

Viread® For Hepatitis B Registration In The Developing World

Approved

1. Albania	July 2011	22. Curacao	October 2011	43. Nauru	December 2010
2. Anguilla	June 2011	23. Dominica	June 2011	44. Pakistan	January 2013
3. Antigua and Barbuda	June 2011	24. Ecuador	August 2012	45. Palau	December 2010
4. Argentina	December 2003	25. Egypt	March 2012	46. Panama	February 2012
5. Armenia	September 2011	26. Fiji	December 2010	47. Paraguay	September 2011
6. Aruba	September 2011	27. Georgia	June 2011	48. Peru	June 2011
7. Azerbaijan	May 2011	28. Grenada	June 2011	49. Saint Kitts and Nevis	June 2011
8. Bahamas	June 2011	29. Guatemala	June 2011	50. Saint Lucia	June 2011
9. Bangladesh	June 2011	30. Haiti	September 2012	51. Saint Vincent and the Grenadines	June 2011
10. Barbados	June 2011	34. Honduras	July 2012	52. Samoa	December 2010
11. Belize	June 2011	32. India	December 2011	53. Solomon Islands	December 2010
12. Bhutan	November 2012	33. Iran	April 2012	54. Syria	June 2013
13. Bolivia	September 2011	34. Kazakhstan	May 2012	55. Thailand	June 2013
14. Bosnia and Herzegovina	June 2012	35. Kiribati	December 2010	56. Timor-Leste	December 2010
15. Brazil	August 2003	36. Kosovo	June 2011	57. Tonga	December 2010
16. British Virgin Islands	June 2011	37. Kyrgyzstan	July 2012	58. Turks and Caicos	June 2011
17. Cambodia	April 2011	38. Lao, People's Dem. Rep	January 2013	59. Truvalu	December 2010
18. Chile	November 2011	39. Mexico	November 2012	60. Ukraine	September 2012
19. Colombia	March 2013	40. Moldova	January 2013	61. Uruguay	March 2006
20. Costa Rica	March 2013	41. Montserrat	June 2011	62. Uzbekistan	May 2011
21. Cuba	June 2011 ✓	42. Myanmar	December 2012	63. Vanuatu	*December 2010

Filed

1. Burkina Faso	April 2008	6. Gabon	February 2014	11. Philippines	March 2013
2. China	January 2013	7. Guinea	February 2014	12. Senegal	February 2014
3. Dominican Republic	March 2012	8. Jamaica	June 2011	13. Tajikistan	August 2011
4. El Salvador	June 2011	9. Malaysia	December 2013	14. Turkmenistan	July 2011
5. Guyana	January 2012	10. Mali	February 2014	15. Uganda	February 2014

Pending Submission

1. Afghanistan	11. Chad	21. Ghana
2. Algeria	12. Comoros	22. Guinea-Bissau
3. Angola	13. Congo	23. Indonesia
4. Belarus	14. Congo, Dem. Rep. of the	24. Iraq
5. Benin	15. Côte d'Ivoire	25. Jordan
6. Botswana	16. Djibouti	26. Kenya
7. Burundi	17. Equatorial Guinea	27. Lesotho
8. Cameroon	18. Eritrea	28. Liberia
9. Cape Verde	19. Ethiopia	29. Libya
10. Central African Republic	20. Gambia	30. Madagascar

Pending Submission (cont.)

31. Malawi	43. Nicaragua	55. Sudan
32. Malaysia	44. Niger	56. Suriname
33. Maldives	45. Nigeria	57. Swaziland
34. Mali	46. Papua New Guinea	58. Tanzania, U. Rep. of
35. Mauritania	47. Rwanda	59. Togo
36. Mauritius	48. São Tomé and Príncipe	60. Trinidad and Tobago
37. Mongolia	49. Seychelles	61. Tunisia
38. Montenegro	50. Sierra Leone	62. Yemen
39. Morocco	51. Somalia	63. Zambia
40. Mozambique	52. South Africa	64. Zimbabwe
41. Namibia	53. South Sudan	
42. Nepal	54. Sri Lanka	

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.

Check Mark (✓): Product available through distributor.

Asterisk (*): Clinical trial application submitted; registration study to begin.

Note

There can be no guarantee that marketing approval for Viread® for the treatment of hepatitis B 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.