



| Country of Registration | INN                 | Strength | Dosage Form              | Manufacturer              | Marketing Authorization Number/Date | Target Group | Therapeutic Category | WHO Pre-Qualified | WHO Pre-Qualified/Approved Sites           | Registered in ICH/PICS Countries  |             |     |
|-------------------------|---------------------|----------|--------------------------|---------------------------|-------------------------------------|--------------|----------------------|-------------------|--|-----------------------------------|-------------|-----|
| South Africa            | Didanosine (ddl)    | 2 g      | Powder for oral solution | Bristol-Myers Squibb      | 27/20.2.8/0045                      | Paediatric   | Antiretroviral       | Yes               | Bristol-Myers Squibb<br>La Goualle, Meymac | France                            | Yes         |     |
|                         | Didanosine (ddl)    | 25 mg    | Buffered tablet          | Aspen Pharmacare Ltd.     | 37/20.2.8/0442                      | Adult        | Antiretroviral       | No                |  |                                   | No          |     |
|                         | Didanosine (ddl)    | 25 mg    | Tablets                  | Bristol-Myers Squibb      | 27/20.2.8/0040                      | Paediatric   | Antiretroviral       | Yes               | Meymac                                     | France                            | Yes         |     |
|                         | Didanosine (ddl)    | 50 mg    | Buffered tablet          | Aspen Pharmacare Ltd.     | 37/20.2.8/0443                      | Adult        | Antiretroviral       | No                |  |                                   | No          |     |
|                         | Didanosine (ddl)    | 50 mg    | Tablets                  | Bristol-Myers Squibb      | 27/20.2.8/0041                      | Paediatric   | Antiretroviral       | Yes               | Meymac<br>Meymac                           | France<br>France                  | Yes         |     |
|                         | Didanosine (ddl)    | 100 mg   | Buffered tablet          | Aspen Pharmacare Ltd.     | 37/20.2.8/0444                      | Adult        | Antiretroviral       | No                |  |                                   | No          |     |
|                         | Didanosine (ddl)    | 100 mg   | Tablets                  | Bristol-Myers Squibb      | 27/20.2.8/0042                      | Paediatric   | Antiretroviral       | Yes               | Meymac<br>Meymac                           | France<br>France                  | Yes         |     |
|                         | Didanosine (ddl)    | 150 mg   | Buffered tablet          | Aspen Pharmacare Ltd.     | 37/20.2.8/0445                      | Adult        | Antiretroviral       | No                |  |                                   | No          |     |
|                         | Didanosine (ddl)    | 150 mg   | Tablets                  | Bristol-Myers Squibb      | 27/20.2.8/0043                      | Paediatric   | Antiretroviral       | Yes               | Bristol-Myers Squibb<br>La Goualle, Meymac | France<br>France                  | Yes         |     |
|                         | Didanosine EC (ddl) | 250 mg   | Capsules                 | Bristol-Myers Squibb      | 36/20.2.8/0065                      | Adult        | Antiretroviral       | Yes               | Bristol-Myers Squibb<br>La Goualle, Meymac | France                            | Yes         |     |
|                         | Didanosine EC (ddl) | 400 mg   | Capsules                 | Bristol-Myers Squibb      | 36/20.2.8/0066                      | Adult        | Antiretroviral       | Yes               | Bristol-Myers Squibb<br>La Goualle, Meymac | France                            | Yes         |     |
|                         | Efavirenz (EFV)     | 50 mg    | Capsules                 | Merck, Sharp & Dohme Ltd. | 10/09/99                            | Adult        | Antiretroviral       | Yes               | Bristol Myers Squibb<br>Pharma Ltd, Manati | Puerto Rico                       | Yes         |     |
|                         | Efavirenz (EFV)     | 100 mg   | Capsules                 | Merck, Sharp & Dohme Ltd. | 10/09/99                            | Adult        | Antiretroviral       | No                |  | Merck Sharp & Dohme<br>BV Haarlem | Netherlands | Yes |
|                         | Efavirenz (EFV)     | 200 mg   | Capsules                 | Merck, Sharp & Dohme Ltd. | 10/09/99                            | Adult        | Antiretroviral       | Yes               | Bristol Myers Squibb<br>Pharma Ltd, Manati | Puerto Rico                       | Yes         |     |
|                         |                     |          |                          |                           |                                     |              |                      |                   | Merck Sharp & Dohme<br>BV Haarlem          | Netherlands                       |             |     |

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|                         | Efavirenz (EFV)                   | 600 mg             | Tablets                  | Merck, Sharp & Dohme Ltd. | 07/05/04                            | Adult        | Antiretroviral       | Yes               | Bristol Myers Squibb Pharma Ltd, Manati<br>Merck Sharp & Dohme BV Haarlem<br>Merck Sharp & Dohme Australia Pty, Ltd South Granville | Puerto Rico<br>Netherlands<br>Australia              | Yes |
|                         | Indinavir (IDV)                   | 200 mg             | Capsules                 | Merck, Sharp & Dohme Ltd. | 01/11/96                            | Adult        | Antiretroviral       | No                |   |  | Yes |
|                         | Indinavir (IDV)                   | 400 mg             | Capsules                 | Merck, Sharp & Dohme Ltd. | 01/11/96                            | Adult        | Antiretroviral       | Yes               | Merck Sharp & Dohme BV Haarlem<br>Merck & Co. Manufacturing division Elkton, Virginia   | Netherlands<br>United States of America              | Yes |
|                         | Lamivudine (3TC)                  | 10 mg/ml           | Oral Liquid              | Aspen Pharmacare Ltd.     | A/38/20.2.8/0357                    | Paediatric   | Antiretroviral       | No                |   |  | No  |
|                         | Lamivudine (3TC)                  | 50 mg/5ml          | Oral Liquid              | Cipla Ltd.                | N/A                                 | Paediatric   | Antiretroviral       | Yes               | Goa<br>Vikhroli   | India<br>India                                       | Yes |
|                         | Lamivudine (3TC)                  | 150 mg             | Tablets                  | Aspen Pharmacare Ltd.     | A38/20.2.8/0343                     | Adult        | Antiretroviral       | Yes               | Korsten, Port Elisabeth   | South Africa   | No  |
|                         | Lamivudine (3TC)                  | 150 mg             | Tablets                  | Cipla Ltd.                | 35/20.2.8/0248                      | Adult        | Antiretroviral       | Yes               | Kurkumbh<br>Goa   | India<br>India                                       | No  |
|                         | Lamivudine (3TC)                  | 150 mg             | Tablets                  | Ranbaxy Ltd.              | A40/20.2.8/0272                     | Adult        | Antiretroviral       | Yes               | Paonta Sahib, Himchal Pradesh   | India  | No  |
|                         | Lamivudine (3TC)                  | 150 mg             | Tablets                  | Strides Arcolab Ltd.      | N/A                                 | Adult        | Antiretroviral       | Yes               | Bangalore   | India  | No  |
|                         | Lopinavir (LPV) + Ritonavir (RTV) | 80 mg + 20 mg/ml   | Oral Liquid              | Abbott Laboratories Ltd.  | N/A                                 | Paediatric   | Antiretroviral       | Yes               | Queensborough, Kent   | United Kingdom of Great Britain and Northern Ireland | Yes |
|                         | Lopinavir (LPV) + Ritonavir (RTV) | 133.3 mg + 33.3 mg | Capsules                 | Abbott Laboratories Ltd.  | N/A                                 | Adult        | Antiretroviral       | Yes               | RP Scherer, Florida,  | United States of America                             | Yes |
|                         | Nelfinavir Mesylate (NFV)         | 50 mg/g            | Powder for oral solution | Hoffman La Roche          | 33/20.2.8/0004                      | Paediatric   | Antiretroviral       | Yes               | Roche, Basle<br>Roche, Basle  | Switzerland<br>Switzerland                           | Yes |
|                         | Nelfinavir Mesylate (NFV)         | 250 mg             | Film coated tablet       | Hoffman La Roche          | 33.20.2.8/0003                      | Adult        | Antiretroviral       | Yes               | Roche, Basle<br>Roche, Madrid   | Switzerland<br>Spain                                 | Yes |
|                         | Nevirapine (NVP)                  | 50 mg/5ml          | Oral Liquid              | Aspen Pharmacare Ltd.     | A39/20.2.8/0262                     | Paediatric   | Antiretroviral       | No                |   |  | No  |

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|                         | Nevirapine (NVP)                    | 50 mg/5ml       | Oral Suspension          | Boehringer Ingelheim  | 33/20.2.8/0504                      | Paediatric   | Antiretroviral       | Yes               | Boehringer Ingelheim<br>Roxane Inc. Columbus                              | United States of America | Yes                              |
|                         | Nevirapine (NVP)                    | 50 mg/5ml       | Oral Suspension          | Cipla Ltd.            | N/A                                 | Paediatric   | Antiretroviral       | No                |   |                          | No                               |
|                         | Nevirapine (NVP)                    | 200 mg          | Tablets                  | Aspen Pharmacare Ltd. | 38/20.2.8/0240                      | Adult        | Antiretroviral       | Yes               | Korsten, Port Elisabeth   | South Africa             | No                               |
|                         | Nevirapine (NVP)                    | 200 mg          | Tablets                  | Boehringer Ingelheim  | 31/20.2.8/0640                      | Adult        | Antiretroviral       | Yes               | Boehringer Ingelheim<br>Pharma GmbH & Co.,<br>KG, Ingelheim               | Germany                  | Yes                              |
|                         | Nevirapine (NVP)                    | 200 mg          | Tablets                  | Cipla Ltd.            | N/A                                 | Adult        | Antiretroviral       | Yes               | Goa<br>Vikhroli   | India<br>India           | Yes                              |
|                         | Saquinavir (SQV)                    | 200 mg          | Capsules                 | Hoffman La Roche      | 31/20.2.8/0034                      | Adult        | Antiretroviral       | Yes               | Roche, Basle  | Switzerland              | Yes                              |
|                         | Stavudine (d4T)                     | 1 mg/ml         | Powder for oral solution | Bristol-Myers Squibb  | 32/20.2.8/0268                      | Paediatric   | Antiretroviral       | Yes               | Bristol-Myers Squibb<br>US Pharmaceutical<br>Group Evansville,<br>Indiana | United States of America | Yes                              |
|                         | Stavudine (d4T)                     | 15 mg           | Capsules                 | Aspen Pharmacare Ltd. | 37/20.2.8/0110                      | Paediatric   | Antiretroviral       | No                |   |                          | No                               |
|                         | Stavudine (d4T)                     | 20 mg           | Capsules                 | Aspen Pharmacare Ltd. | 37/20.2.8/0111                      | Paediatric   | Antiretroviral       | Yes               | Korsten, Port Elisabeth   | South Africa             | No                               |
|                         | Stavudine (d4T)                     | 20 mg           | Capsules                 | Bristol-Myers Squibb  | 32/20.2.8/0265                      | Paediatric   | Antiretroviral       | Yes               | Bristol-Myers Squibb<br>La Goualle, Meymac                                | France                   | Yes                              |
|                         | Stavudine (d4T)                     | 20 mg           | Capsules                 | Bristol-Myers Squibb  | 32/20.2.8/0265                      | Paediatric   | Antiretroviral       | Yes               | Bristol-Myers Squibb<br>La Goualle, Meymac                                | France                   | Yes                              |
|                         | Stavudine (d4T)                     | 30 mg           | Capsules                 | Aspen Pharmacare Ltd. | 37/20.2.8/0112                      | Adult        | Antiretroviral       | Yes               | Korsten, Port Elisabeth   | South Africa             | No                               |
|                         | Stavudine (d4T)                     | 30 mg           | Capsules                 | Bristol-Myers Squibb  | 32/20.2.8/0266                      | Adult        | Antiretroviral       | Yes               | Meymac  | France                   | Yes                              |
|                         | Stavudine (d4T)                     | 30 mg           | Capsules                 | Cipla Ltd.            | N/A                                 | Adult        | Antiretroviral       | No                |   |                          | Yes                              |
|                         | Stavudine (d4T)                     | 40 mg           | Capsules                 | Aspen Pharmacare Ltd. | 37/20.2.8/0113                      | Adult        | Antiretroviral       | Yes               | Korsten, Port Elisabeth   | South Africa             | No                               |
|                         | Stavudine (d4T)                     | 40 mg           | Capsules                 | Bristol-Myers Squibb  | 32/20.2.8/0267                      | Adult        | Antiretroviral       | Yes               | Bristol-Myers Squibb<br>La Goualle, Meymac                                | France                   | Yes                              |
|                         | Stavudine (d4T)                     | 40 mg           | Capsules                 | Cipla Ltd.            | N/A                                 | Adult        | Antiretroviral       | No                |   |                          | Yes                              |
|                         | Zidovudine (ZDV) + Lamivudine (3TC) | 300 mg + 150 mg | Tablets                  | Aspen Pharmacare Ltd. | 38/20.2.8/0112                      | Adult        | Antiretroviral       | No                | Korsten, Port Elisabeth   | South Africa             | Yes                              |
|                         | Zidovudine (ZDV) + Lamivudine (3TC) | 300 mg + 150 mg | Tablets                  | Cipla Ltd.            | N/A                                 | Adult        | Antiretroviral       | Yes               | Goa<br>Vikhroli   | India<br>India           | Yes                              |

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|                         | Zidovudine (ZDV) + Lamivudine (3TC)                                  | 300 mg + 150 mg          | Tablets     | Ranbaxy Ltd.          | A40/20.2.8/0254                     | Adult        | Antiretroviral       | Yes               | Paonta Sahib, Himchal Pradesh India  | No                               |
|                         | Zidovudine (ZDV) + Lamivudine (3TC) copackaged with Nevirapine (NVP) | 300 mg + 150 mg / 200 mg | Tablets     | Aspen Pharmacare Ltd. | A39/20.2.8/0446                     | Adult        | Antiretroviral       | No                | Korsten, Port Elisabeth South Africa | Yes                              |
|                         | Zidovudine (ZDV)   | 10 mg/ml                 | Oral Liquid | Aspen Pharmacare Ltd. | A38/20.2.8/0635                     | Paediatric   | Antiretroviral       | No                |                                      | No                               |
|                         | Zidovudine (ZDV)   | 50 mg/5ml                | Oral Liquid | Cipla Ltd.            | N/A                                 | Paediatric   | Antiretroviral       | Yes               | Goa India<br>Vikhroli India          | No                               |
|                         | Zidovudine (ZDV)   | 100 mg                   | Capsules    | Aspen Pharmacare Ltd. | A39/20.2.8/0249                     | Adult        | Antiretroviral       | No                | Korsten, Port Elisabeth South Africa | No                               |
|                         | Zidovudine (ZDV)   | 100 mg                   | Capsules    | Cipla Ltd.            | 34/20.2.8/0142                      | Adult        | Antiretroviral       | Yes               | Goa India<br>Vikhroli India          | No                               |
|                         | Zidovudine (ZDV)   | 250 mg                   | Capsules    | Aspen Pharmacare Ltd. | A39/20.2.8/0250                     | Adult        | Antiretroviral       | No                | Korsten, Port Elisabeth South Africa | No                               |
|                         | Zidovudine (ZDV)   | 300 mg                   | Tablets     | Aspen Pharmacare Ltd. | 38/20.2.8/230                       | Adult        | Antiretroviral       | Yes               | Korsten, Port Elisabeth South Africa | No                               |
|                         | Zidovudine (ZDV)   | 300 mg                   | Tablets     | Cipla Ltd.            | N/A                                 | Adult        | Antiretroviral       | Yes               | Vikhroli India                       | No                               |