

Truvada® Registration In The Developing World

Approved

1. Albania	October 2009	39. Egypt	March 2012	76. Pakistan	December 2012
2. Angola	July 2006	40. El Salvador	December 2008	77. Palau	May 2007
3. Anguilla	April 2008	41. Ethiopia	November 2006	78. Panama	June 2010
4. Antigua and Barbuda	April 2008	42. Fiji	October 2006	79. Papua New Guinea	November 2009
5. Argentina	April 2006	43. Gabon	May 2008	80. Paraguay	November 2009
6. Armenia	March 2009	44. Georgia	September 2009	81. Peru	August 2014
7. Aruba	July 2011	45. Ghana	April 2005	82. Philippines	May 2015
8. Azerbaijan	May 2009	46. Grenada	April 2008	83. Rwanda	January 2005
9. Bahamas	August 2007	47. Guatemala	September 2008	84. Saint Kitts and Nevis	April 2008
10. Bangladesh	April 2010	48. Guinea	June 2008	85. Saint Lucia	April 2008
11. Barbados	November 2006	49. Guyana	April 2006	86. Saint Vincent & the Grenadines	April 2008
12. Belarus	August 2008	50. Haiti	May 2008	87. Samoa	May 2007
13. Belize	March 2008	51. Honduras	July 2008	88. Senegal	August 2008
14. Benin	April 2010	52. India	July 2010	89. Seychelles	March 2006
15. Bhutan	January 2012	53. Indonesia	March 2011	90. Solomon Islands	October 2005
16. Bolivia	December 2009	54. Jamaica	October 2008	91. South Africa	April 2007
17. Bosnia and Herzegovina	May 2010	55. Kazakhstan	October 2010	92. Suriname	August 2008 *
18. Botswana	March 2006	56. Kenya	May 2005	93. Swaziland	April 2007
19. Brazil	May 2012	57. Kiribati	May 2007	94. Syria	April 2013
20. British Virgin Islands	April 2008	58. Kosovo	November 2010	95. Tajikistan	August 2008
21. Burkina Faso	April 2008	59. Kyrgyzstan	July 2009	96. Tanzania, U. Rep. of	October 2006
22. Cambodia	February 2010	60. Lao, People's Dem. Rep.	July 2008	97. Thailand	September 2008
23. Cameroon	May 2009	61. Lesotho	April 2007	98. Timor-Leste	May 2007
24. Central African Republic	March 2008	62. Madagascar	August 2007	99. Togo	September 2007
25. Chad	March 2011	63. Malawi	May 2007	100. Tonga	May 2007
26. Chile	October 2007	64. Mali	March 2008	101. Trinidad and Tobago	September 2008
27. Colombia	August 2010	65. Mauritania	May 2008	102. Turkmenistan	February 2009
28. Comoros	June 2007	66. Mauritius	April 2006	103. Turks and Caicos	May 2008
29. Congo, Dem. Rep. of the	July 2006	67. Mexico	June 2005	104. Tuvalu	May 2007
30. Congo	April 2008	68. Moldova, Rep. of	May 2008	105. Uganda	January 2005
31. Costa Rica	September 2012	69. Montserrat	April 2008	106. Ukraine	May 2008
32. Côte d'Ivoire	June 2012	70. Mozambique	April 2009	107. Uruguay	March 2007
33. Cuba	May 2007 *	71. Myanmar	September 2011	108. Uzbekistan	January 2010
34. Curacao	September 2009	72. Namibia	July 2006	109. Vanuatu	May 2007
35. Dominica	April 2008	73. Nauru	May 2007	110. Zambia	May 2005
37. Dominican Republic	October 2009	74. Niger	July 2007	111. Zimbabwe	April 2009
38. Ecuador	September 2012	75. Nigeria	June 2006		

Filed

1. Algeria	March 2007	8. Guinea-Bissau	March 2007	14. Sierra Leone	March 2007
2. Burundi	June 2007	9. Iran	January 2010	15. Sudan	March 2007
3. Cape Verde	March 2007	10. Liberia	March 2007	16. Tunisia	March 2007
4. Djibouti	March 2007	11. Libya	March 2007	17. Venezuela	January 2011
5. Equatorial Guinea	March 2007	12. Morocco	March 2007	18. Vietnam	February 2014
6. Eritrea	March 2007	13. São Tomé and Príncipe	March 2007		
7. Gambia	March 2007				

Pending Submission

1. Afghanistan	6. 6. Mongolia	11. South Sudan
2. Iraq	7. Montenegro	12. Sri Lanka
3. Jordan	8. Nepal	13. Yemen
4. Malaysia	9. Nicaragua	
5. Maldives	10. Somalia	

Note:

To facilitate access to Truvada for PrEP in developing countries, we have filed for regulatory approval for this indication in South Africa (2013), Brazil (2014) and Thailand (2014).

Terms and Definitions

Approved: Dossier submitted and approved by country or no formal regulatory process in place; approval confirmed by country.

Filed: Dossier submitted and review pending.

Pending Submission:

Dossier has not been submitted to date; standard dossier filed - specific documentation required in order to further application process; or all relevant documentation provided to distributor for in-country submission (submission may be pending translation into local language).

Italicized: Countries where approval is granted via Notification and/or Import Permit. Notification refers to documentation, other than a registration dossier, that is reviewed and approved by the Health Authority; an Import Permit is an authorization by a competent authority for the importation of product into the country.

Asterisk (*): Product available through distributor.

Note

There can be no guarantee that marketing approval for Truvada® will be granted in any of the low- and middle-income countries where registration is pending; any marketing approval, if granted, may have significant limitations on its use.