLORIDE (2000008318)
SPIRONOLACTONE MICRONISED (2000018722)
LACTIC ACID (1000008218)
LEVOTHYROXINE SODIUM (2000013292)
PHENYLEPHRINE HYDROCHLORIDE (2000008067)
DIMETHYL SULFOXIDE (3000005283)
SODIUM CHLORIDE (1000009536)
MAGNESIUM TRISILICATE (1000000774)
METOPROLOL TARTRATE (2000008259)
CHLORAL HYDRATE (1000005193)
BENZOYL PEROXIDE (1000009105)
GLYCEROL (1000001659)
MINOCYCLINE HYDROCHLORIDE (2000008251)
PROFLAVINE HEMISULPHATE (2000007900)
SODIUM CITRATE (1000009535)
HYDROCORTISONE ACETATE (2000007338)
TRETINOIN (1000009303)
TRICHLOROACETIC ACID (1000007071)
SODIUM BICARBONATE (1000009540)
ICHTHAMMOL (1000008905)
AMBROXOL HYDROCHLORIDE (2000006335)
NITRAZEPAM (1000009676)
TESTOSTERONE PROPIONATE (2000007380)
AMLODIPINE BESILATE (2000015864)
BISMUTH SUBGALLATE (2000008349)
CAFFEINE CITRATE (2000008271)
CETIRIZINE DIHYDROCHLORIDE (4000006373)
ISONIAZID (1000007745)
CALCIUM CHLORIDE DIHYDRATE (4000009373)
CLOBETASONE BUTYRATE (2000008013)
CLOBETASOL 17-PROPIONATE (4000007268)
CYANOCOBALAMIN (4000010977)
AMMONIUM CHLORIDE (1000008021)
AMITRIPTYLINE HYDROCHLORIDE (2000008522)

BENZOCAINE (1000009160)
DISODIUM PHOSPHATE ANHYDROUS (3000006909)
PHENYTOIN (1000009887)
ERGOCALCIFEROL (2000007667)
WHITE SOFT PARAFFIN (4000006817)
DL-ALPHA TOCOPHEROL (4000011023)
BENZOIC ACID (1000009143)
SODIUM THIOSULPHATE (1000007419)
NALTREXONE HYDROCHLORIDE (2000007614)
SODIUM OXYBATE (2000013094)
CLIOQUINOL (1000004182)
CHLORAMPHENICOL MICRONISED (3000020176)
HYDROCORTISONE BUTYRATE (2000007337)
COCONUT OIL (2000007942)
WARFARIN SODIUM (2000008471)
CETRIMIDE (1000006286)
GLUCOSE MONOHYDRATE (4000006254)
KETOCONAZOLE (1000008441)
CHLOROBUTANOL HEMIHYDRATE (2000011272)
DITHRANOL (1000002937)
HYDROCHLOROTHIAZIDE (1000008764)
GENTAMICIN SULFATE (4000011668)
PHENOBARBITAL SODIUM (2000008072)
NEOMYCIN SULPHATE MICRONISED (2000018721)
MAGNESIUM CHLORIDE (2000012207)
CLOBAZAM (1000004171)
MACROGOL 300 (1000009031)
CHLORHEXIDINE DIACETATE (4000007351)
UREA (1000009262)
FOLIC ACID (1000001996)
PYRIDOXINE HYDROCHLORIDE (4000010966)
LEVOMENTHOL SYNTHETIC (3000003004)
YELLOW SOFT PARAFFIN (4000006813)
METRONIDAZOLE (1000001131)
CARBAMAZEPINE (1000006757)
TOCOPHERYL ACETATE (4000010502)
BUSULPHAN (1000007138)
LACTOSE (1000008197)
ALMOND OIL (4000010203)
MICONAZOLE (1000001002)
PHENOL (1000009902)

TETRACAINE HYDROCHLORIDE (2000010807)
CHLORHEXIDINE ACETATE (2000008103)
DUTASTERIDE (1000007791)
ALUMINIUM SULPHATE (1000002620)
ALLOPURINOL (1000003843)
GLUCOSE ANHYDROUS (4000009250)
TRIAMCINOLONE ACETONIDE (2000008586)
AMISULPRIDE (1000003074)
QUININE SULFATE (4000007240)
URIDINE (1000006884)
CAPTOPRIL (1000006787)
ADAPALENE (1000002293)
PREGNENOLONE (1000011186)
FRUCTOSE (1000002379)
CHLORHEXIDINE DIGLUCONATE SOLUTION 20% (4000003169)
HISTIDINE (1000008814)
SULPHUR (1000009383)
CLOPIDOGREL BISULFATE (4000011216)
SILDENAFIL CITRATE (2000006954)
L-ARGININE (3000004673)
BENZYLAMINE HYDROCHLORIDE (2000008364)
MACROGOL 1000 (1000007757)
ESTRIOL (3000004591)
BISACODYL (1000007386)
LATANOPROST (1000003257)
QUININE HYDROCHLORIDE (2000007815)
DEXAMETHASONE (1000003334)
IVERMECTIN (1000001158)
CLONIDINE HYDROCHLORIDE (2000008010)
OXYTOCIN (1000009622)
L-CARNITINE (3000007571)
NICOTINAMIDE (2000012339)
HYDROXYETHYLCELLULOSE (1000008666)
GLUCOSE (1000012489)
SODIUM BENZOATE (2000013061)
MACROGOL 4000 POWDER (4000015282)
PROGESTERONE (1000009777)
PREDNISOLONE SODIUM PHOSPHATE (2000007914)
PAPAVERINE HYDROCHLORIDE (2000008091)
DIAZEPAM (1000003208)
MACROGOL 1500 (1000008431)

ARTICAINE HYDROCHLORIDE (2000011172)
FINASTERIDE (1000007415)
QUININE DIHYDROCHLORIDE (2000007816)
LOPERAMIDE HYDROCHLORIDE (2000008494)
CAPSAICIN (1000006807)
CALCIUM LACTATE PENTAHYDRATE (4000009405)
HYDROXYCHLOROQUINE SULPHATE (2000007327)
PROPRANOLOL HYDROCHLORIDE (2000007892)
PARACETAMOL (1000009609)
CADE OIL (4000009842)
DISODIUM PHOSPHATE DODECAHYDRATE (3000014453)
CHLOROFORM (1000004649)
COCAINE HYDROCHLORIDE (2000007943)
BUMETANIDE (1000007192)
%SODIUM BORATE ANHYDROUS% (3000000001)
BACLOFEN (1000009324)
SUCRALFATE (1000009411)
VITAMIN A PALMITATE (4000006828)
MIDAZOLAM HYDROCHLORIDE (2000008252)
MAGNESIUM GLYCEROPHOSPHATE (2000012211)
KETAMINE HYDROCHLORIDE (2000008609)
DIAZOXIDE (1000003204)
AZATHIOPRINE (1000009761)
THEOPHYLLINE (1000009347)
RIBOFLAVIN SODIUM PHOSPHATE (4000007238)
TRANEXAMIC ACID (1000009308)
BECLOMETASONE DIPROPIONATE (4000006191)
COPPER SULPHATE (2000007927)
PHENOL CRYSTALS (3000020190)
FLUORESCEIN SODIUM (2000007506)
PRASTERONE (1000006301)
MAGNESIUM OXIDE (1000000883)
CALCIUM CITRATE ANHYDROUS (4000009380)
BETAINE (1000007477)
ESTRADIOL (1000017043)
TOBRAMYCIN SULPHATE (2000008597)
MAGNESIUM STEARATE (1000008714)
NYSTATIN (1000009661)
BUDESONIDE (1000007214)
ENALAPRIL MALEATE (2000007672)
MEXILETINE HYDROCHLORIDE (2000008257)

ZINC PYRITHIONE (4000008930)
AMOXICILLIN (3000006129)
ALUMINIUM OXIDE HYDRATED (3000010996)
CLOZAPINE (1000009115)
RIBOFLAVIN (4000010954)
CYPROTERONE ACETATE (2000007860)
DILTIAZEM HYDROCHLORIDE (2000007763)
CYSTEINE HYDROCHLORIDE (2000007859)
BENZALKONIUM CHLORIDE SOLUTION 50% (4000007313)
OXETACAIN (3000004664)
VANCOMYCIN HYDROCHLORIDE (2000008485)
METHENAMINE (1000000630)
HYDROXOCOBALAMIN CHLORIDE (4000010981)
BENDROFLUMETHIAZIDE (3000006463)
CHLOROTHIAZIDE (1000004605)
KETOPROFEN (1000008346)
LEVOMENTHOL NATURAL (3000003005)
MAGNESIUM SULPHATE HEPTAHYDRATE (4000009924)
CIPROFLOXACIN HYDROCHLORIDE (2000008038)
LEVOMEPRIMAZINE MALEATE (2000012271)
ATROPINE SULPHATE (2000008446)
OMEPRazole (1000009101)
HYDROCORTISONE (1000008762)
DISODIUM PHOSPHATE DIHYDRATE (3000014468)
DOXYLAMINE SUCCINATE (2000007681)
TRIAMCINOLONE MICRONISED (2000018724)
DIMETHICONE 350 (4000009591)
PIROXICAM (1000009856)
AZITHROMYCIN (1000009476)
CLOTRIMAZOLE (1000003999)
PHENTOLAMINE MESILATE (4000007412)
CALAMINE (1000007496)
AMIODARONE HYDROCHLORIDE (2000008524)
FLUOXETINE HYDROCHLORIDE (2000008390)
CHOLESTEROL (1000004479)
FEXOFENADINE HYDROCHLORIDE (2000007522)
POVIDONE-IODINE (1000009800)
MACROGOL 400 (1000008642)
BETAMETHASONE DIPROPIONATE (2000008360)
CANNABIDIOL (1000000540)
POTASSIUM IODIDE (1000009810)

IODINE (1000008377)
CINNARIZINE (1000004760)
POLIHEXANIDE 20% SOLUTION (3000020193)
CHOLECALCIFEROL (2000008032)
PHENOBARBITAL (1000014071)
MACROGOL 6000 (3000003702)
ACETYLCYSTEINE (1000009816)
CHLORHEXIDINE HYDROCHLORIDE (2000008100)
CASTOR OIL (2000011186)
LOCUST BEAN GUM (3000001000)
ALLANTOIN (1000004055)
TACROLIMUS (1000002882)
DEXTROMETHORPHAN HYDROBROMIDE (2000007835)
MAGNESIUM CARBONATE HEAVY (2000008430)
ADRENALINE TARTRATE (4000006411)
CITRIC ACID MONOHYDRATE (2000008022)
TROMETAMOL (1000009280)
HYDROXYZINE HYDROCHLORIDE (2000007325)
FURAZOLIDONE (1000007453)
FERRIC CHLORIDE HEXAHYDRATE (4000004546)
TETRACAINE (1000012475)
SODIUM DIHYDROGEN PHOSPHATE (3000010117)
CHLORPHENIRAMINE MALEATE (2000008095)
METHYL SALICYLATE (1000000149)
GALACTOSE (1000008044)
ACETYLSALICYLIC ACID (3000006351)
DICLOFENAC SODIUM (2000007774)
MINOXIDIL (1000000832)
POTASSIUM CITRATE (1000009817)
NITROFURANTOIN (1000009675)
EOSIN (1000005976)
BORAX (1000007346)
LIDOCAINE HYDROCHLORIDE (2000014083)
TROMETAMOL HYDROCHLORIDE (2000003893)
POTASSIUM DIHYDROGEN PHOSPHATE (4000011338)
TOPIRAMATE (1000002932)
CHLORHEXIDINE GLUCONATE SOLUTION 20% (4000003482)
TOBRAMYCIN (1000009320)
HYDROQUINONE (1000008752)
TADALAFIL (1000000162)
BORIC ACID (1000007337)

BENZALKONIUM CHLORIDE (2000010983)
NIFEDIPINE (1000009680)
PEPPERMINT OIL (4000010071)
CAMPOR RACEMIC (4000000347)
DIMETHICONE 1000 (4000009592)
THEOPHYLLINE MONOHYDRATE (4000006918)
ZINC GLUCONATE (2000005863)
PREDNISOLONE (1000009794)
CLINDAMYCIN HYDROCHLORIDE (2000006497)
L-METHIONINE (3000004549)
CITRIC ACID ANHYDROUS (3000004479)
GLYCINE (1000012477)
FUROSEMIDE (3000005943)
METHIONINE (1000000542)
METFORMIN HYDROCHLORIDE (2000008338)
MAGNESIUM CHLORIDE HEXAHYDRATE (4000009913)
POTASSIUM CHLORIDE (1000009818)
GLYCEROL MONOSTEARATE (3000001363)
DISODIUM EDETATE (2000007753)
MELATONIN (1000000731)
MANNITOL (1000000458)
NORADRENALINE TARTRATE (4000003578)
TESTOSTERONE MICRONISED (2000018723)
SALICYLIC ACID (1000009710)
SILDENAFIL (1000008149)
QUETIAPINE MICRONISED (3000020192)
QUINIDINE SULPHATE (2000007818)
CALCIUM CARBONATE HEAVY (4000007498)
GLYCOPYRROLONIUM BROMIDE (2000011773)
AMPHOTERICIN B (1000012483)
ZINC OXIDE (2000008399)
AZELAIC ACID (1000007411)
L-CITRULLINE (3000016930)
MIDAZOLAM MALEATE (2000015392)
DOXYCYCLINE HYCLATE (4000006937)
GABAPENTIN (1000007380)
SODIUM METABISULPHITE (1000008708)
L-ARGININE HYDROCHLORIDE (4000006512)
FLUOCINOLONE ACETONIDE (2000007511)
DEFEROXAMINE MESYLATE (4000006726)
AMILORIDE HYDROCHLORIDE (2000008529)

CALCIUM CARBONATE LIGHT (2000006127)
BETAMETHASONE VALERATE (2000008358)
GRISEOFULVIN (1000001953)
NADOLOL (1000000391)
NEOMYCIN SULPHATE (2000008175)
CALCIUM GLUCONATE MONOHYDRATE (4000009385)
ESTRADIOL BENZOATE (2000016107)
PHENOXYETHANOL (1000009898)
CAFFEINE (1000007507)