

**Authorised Products Containing Substances Listed in Schedule 2 of  
the Misuse of Drugs Regulations 1988, as amended**

**Human medicines**

| Product Name                                    | Marketing Authorisation Number | Controlled Substance                              |
|---|--------------------------------|---|
| Rapifen 500mcg/ml Solution for Inj/Inf          | PA0748/040/001                 | Alfentanil HCl                                    |
| BuTrans 5mcg/hr Transdermal patch               | PPA1151/194/001                | Buprenorphine                                     |
| BuTrans 10mcg/hr Transdermal patch              | PPA1151/194/002                | Buprenorphine                                     |
| BuTrans 20mcg/hr Transdermal patch              | PPA1151/194/003                | Buprenorphine                                     |
| BuTrans 15mcg/hr Transdermal patch              | PA1688/002/004                 | Buprenorphine                                     |
| BuTrans 10mcg/hr Transdermal patch              | PA1688/002/002                 | Buprenorphine                                     |
| BuTrans 20mcg/hr Transdermal patch              | PA1688/002/003                 | Buprenorphine                                     |
| BuTrans 5mcg/hr Transdermal patch               | PA1688/002/001                 | Buprenorphine                                     |
| Transtec 35mcg/hr Transdermal patch             | PA1032/001/001                 | Buprenorphine                                     |
| Transtec 52.5mcg/hr Transdermal patch           | PA1032/001/002                 | Buprenorphine                                     |
| Transtec 70mcg/hr Transdermal patch             | PA1032/001/003                 | Buprenorphine                                     |
| Transtec 35mcg/hr Transdermal patch             | PPA0465/315/001                | Buprenorphine                                     |
| Transtec 52.5mcg/hr Transdermal patch           | PPA0465/315/002                | Buprenorphine                                     |
| Transtec 70mcg/hr Transdermal patch             | PPA0465/315/003                | Buprenorphine                                     |
| Buprenorphine 2mg Sublingual tablets            | PA1333/003/002                 | Buprenorphine HCl                                 |
| Buprenorphine 8mg Sublingual tablets            | PA1333/003/003                 | Buprenorphine HCl                                 |
| Buprenorphine 0.4mg Sublingual tablets          | PA1567/001/001                 | Buprenorphine HCl                                 |
| Buprenorphine 2mg Sublingual tablets            | PA1567/001/002                 | Buprenorphine HCl                                 |
| Buprenorphine 8mg Sublingual tablets            | PA1567/001/003                 | Buprenorphine HCl                                 |
| Subutex 0.4mg Sublingual tablets                | PA1657/001/001                 | Buprenorphine HCl                                 |
| Subutex 2mg Sublingual tablets                  | PA1657/001/002                 | Buprenorphine HCl                                 |
| Subutex 8mg tablet                              | PA1657/001/003                 | Buprenorphine HCl                                 |
| Temgesic 300microgram/ml solution for injection | PA1657/002/002                 | Buprenorphine HCl                                 |
| Temgesic 200microgram Sublingual tablets        | PA1657/002/001                 | Buprenorphine HCl                                 |
| Suboxone 2/0.5mg Sublingual tablets             | EU/1/06/359/01-02              | Buprenorphine HCl                                 |
| Suboxone 8/2mg Sublingual tablets               | EU/1/06/359/03-04              | Buprenorphine HCl                                 |
| Sativex Oromucosal Spray                        | PA1042/001/001                 | Delta-9-tetrahydrocannabinol (THC)<br>Cannabidiol |
| Tentin 5mg Tablets                              | PA1555/003/001                 | Dexamphetamine sulphate                           |
| DF118 Tablets 30mg                              | PA1329/007/001                 | Dihydrocodeine tartrate                           |
| Durogesic Dtrans 25mcg/hour Transdermal Patch   | PA0748/002/001                 | Fentanyl  |
| Durogesic Dtrans 50mcg/hour Transdermal Patch   | PA0748/002/002                 | Fentanyl  |
| Durogesic Dtrans 75mcg/hour Transdermal Patch   | PA0748/002/003                 | Fentanyl  |
| Durogesic Dtrans 100mcg/hour Transdermal Patch  | PA0748/002/004                 | Fentanyl  |
| Durogesic Dtrans 12mcg/hour Transdermal Patch   | PA0748/002/005                 | Fentanyl  |
| Durogesic Dtrans 25mcg/hour Transdermal Patch   | PPA0465/314/001                | Fentanyl  |
| Durogesic Dtrans 50mcg/hour Transdermal Patch   | PPA0465/314/002                | Fentanyl  |
| Durogesic Dtrans 75mcg/hour Transdermal Patch   | PPA0465/314/003                | Fentanyl  |

|  |                         |                          |
|--|-------------------------|--------------------------|
| Durogesic Dtrans 100mcg/hour Transdermal Patch   | PPA0465/314/004         | Fentanyl                 |
| Durogesic Dtrans 12mcg/hour Transdermal Patch    | PPA0465/314/005         | Fentanyl                 |
| Durogesic Dtrans 50mcg/hour Transdermal Patch    | PPA1151/252/001         | Fentanyl                 |
| Durogesic Dtrans 75mcg/hour Transdermal Patch    | PPA1151/252/002         | Fentanyl                 |
| Durogesic Dtrans 25mcg/hour Transdermal Patch    | PPA1151/252/003         | Fentanyl                 |
| Durogesic Dtrans 100mcg/hour Transdermal Patch   | PPA1151/252/004         | Fentanyl                 |
| Fentadur 25mcg/hr Transdermal Patch              | PA0822/070/001          | Fentanyl                 |
| Fentadur 50mcg/hr Transdermal Patch              | PA0822/070/002          | Fentanyl                 |
| Fentadur 75mcg/hour Transdermal Patch            | PA0822/070/003          | Fentanyl                 |
| Fentadur 100mcg/hr Transdermal Patch             | PA0822/070/004          | Fentanyl                 |
| Fentadur 12mcg/hr Transdermal Patch              | PA0822/070/005          | Fentanyl                 |
| Fental Matrix 25mcg/hr Transdermal Patch         | PA0711/146/001          | Fentanyl                 |
| Fental Matrix 50mcg/hr Transdermal Patch         | PA0711/146/002          | Fentanyl                 |
| Fental Matrix 75mcg/hr Transdermal Patch         | PA0711/146/003          | Fentanyl                 |
| Fental Matrix 100mcg/hr Transdermal Patch        | PA0711/146/004          | Fentanyl                 |
| Fetanex 12.5mcg/hr Transdermal Patch             | PA0711/137/001          | Fentanyl                 |
| Fetanex 37.5mcg/hr Transdermal Patch             | PA0711/137/003          | Fentanyl                 |
| Matrifen 12mcg/hr transdermal patch              | PA1547/004/001          | Fentanyl                 |
| Matrifen 25mcg/hr transdermal patch              | PA1547/004/002          | Fentanyl                 |
| Matrifen 50mcg/hr transdermal patch              | PA1547/004/003          | Fentanyl                 |
| Matrifen 75mcg/hr transdermal patch              | PA1547/004/004          | Fentanyl                 |
| Matrifen 100mcg/hr transdermal patch             | PA1547/004/005          | Fentanyl                 |
| Mylafent 12mcg/hr transdermal patch              | PA0405/061/001          | Fentanyl                 |
| Mylafent 100mcg/hr transdermal patch             | PA0405/061/005          | Fentanyl                 |
| Mylafent 75mcg/hr transdermal patch              | PA0405/061/004          | Fentanyl                 |
| Mylafent 50mcg/hr transdermal patch              | PA0405/061/003          | Fentanyl                 |
| Mylafent 25mcg/hr transdermal patch              | PA0405/061/002          | Fentanyl                 |
| Abstral 100mcg Sublingual tablets                | PA1049/006/002          | Fentanyl as citrate salt |
| Abstral 200mcg Sublingual tablets                | PA1049/006/003          | Fentanyl as citrate salt |
| Abstral 300mcg Sublingual tablets                | PA1049/006/004          | Fentanyl as citrate salt |
| Abstral 400mcg Sublingual tablets                | PA1049/006/005          | Fentanyl as citrate salt |
| Abstral 600mcg Sublingual tablets                | PA1049/006/006          | Fentanyl as citrate salt |
| Abstral 800mcg Sublingual tablets                | PA1049/006/007          | Fentanyl as citrate salt |
| Pecfent 100mcg/spray nasal spray, solution       | EU/1/10/644/001-002-005 | Fentanyl as citrate salt |
| Pecfent 400mcg/spraynasal spray, solution        | EU/1/10/644/003-004-006 | Fentanyl as citrate salt |
| Actiq 200mcg compressed lozenge with applicator  | PA0749/195/001          | Fentanyl Citrate         |
| Actiq 400mcg compressed lozenge with applicator  | PA0749/195/002          | Fentanyl Citrate         |
| Actiq 600mcg compressed lozenge with applicator  | PA0749/195/003          | Fentanyl Citrate         |
| Actiq 800mcg compressed lozenge with applicator  | PA0749/195/004          | Fentanyl Citrate         |
| Actiq 1200mcg compressed lozenge with applicator | PA0749/195/005          | Fentanyl Citrate         |
| Actiq 1600mcg compressed lozenge with applicator | PA0749/195/006          | Fentanyl Citrate         |
| Actiq 200mcg compressed lozenge with applicator  | PPA0465/407/001         | Fentanyl Citrate         |
| Actiq 400mcg compressed lozenge with applicator  | PPA0465/407/002         | Fentanyl Citrate         |
| Breakyl 1200mcg buccal film                      | PA1332/027/005          | Fentanyl Citrate         |
| Breakyl 800mcg buccal film                       | PA1332/027/004          | Fentanyl Citrate         |

|   |                   |                     |
|---|-------------------|---------------------|
| Breakyl 600mcg buccal film                              | PA1332/027/003    | Fentanyl Citrate    |
| Breakyl 400mcg buccal film                              | PA1332/027/002    | Fentanyl Citrate    |
| Breakyl 200mcg buccal film                              | PA1332/027/001    | Fentanyl Citrate    |
| Breakyl Start 200,400,600,800mcg buccal film            | PA1332/027/006    | Fentanyl Citrate    |
| Effentora 100mcg Buccal Tablets                         | EU/1/08/441/1-2   | Fentanyl Citrate    |
| Effentora 200mcg Buccal Tablets                         | EU/1/08/441/3-4   | Fentanyl Citrate    |
| Effentora 400mcg Buccal Tablets                         | EU/1/08/441/5-6   | Fentanyl Citrate    |
| Effentora 600mcg Buccal Tablets                         | EU/1/08/441/7-8   | Fentanyl Citrate    |
| Effentora 800mcg Buccal Tablets                         | EU/1/08/441/9-10  | Fentanyl Citrate    |
| Fentanyl 100mcg in 2ml                                  | PA0073/122/001    | Fentanyl Citrate    |
| Fentanyl 500mcg in 10ml solution for injection          | PA0073/122/002    | Fentanyl Citrate    |
| Instanyl 50mcg/dosenasal spray, solution                | EU/1/09/531/1-3   | Fentanyl Citrate    |
| Instanyl 100mcg/dosenasal spray, solution               | EU/1/09/531/4-6   | Fentanyl Citrate    |
| Instanyl 200mcg/dose nasal spray, solution              | EU/1/09/531/7-9   | Fentanyl Citrate    |
| Instanyl 50mcg nasal spray, solution                    | EU/1/09/531/10-13 | Fentanyl Citrate    |
| instanyl 100mcg nasal spray, solution                   | EU/1/09/531/14-17 | Fentanyl Citrate    |
| Instanyl 200mcg nasal spray, solution                   | EU/1/09/531/18-21 | Fentanyl Citrate    |
| Recivit 67mcg, Sublingual Tablet                        | PA1189/011/001    | Fentanyl Citrate    |
| Recivit 133mcg, Sublingual Tablet                       | PA1189/011/002    | Fentanyl Citrate    |
| Recivit 267mcg, Sublingual Tablet                       | PA1189/011/003    | Fentanyl Citrate    |
| Recivit 400mcg, Sublingual Tablet                       | PA1189/011/004    | Fentanyl Citrate    |
| Recivit 533mcg, Sublingual Tablet                       | PA1189/011/005    | Fentanyl Citrate    |
| Recivit 800mcg, Sublingual Tablet                       | PA1189/011/006    | Fentanyl Citrate    |
| Sublimaze 50mcg/ml, Solution for injection              | PA0748/044/001    | Fentanyl Citrate    |
| Hydromorphone HCL 20mg/ml solution for inj/inf          | PA0361/018/001    | Hydromorphone HCl   |
| Hydromorphone HCL 50mg/ml solution for inj/inf          | PA0361/018/002    | Hydromorphone HCl   |
| Palladone 1.3 mg Capsules                               | PA1688/007/001    | Hydromorphone HCl   |
| Palladone 2.6mg Capsules                                | PA1688/007/002    | Hydromorphone HCl   |
| Palladone SR 2mg prolonged release Capsules             | PA1688/007/007    | Hydromorphone HCl   |
| Palladone SR 4mg prolonged release Capsules             | PA1688/007/008    | Hydromorphone HCl   |
| Palladone SR 8mg prolonged release Capsules             | PA1688/007/009    | Hydromorphone HCl   |
| Palladone SR 16mg prolonged release Capsules            | PA1688/007/010    | Hydromorphone HCl   |
| Palladone SR 24mg prolonged release Capsules            | PA1688/007/011    | Hydromorphone HCl   |
| Methadone 1mg/ml oral solution sugar free               | PA1352/003/001    | Methadone HCl       |
| Methadone mixture DTF (Sugar free) 1mg/ml oral solution | PA0361/007/006    | Methadone HCl       |
| Methadone HCl Sugar Free 1mg/ml oral solution           | PA0312/007/002    | Methadone HCl       |
| Methadone TEVA 1mg/ml oral solution                     | PA0749/116/001    | Methadone HCl       |
| Phymet DTF 1mg/ml syrup                                 | PA1077/074/001    | Methadone HCl       |
| Pinadone Methadone DTF 1mg/ml oral solution             | PA0281/061/001    | Methadone HCl       |
| Concerta XL 18 mg prolonged-release tablet              | PA0748/049/001    | Methylphenidate HCl |
| Concerta XL 36 mg prolonged-release tablet              | PA0748/049/002    | Methylphenidate HCl |
| Concerta XL 54 mg prolonged-release tablet              | PA0748/049/003    | Methylphenidate HCl |
| Concerta XL 27 mg prolonged-release tablet              | PA0748/049/004    | Methylphenidate HCl |
| Concerta XL 18 mg prolonged-release tablet              | PPA1151/243/001   | Methylphenidate HCl |
| Concerta XL 36 mg prolonged-release tablet              | PPA1151/243/003   | Methylphenidate HCl |
| Concerta XL 27 mg prolonged-release tablet              | PPA1151/243/002   | Methylphenidate HCl |

|   |                 |                     |
|---|-----------------|---------------------|
| Concerta XL 18 mg prolonged release tablet                        | PPA0465/417/001 | Methylphenidate HCL |
| Concerta XL 36 mg prolonged release tablet                        | PPA0465/417/002 | Methylphenidate HCL |
| Equasym 5mg tablets   | PA1575/001/004  | Methylphenidate HCl |
| Equasym 10mg tablets  | PA1575/001/005  | Methylphenidate HCl |
| Equasym 20mg tablets  | PA1575/001/006  | Methylphenidate HCl |
| Equasym XL 10mg Modified-release capsules, hard                   | PA1575/001/001  | Methylphenidate HCl |
| Equasym XL 20mg Modified-release capsules, hard                   | PA1575/001/002  | Methylphenidate HCl |
| Equasym XL 30mg Modified-release capsules, hard                   | PA1575/001/003  | Methylphenidate HCl |
| Equasym XL 40mg Modified-release capsules, hard                   | PA1575/001/007  | Methylphenidate HCl |
| Equasym XL 50mg Modified-release capsules, hard                   | PA1575/001/008  | Methylphenidate HCl |
| Equasym XL 60mg Modified-release capsules, hard                   | PA1575/001/009  | Methylphenidate HCl |
| Medikinet 5 mg tablets  | PA1555/001/006  | Methylphenidate HCl |
| Medikinet 10 mg tablets   | PA1555/001/007  | Methylphenidate HCl |
| Medikinet 20 mg tablets   | PA1555/001/008  | Methylphenidate HCl |
| Medikinet MR 5mg modified – release capsules, hard                | PA1555/001/001  | Methylphenidate HCl |
| Medikinet MR 10mg modified – release capsules, hard               | PA1555/001/002  | Methylphenidate HCl |
| Medikinet MR 20mg modified – release capsules, hard               | PA1555/001/003  | Methylphenidate HCl |
| Medikinet MR 30mg modified - release capsules, hard               | PA1555/001/004  | Methylphenidate HCl |
| Medikinet MR 40mg modified – release capsules, hard               | PA1555/001/005  | Methylphenidate HCl |
| Metidate XL 54mg Prolonged Release tablets                        | PA0711/200/003  | Methylphenidate HCl |
| Metidate XL 18mg Prolonged Release tablets                        | PA0711/200/001  | Methylphenidate HCl |
| Metidate XL 27mg Prolonged Release tablets                        | PA0711/200/004  | Methylphenidate HCl |
| Metidate XL 36mg Prolonged Release tablets                        | PA0711/200/002  | Methylphenidate HCl |
| Ritalin 10mg tablets  | PA0013/066/001  | Methylphenidate HCl |
| Ritalin LA 20mg Prolonged Release capsules                        | PA0013/066/002  | Methylphenidate HCl |
| Ritalin LA 30mg Prolonged Release capsules                        | PA0013/066/003  | Methylphenidate HCl |
| Ritalin LA 40mg Prolonged Release capsules                        | PA0013/066/004  | Methylphenidate HCl |
| Morphine Sulphate 20mg/ml Oral Solution                           | PA1339/051/001  | Morphine Sulphate   |
| Morphine Sulphate 10mg/ml Solution for injection                  | PA0073/020/001  | Morphine Sulphate   |
| Morphine Sulphate 30mg/ml Solution for injection                  | PA0073/020/004  | Morphine Sulphate   |
| Morphine Sulphate 60mg/ml Solution for injection                  | PA0073/020/008  | Morphine Sulphate   |
| Morphine sulphate injection BP 10mg in 1ml solution for injection | PA0361/004/004  | Morphine Sulphate   |
| Morphine sulphate injection BP 30mg/ml, solution for injection    | PA0361/004/005  | Morphine Sulphate   |
| MST continus suspension 20mg                                      | PA1688/004/008  | Morphine Sulphate   |
| MST continus suspension 30mg                                      | PA1688/004/009  | Morphine Sulphate   |
| MST continus suspension 60mg                                      | PA1688/004/010  | Morphine Sulphate   |
| MST continus 10mg prolonged release tablets                       | PA1688/004/002  | Morphine Sulphate   |
| MST continus 30mg prolonged release tablets                       | PA1688/004/004  | Morphine Sulphate   |
| MST continus 60mg prolonged release tablets                       | PA1688/004/005  | Morphine Sulphate   |
| MST continus 100mg prolonged release tablets                      | PA1688/004/006  | Morphine Sulphate   |
| MST continus 5mg prolonged release tablet                         | PA1688/004/001  | Morphine Sulphate   |
| MST continus 15mg prolonged release tablet                        | PA1688/004/003  | Morphine Sulphate   |
| Oramorph concentrated oral solution 20mg/ml                       | PA0007/044/002  | Morphine Sulphate   |
| Sevredol 10mg Film-Coated Tablets                                 | PA1688/009/001  | Morphine Sulphate   |
| Sevredol 20mg Film-Coated Tablets                                 | PA1688/009/002  | Morphine Sulphate   |

|   |                |                   |
|---|----------------|-------------------|
| Sevredol 50mg Film-Coated Tablets                     | PA1688/009/003 | Morphine Sulphate |
| Cyclimorph 10 Solution for injection                  | PA1142/003/001 | Morphine tartrate |
| Cyclimorph 15 Solution for injection                  | PA1142/003/002 | Morphine tartrate |
| Dancex SR 5mg Prolonged-Release tablets               | PA0711/143/001 | Oxycodone HCl     |
| Dancex SR 10mg Prolonged-Release tablets              | PA0711/143/002 | Oxycodone HCl     |
| Dancex SR 20mg Prolonged-Release tablets              | PA0711/143/003 | Oxycodone HCl     |
| Dancex SR 40mg Prolonged-Release tablets              | PA0711/143/004 | Oxycodone HCl     |
| Dancex SR 60mg Prolonged-Release tablets              | PA0711/143/005 | Oxycodone HCl     |
| Dancex SR 80mg Prolonged-Release tablets              | PA0711/143/006 | Oxycodone HCl     |
| Oximel 5mg Prolonged Release tablets                  | PA0126/264/001 | Oxycodone HCl     |
| Oximel 10mg Prolonged Release tablets                 | PA0126/264/002 | Oxycodone HCl     |
| Oximel 15mg Prolonged Release tablets                 | PA0126/264/003 | Oxycodone HCl     |
| Oximel 20mg Prolonged Release tablets                 | PA0126/264/004 | Oxycodone HCl     |
| Oximel 30mg Prolonged Release tablets                 | PA0126/264/005 | Oxycodone HCl     |
| Oximel 40mg Prolonged Release tablets                 | PA0126/264/006 | Oxycodone HCl     |
| Oximel 60mg Prolonged Release tablets                 | PA0126/264/007 | Oxycodone HCl     |
| Oximel 80mg Prolonged Release tablets                 | PA0126/264/008 | Oxycodone HCl     |
| Oxycodone Actavis 5mg capsules, hard                  | PA1380/129/001 | Oxycodone HCl     |
| Oxycodone Actavis 10 mg capsules, hard                | PA1380/129/002 | Oxycodone HCl     |
| Oxycodone Actavis 20mg capsules, hard                 | PA1380/129/003 | Oxycodone HCl     |
| Oxycodone HCl 10mg/ml solution for inf/inj            | PA1339/025/001 | Oxycodone HCl     |
| Oxycodone HCl 50mg/ml solution for inf/inj            | PA1339/025/002 | Oxycodone HCl     |
| Oxycodone HCl Teva 5mg capsules, hard                 | PA0749/211/001 | Oxycodone HCl     |
| Oxycodone HCl Teva 10mg capsules, hard                | PA0749/211/002 | Oxycodone HCl     |
| Oxycodone HCl Teva 20mg capsule, hard                 | PA0749/211/003 | Oxycodone HCl     |
| Oxycodone Lannacher SR 5mg prolonged-release tablets  | PA0947/003/001 | Oxycodone HCl     |
| Oxycodone Lannacher SR 10mg prolonged-release tablets | PA0947/003/002 | Oxycodone HCl     |
| Oxycodone Lannacher SR 20mg prolonged-release tablets | PA0947/003/003 | Oxycodone HCl     |
| Oxycodone Lannacher SR 40mg prolonged-release tablets | PA0947/003/004 | Oxycodone HCl     |
| Oxycodone Lannacher SR 80mg prolonged-release tablets | PA0947/003/005 | Oxycodone HCl     |
| Oxycontin 15mg prolonged release tablet               | PA1688/005/006 | Oxycodone HCl     |
| Oxycontin 30mg prolonged release tablet               | PA1688/005/007 | Oxycodone HCl     |
| Oxycontin 60mg prolonged release tablet               | PA1688/005/008 | Oxycodone HCl     |
| Oxycontin 120mg prolonged release tablet              | PA1688/005/009 | Oxycodone HCl     |
| Oxycontin 160mg prolonged release tablet              | PA1688/005/010 | Oxycodone HCl     |
| Oxycontin 10mg prolonged release tablets              | PA1688/005/002 | Oxycodone HCl     |
| Oxycontin 20mg prolonged release tablets              | PA1688/005/003 | Oxycodone HCl     |
| Oxycontin 40mg prolonged release tablets              | PA1688/005/004 | Oxycodone HCl     |
| Oxycontin 80mg prolonged release tablets              | PA1688/005/005 | Oxycodone HCl     |
| Oxycontin 5mg prolonged release tablets               | PA1688/005/001 | Oxycodone HCl     |
| Oxydon 20mg prolonged-release tablets                 | PA0711/115/001 | Oxycodone HCl     |
| Oxydon 40mg prolonged-release tablets                 | PA0711/115/002 | Oxycodone HCl     |
| Oxydon 80mg prolonged-release tablets                 | PA0711/115/003 | Oxycodone HCl     |

|  |                |                         |
|--|----------------|-------------------------|
| Oxydon 5mg prolonged-release tablets                             | PA0711/115/004 | Oxycodone HCl           |
| Oxydon 10mg prolonged-release tablets                            | PA0711/115/005 | Oxycodone HCl           |
| OxyNorm 10mg/ml, Solution for inj/inf                            | PA1688/006/001 | Oxycodone HCl           |
| OxyNorm 5mg capsules   | PA1688/006/004 | Oxycodone HCl           |
| OxyNorm 10mg capsules  | PA1688/006/005 | Oxycodone HCl           |
| OxyNorm 20mg capsules  | PA1688/006/006 | Oxycodone HCl           |
| OxyNorm 50mg/ml, solution for inj/inf                            | PA1688/006/010 | Oxycodone HCl           |
| OxyNorm Concentrate 10mg/ml oral solution                        | PA1688/006/003 | Oxycodone HCl           |
| OxyNorm Dispersa 5mg orodispersible tablets                      | PA1688/006/007 | Oxycodone HCl           |
| OxyNorm Dispersa 10mg orodispersible tablets                     | PA1688/006/008 | Oxycodone HCl           |
| OxyNorm Dispersa 20mg orodispersible tablets                     | PA1688/006/009 | Oxycodone HCl           |
| OxyNorm liquid 1mg/ml oral solution                              | PA1688/006/002 | Oxycodone HCl           |
| Reltebon 5mg Prolonged-release Tablets                           | PA1380/129/004 | Oxycodone HCl           |
| Reltebon 10mg Prolonged-release Tablets                          | PA1380/129/005 | Oxycodone HCl           |
| Reltebon 20mg Prolonged-release Tablets                          | PA1380/129/006 | Oxycodone HCl           |
| Reltebon 40mg Prolonged-release Tablets                          | PA1380/129/007 | Oxycodone HCl           |
| Reltebon 80mg Prolonged-release Tablets                          | PA1380/129/008 | Oxycodone HCl           |
| Zomestine 5mg Prolonged-release Tablets                          | PA1390/040/001 | Oxycodone HCl           |
| Zomestine 10mg Prolonged-release Tablets                         | PA1390/040/002 | Oxycodone HCl           |
| Zomestine 20mg Prolonged-release Tablets                         | PA1390/040/003 | Oxycodone HCl           |
| Zomestine 40mg Prolonged-release Tablets                         | PA1390/040/004 | Oxycodone HCl           |
| Zomestine 80mg Prolonged Tablets                                 | PA1390/040/005 | Oxycodone HCl           |
| Targin 2.5/1.25mg prolonged-release tablet                       | PA1688/010/005 | Oxycodone HCl           |
| Targin 15/7.5mg prolonged-release tablet                         | PA1688/010/006 | Oxycodone HCl           |
| Targin 30/15mg prolonged-release Tablet                          | PA1688/010/007 | Oxycodone HCl           |
| Targin 10mg/5mg prolonged-release tablets                        | PA1688/010/002 | Oxycodone HCl           |
| Targin 20mg/10mg prolonged-release tablets                       | PA1688/010/003 | Oxycodone HCl           |
| Targin 40mg/20mg prolonged-release tablets                       | PA1688/010/004 | Oxycodone HCl           |
| Targin 5mg/2.5mg prolonged-release tablets                       | PA1688/010/001 | Oxycodone HCl           |
| Dypracet 20/500mg Tablets  | PA1352/012/001 | Dihydrocodeine tartrate |
| Dypracet 30/500mg Tablets  | PA1352/012/002 | Dihydrocodeine tartrate |
| Pethidine Tablets BP 50mg  | PA0361/008/001 | Pethidine HCl           |
| Pethidine HCl 50 mg/ml Solution for Injection                    | PA0073/014/001 | Pethidine HCl           |
| Pethidine HCl 50 mg/ml solution for injection                    | PA1140/004/001 | Pethidine HCl           |
| Pethidine Hydrochloride 50mg/ml solution for injection           | PA1390/050/001 | Pethidine HCl           |
| Pethidine Injection BP 100mg/2ml                                 | PA0361/008/003 | Pethidine HCl           |
| Pethidine Injection BP 50mg/ml                                   | PA0361/008/002 | Pethidine HCl           |
| Remifentanil 1mg powder for concentrate for Solution for Inj/inf | PA1380/112/001 | Remifentanil            |
| Remifentanil 2mg powder for concentrate for solution for inj/inf | PA1380/112/002 | Remifentanil            |
| Remifentanil 5mg powder for concentrate for solution for inj/inf | PA1380/112/003 | Remifentanil            |
| Remifentanil 1mg powder for concentrate for solution for inj/inf | PA0566/052/001 | Remifentanil HCl        |
| Remifentanil 2mg powder for concentrate for solution for inj/inf | PA0566/052/002 | Remifentanil HCl        |

|  |                 |                  |
|--|-----------------|------------------|
| Remifentanil 5mg powder for concentrate for solution for inj/inf         | PA0566/052/003  | Remifentanil HCl |
| Remifentanil 1mg powder for concentrate for solution for inj/inf         | PA1339/030/001  | Remifentanil HCl |
| Remifentanil 2mg powder for concentrate for solution for inj/inf         | PA1339/030/002  | Remifentanil HCl |
| Remifentanil 5mg powder for concentrate for solution for inj/inf         | PA1339/030/003  | Remifentanil HCl |
| Remifentanil 1mg powder for concentrate for solution for inj/inf         | PA0437/068/001  | Remifentanil HCl |
| Remifentanil 2mg powder for concentrate for solution for inj/inf         | PA0437/068/002  | Remifentanil HCl |
| Remifentanil 5mg powder for concentrate for solution for inj/inf         | PA0437/068/003  | Remifentanil HCl |
| Remifentanil Noridem 1mg powder for concentrate for solution for inj/inf | PA1122/014/001  | Remifentanil HCl |
| Remifentanil Noridem 2mg powder for concentrate for solution for inj/inf | PA1122/014/002  | Remifentanil HCl |
| Remifentanil Noridem 5mg powder for concentrate for solution for inj/inf | PA1122/014/003  | Remifentanil HCl |
| Ultiva 1mg powder for concentrate for solution for infusion              | PA1077/100/001  | Remifentanil HCl |
| Ultiva 2mg powder for concentrate for solution for infusion              | PA1077/100/002  | Remifentanil HCl |
| Ultiva 5mg powder for concentrate for solution for infusion              | PA1077/100/003  | Remifentanil HCl |
| Palexia 50mg film-coated tablets   | PA1189/007/001  | Tapentadol HCl   |
| Palexia 75mg film-coated tablets   | PA1189/007/002  | Tapentadol HCl   |
| Palexia 100mg film-coated tablets  | PA1189/007/003  | Tapentadol HCl   |
| Palexia 4mg/ml Oral Solution   | PA1189/007/010  | Tapentadol HCl   |
| Palexia 20mg/ml Oral Solution  | PA1189/007/011  | Tapentadol HCl   |
| Palexia 25mg film-coated tablets   | PA1189/007/012  | Tapentadol HCl   |
| Palexia SR 50mg prolonged-release tablets                                | PA1189/007/004  | Tapentadol HCl   |
| Palexia SR 100mg prolonged-release tablets                               | PA1189/007/005  | Tapentadol HCl   |
| Palexia SR 150mg prolonged-release tablets                               | PA1189/007/006  | Tapentadol HCl   |
| Palexia SR 200mg prolonged-release tablets                               | PA1189/007/007  | Tapentadol HCl   |
| Palexia SR 250mg prolonged-release tablets                               | PA1189/007/008  | Tapentadol HCl   |
| Palexia SR 25mg prolonged-release tablets                                | PA1189/007/009  | Tapentadol HCl   |
| Xyrem 500mg/ml Oral Solution   | EU/1/05/312/001 | Sodium Oxybate   |

### Veterinary medicines

| <b>Product Name</b>  | <b>Licence number</b> | <b>Active</b>           |
|--|-----------------------|-------------------------|
| Vetergesic Multidose, 0.3mg/ml, solution for injection for dogs and cats         | 10815/028/001         | Buprenorphine           |
| Buprenodale Multidose, 0.3mg/ml solution for injection for dogs, cats and horses | 10799/026/001         | Buprenorphine HCl       |
| Bupaq Multidose 0.3mg/ml solution for injection for dogs and cats                | 10801/005/001         | Buprenorphine HCl       |
| Butador 10mg/ml solution for injection for horses, dogs and cats                 | 10801/004/001         | Butorphanol             |
| Torbuphanol Vet 10mg/ml solution for injection for horses, dogs and cats         | 10438/107/001         | Butorphanol as Tartrate |
| Alvegesic vet. 10mg/ml solution for injection for Horses, Dogs and Cats          | 10661/001/001         | Butorphanol Tartrate    |
| Dolorex 10mg/ml solution for injection for horse, dog and cat.                   | 10996/185/001         | Butorphanol Tartrate    |
| Morphasol 10mg/ml solution for injection for horses                              | 10826/009/001         | Butorphanol Tartrate    |
| Morphasol 4mg/ml solution for injection for dogs and cats                        | 10826/007/001         | Butorphanol Tartrate    |
| Torbugesic 10mg/ml solution for injection  | 10438/106/001         | Butorphanol Tartrate    |
| Recuvyra 50mg/ml transdermal solution for dogs                                   | EU/2/11/127/001       | Fentanyl                |
| Synthadon 10mg/ml solution for injection for cats and dogs.                      | 10475/011/002         | Methadone HCl           |



**Authorised Products Containing Substances Listed in Schedule 3 of  
the Misuse of Drugs Regulations 1988, as amended**

**Human medicines**

| <b>Product Name</b>                                 | <b>Licence number</b> | <b>Active</b>          |
|---|-----------------------|------------------------|
| Ketalar 10mg/ml solution for injection/ infusion    | PA0822/013/001        | Ketamine Hydrochloride |
| Ketalar 50mg/ml solution for injection/ infusion    | PA0822/013/002        | Ketamine Hydrochloride |
| Phenobarbital Sodium 15mg/ml solution for injection | PA0361/005/001        | Pentobarbital Sodium   |
| Phenobarbital Sodium 30mg/ml solution for injection | PA0361/005/002        | Pentobarbital Sodium   |
| Phenobarbital Sodium 60mg/ml solution for injection | PA0361/005/003        | Pentobarbital Sodium   |
| Insomniger 10mg tablets                             | PA0405/004/003        | Temazepam              |
| Insomniger 20mg tablets                             | PA0405/004/004        | Temazepam              |
| Nortem 10mg tablets                                 | PA0282/055/001        | Temazepam              |
| Nortem 20mg tablets                                 | PA0282/055/002        | Temazepam              |

**Veterinary medicines**

| <b>Product Name</b>                           | <b>Licence number</b> | <b>Active</b>        |
|---|-----------------------|----------------------|
| Euthasol Vet. 400mg/ml solution for injection | 10816/011/001         | Pentobarbital Sodium |
| Release 300mg/ml, solution for injection      | 10660/001/001         | Pentobarbital Sodium |
| Dolethal 200mg/ml solution for injection      | 10983/015/001         | Pentobarbital Sodium |
| Euthatal solution for injection 200mg in 1ml  | 10857/043/001         | Pentobarbital Sodium |

**Authorised Products Containing Substances Listed in Schedule 4 of  
the Misuse of Drugs Regulations 1988, as amended**

**Human medicines**

| <b>Product Name</b>                         | <b>Licence number</b> | <b>Active</b>                  |
|---|-----------------------|--------------------------------|
| Gerax 250mcg tablets                        | PA0577/010/001        | Alprazolam                     |
| Gerax 500mcg tablets                        | PA0577/010/002        | Alprazolam                     |
| Gerax 1mg tablets                           | PA0577/010/003        | Alprazolam                     |
| Alprazolam 0.25mg tablets                   | PA0711/140/001        | Alprazolam                     |
| Alprazolam 0.5mg tablets                    | PA0711/140/002        | Alprazolam                     |
| Alprazolam 1mg tablets                      | PA0711/140/003        | Alprazolam                     |
| Xanax 250mcg tablets                        | PA0822/141/002        | Alprazolam                     |
| Xanax 500mcg tablets                        | PA0822/141/003        | Alprazolam                     |
| Xanax 1mg tablets                           | PA0822/141/001        | Alprazolam                     |
| Lexotan 1.5mg Tablets                       | PA0050/049/001        | Bromazepam                     |
| Lexotan 3mg Tablets                         | PA0050/049/002        | Bromazepam                     |
| Librium 5mg hard capsules                   | PA1332/033/001        | Chlordiazepoxide Hydrochloride |
| Librium 10mg hard capsules                  | PA1332/033/002        | Chlordiazepoxide Hydrochloride |
| Frisium 10mg tablets                        | PA0540/043/001        | Clobazam                       |
| Perizam 1mg/ml oral suspension              | PA0312/033/001        | Clobazam                       |
| Perizam 2mg/ml oral suspension              | PA0312/033/002        | Clobazam                       |
| Rivotril 0.5mg tablets                      | PA0050/014/001        | Clonazepam                     |
| Rivotril 2mg tablets                        | PA0050/014/002        | Clonazepam                     |
| Clonazepam Rosemont 0.5mg/5ml oral solution | PA0312/022/001        | Clonazepam                     |
| Clonazepam Rosemont 2mg/5ml oral solution   | PA0312/022/002        | Clonazepam                     |
| Anxicalm 2mg tablets                        | PA0126/011/001        | Diazepam                       |
| Anxicalm 5mg tablets                        | PA0126/011/002        | Diazepam                       |
| Anxicalm 10mg tablets                       | PA0126/011/003        | Diazepam                       |
| Diazemuls emulsion for injection 5mg/ml     | PA1380/032/001        | Diazepam                       |
| Stesolid rectal solution 10mg               | PA1380/010/002        | Diazepam                       |
| Stesolid rectal solution 5mg                | PA1380/010/001        | Diazepam                       |
| Diazepam 5mg/ml solution for injection      | PA1339/006/001        | Diazepam                       |
| Diazepam 5mg/ml solution for injection      | PA1339/006/002        | Diazepam                       |
| Diazepam RecTube 5mg rectal solution        | PA1339/006/004        | Diazepam                       |
| Diazepam RecTube 10mg rectal solution       | PA1339/006/005        | Diazepam                       |
| Diazepam RecTube 2.5mg rectal solution      | PA1339/006/003        | Diazepam                       |
| Diazepam Actavis 2mg tablets                | PA1380/108/001        | Diazepam                       |
| Diazepam Actavis 5mg tablets                | PA1380/108/002        | Diazepam                       |
| Diazepam Actavis 10mg tablets               | PA1380/108/003        | Diazepam                       |
| Dalmane 15mg hard capsules                  | PA1332/031/001        | Flurazepam                     |
| Dalmane 30mg hard capsules                  | PA1332/031/002        | Flurazepam                     |
| Dalmapam 15mg hard capsules                 | PA0281/073/001        | Flurazepam Hydrochloride       |
| Dalmapam 30mg hard capsules                 | PA0281/073/002        | Flurazepam Hydrochloride       |
| Lorazepam 1mg tablets                       | PA1333/013/001        | Lorazepam                      |
| Lorazepam 2.5mg tablets                     | PA1333/013/002        | Lorazepam                      |
| Ativan 4mg/ml Solution for Injection        | PA0822/090/002        | Lorazepam                      |
| Ativan 1mg tablets                          | PA0822/090/001        | Lorazepam                      |
| Noctamid tablets 1mg                        | PA1410/009/001        | Lormetazepam                   |

|  |                 |                          |
|--|-----------------|--------------------------|
| Noctamid tablets 1mg                               | PPA1328/158/001 | Lormetazepam             |
| Noctamid tablets 1mg                               | PPA1151/192/001 | Lormetazepam             |
| Noctamid tablets 1mg                               | PPA0465/402/001 | Lormetazepam             |
| Hypnovel 10mg/2ml Solution for Injection           | PA0050/061/001  | Midazolam                |
| Hypnovel 10mg/5ml Solution for Injection           | PA0050/061/002  | Midazolam                |
| Midazolam 1mg/ml Solution for inj/inf              | PA1390/010/001  | Midazolam                |
| Midazolam 5mg/ml Solution for inj/inf              | PA1390/010/002  | Midazolam                |
| Midazolam 5mg/ml Solution for Inj/Inf              | PA0073/147/001  | Midazolam                |
| Midazoalm 5mg/ml solution for inj/inf              | PA0361/021/001  | Midazolam                |
| Midazolam 2mg/ml Solution for Inj/Inf              | PA0073/147/002  | Midazolam                |
| Buccolam 5mg Oromucosal Solution                   | EU/1/11/709/002 | Midazolam                |
| Buccolam 2.5mg Oromucosal Solution                 | EU/1/11/709/001 | Midazolam                |
| Buccolam 7.5mg Oromucosal Solution                 | EU/1/11/709/003 | Midazolam                |
| Buccolam 10mg Oromucosal Solution                  | EU/1/11/709/004 | Midazolam                |
| Midazolam Injection BP 2mg/ml Solution for inj/Inf | PA1390/010/003  | Midazolam                |
| Midazolam Injection BP 5mg/ml Solution for inj/Inf | PA1390/010/004  | Midazolam                |
| Midazolam Injection BP 2mg/ml Solution for inj/Inf | PA1390/010/005  | Midazolam                |
| Midazolam Injection BP 5mg/ml Solution for inj/Inf | PA1390/010/006  | Midazolam                |
| Mogadon 5mg tablets                                | PA1332/035/001  | Nitrazepam               |
| Phenobarbital 15mg tablets                         | PA0126/019/001  | Phenobarbital            |
| Phenobarbital 30mg tablets                         | PA0126/019/002  | Phenobarbital            |
| Phenobarbital 60mg tablets                         | PA0126/019/003  | Phenobarbital            |
| Centrax 10mg tablets                               | PA0822/010/001  | Prazepam                 |
| Eldepryl 5mg tablets                               | PA1327/003/001  | Selegiline Hydrochloride |
| Eldepryl 5mg tablets                               | PPA0465/304/001 | Selegiline Hydrochloride |
| Halcion 250mcg tablets                             | PA0822/129/001  | Triazolam                |
| Halcion 125mcg tablets                             | PA0822/129/002  | Triazolam                |
| Edluar 5mg sublingual tablet                       | PA1332/040/001  | Zolpidem Tartrate        |
| Edluar 10mg sublingual tablet                      | PA1332/040/002  | Zolpidem Tartrate        |
| Nytamel 5mg film-coated tablets                    | PA0126/117/001  | Zolpidem Tartrate        |
| Nytamel 10mg film-coated tablets                   | PA0126/117/002  | Zolpidem Tartrate        |
| Stilnoct 10mg film coated tablets                  | PPA1151/030/001 | Zolpidem Tartrate        |
| Stilnoct 5mg film-coated tablets                   | PA0540/160/001  | Zolpidem Tartrate        |
| Stilnoct 10mg filmcoated tablets                   | PA0540/160/002  | Zolpidem Tartrate        |
| Stilnoct 5mg film-coated tablets                   | PPA1151/030/002 | Zolpidem Tartrate        |
| Zolnod 10mg film-coated tablets                    | PA0711/039/001  | Zolpidem Tartrate        |
| Zoldem 10mg film coated tablets                    | PA0577/048/001  | Zolpidem Tartrate        |
| Zolpidem Tartrate Teva 5mg film-coated tablet      | PA0749/095/001  | Zolpidem Tartrate        |
| Zolpidem Tartrate Teva 10mg film-coated tablet     | PA0749/095/002  | Zolpidem Tartrate        |

### **Veterinary medicines**

| Product Name                           | Licence number | Active                   |
|--|----------------|--------------------------|
| Phenoleptil 12.5mg tablets for dogs    | 10816/012/001  | Phenobarbital            |
| Phenoleptil 50mg tablets for dogs      | 10816/012/002  | Phenobarbital            |
| Phenoleptil 25mg tablets for dogs      | 10816/012/003  | Phenobarbital            |
| Phenoleptil 100mg tablets for dogs     | 10816/012/004  | Phenobarbital            |
| Epityl 60mg flavoured tablets for dogs | 10987/100/001  | Phenobarbital            |
| Selgian 8kg film coated tablets        | 10995/017/001  | Selegiline Hydrochloride |
| Selgian 20kg film coated tablets       | 10995/017/002  | Selegiline Hydrochloride |
| Selgian 40kg film coated tablets       | 10995/017/003  | Selegiline Hydrochloride |