

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 43995 |
| 2. Name or corporate name of registrant | H.W. COATES LIMITED |
| 3. Permanent or legal address of registrant | H.W. COATES LIMITED, COSFORD LANE, SWIFT VALLEY
INDUSTRIAL ESTATE, RUGBY, CV21 1QN, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | H.W. COATES LIMITED, MIDDLEWICH ROAD INDUSTRIAL ESTATE,
BYLEY, MIDDLEWICH, CW10 9NT, UNITED KINGDOM

H.W. COATES LIMITED, ASTON WAY, MIDPOINT 18, MIDDLEWICH,
CW10 0HS, 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 | 11/06/2025 |

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

H.W. COATES LIMITED, MIDDLEWICH ROAD INDUSTRIAL ESTATE, BYLEY, MIDDLEWICH, CW10 9NT, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

- | | |
|---|---|
| B | Distribution |
| | BENAZEPRIL (1000008011) |
| | GUAIFENESIN (3000005625) |
| | PRAZQUANTEL (1000015572) |
| | PROPRANOLOL HYDROCHLORIDE (2000007892) |
| | SIMETHICONE ANTIFOAM PD30S (2000019405) |
| | CISAPRIDE (1000009097) |
| | DOXYCYCLINE MONOHYDRATE (2000007682) |

ENROFLOXACIN (1000017859)
SUCRALFATE (1000009411)
PARACETAMOL (1000009609)
ENALAPRIL MALEATE (2000007672)
HYDROQUINONE (1000008752)
EMODEPSIDE (1000018388)
FERRIC SODIUM EDTA (4000016917)
METRONIDAZOLE BENZOATE (2000008258)
SIMETHICONE ANTIFOAM C100LV (2000020616)
ACETYLCYSTEINE (1000009816)
NEOMYCIN SULPHATE (2000008175)
SODIUM BICARBONATE (1000009540)
WITCH HAZEL (3000009497)
TACROLIMUS (1000002882)
METFORMIN HYDROCHLORIDE (2000008338)
GABAPENTIN (1000007380)
ALLANTOIN (1000004055)
CYANOCOBALAMIN (4000010977)
PREDNISOLONE ACETATE (2000007916)
CALCIUM L-5-METHYLTETRAHYDROFOLATE (4000016072)
ZINC OXIDE (2000008399)
SODIUM ALGINATE (2000011136)
SODIUM FEREDATE (4000007079)
SODIUM IRON (III) ETHYLENEDIAMINETETRAACETATE (2000020259)
SIMETHICONE ANTIFOAM C100EP (2000020615)
FAMOTIDINE (1000002421)
SPIRONOLACTONE (1000009436)
DIMETHYL SULFOXIDE (3000005283)
DEXAMETHASONE (1000003334)
AZITHROMYCIN DIHYDRATE (2000007794)
TRIMETHOPRIM (1000009283)

Name and address of the site

H.W. COATES LIMITED, ASTON WAY, MIDPOINT 18, MIDDLEWICH, CW10 0HS, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution
 CETRIMIDE (1000006286)
 CAFFEINE (1000007507)
 PHENOBARBITAL (1000014071)
 EPHEDRINE HYDROCHLORIDE (2000007671)
 PENICILLIN (1000005610)

CHLORDIAZEPOXIDE HYDROCHLORIDE (2000008104)
METRONIDAZOLE (1000001131)
LABETALOL HYDROCHLORIDE (2000008520)
GRANISETRON (1000009464)
ICHTHAMMOL (1000008905)
DIMETHICONE (3000011022)
METHYL SALICYLATE (1000000149)
3-AMINO-4-CHLOROBENZOTRIFLUORIDE (3000018305)
SODIUM BICARBONATE (1000009540)
SALICYLIC ACID (1000009710)
DEFEROXAMINE MESYLATE (4000006726)
DIHYDROCODEINE TARTRATE (2000007767)
SIMETHICONE (1000009128)
CODEINE PHOSPHATE HEMIHYDRATE (4000006570)
INOSITOL (1000008613)
CHLORHEXIDINE GLUCONATE (2000008102)
PSEUDOEPHEDRINE HYDROCHLORIDE (2000007829)
SODIUM CHLORIDE (1000009536)
BENZALKONIUM CHLORIDE (2000010983)
PHENYTOIN (1000009887)
STRONG CETRIMIDE SOLUTION 40% (4000009467)
PHENOBARBITONE (3000014222)
PARACETAMOL (1000009609)
ACETYLSALICYLIC ACID (3000006351)
NYSTATIN (1000009661)
LOFEPRAMINE HYDROCHLORIDE (2000008496)
DIAZEPAM (1000003208)