

Truvada® Registration In The Developing World

Approved

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

Filed

1. Dominican Republic	October 2015	3. Vietnam	February 2014
2. St. Maarten	November 2015		

Note: Truvada for pre-exposure prophylaxis (PrEP)

- Truvada for pre-exposure prophylaxis (PrEP) is approved for use in Kenya, Peru, South Africa, Tanzania and Thailand, and in Lesotho and Swaziland through import license.
- We have also filed for regulatory approval for this indication in Brazil (2014) and Chile (2016).
- In addition, PrEP regulatory submissions are planned in Malawi, Mozambique, Uganda, Zambia and Zimbabwe.

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.