Viread® For Hepatitis B Registration In The Developing World

Approved

4 411 :	1.1.0044
1. Albania	July 2011
2. Anguilla	June 2011
Antigua and Barbuda	June 2011
Argentina	May 2011
5. Armenia	September 2011
6. Aruba	September 2011
7. Azerbaijan	May 2011
8. Bahamas	June 2011
9. Bangladesh	June 2011
10. Barbados	June 2011
11. Belize	June 2011
12. Belarus	December 2013
13. Bhutan	November 2012
14. Bolivia	September 2011
15. Bosnia and Herzegovina	June 2012
16. Brazil	December 2010
17. British Virgin Islands	June 2011
18. Burkina Faso	September 2014
19. Cambodia	April 2011
20. Chile	November 2011
21. Colombia	March 2013
22. Costa Rica	March 2013
23. Cuba	June 2011 *
24. Curacao	October 2011
25. Dominica	June 2011

26. Ecuador	August 2012
27. Egypt	March 2012
28. Fiji	June 2011
29. Gabon	November 2014
30. Georgia	June 2011
31. Grenada	June 2011
32. Guatemala	June 2011
33. Guinea	February 2014
34. Haiti	September 2012
35. Honduras	July 2012
36. India	December 2011
37. Iran	April 2012
38. Kazakhstan	May 2012
39. Kenya	September 2014
40. Kiribati	June 2011
41. Kosovo	June 2011
42. Kyrgyzstan	July 2012
43. Lao, People's Dem. Rep	January 2013
44. Mali	November 2014
45. Mexico	November 2012
46. Moldova	January 2013
47. Mongolia	September 2014
48. Montserrat	June 2011
49. Myanmar	December 2012
50. Nauru	June 2011

53. Pakistan	January 2013
54. Palau	June 2011
55. Panama	February 2012
56. Paraguay	September 2011
57. Peru	June 2011
58. Philippines	March 2014
59. Saint Kitts and Nevis	June 2011
60. Saint Lucia	June 2011
61. Saint Vincent & the Grenadines	June 2011
62. Samoa	June 2011
63. Solomon Islands	June 2011
64. Syria	April 2013
65. Thailand	May 2013
66. Timor-Leste	June 2011
67. Tonga	June 2011
68. Turkmenistan	April 2014
69. Turks and Caicos	June 2011
70. Tuvalu	June 2011
71. Ukraine	September 2012
72. Uruguay	April 2011
73. Uzbekistan	May 2011
74. Vanuatu	June 2011
75. Namibia	August 2015
76. Ethiopia	August 2015
77. Zimbabwe	September 2015
11 Courth Africa	December 2012

September 2014

March 2014

51. Nepal

52. Niger

Filed

1.	Cameroon	May 2014
2.	Central African Republic	June 2014
3.	Chad	November 2014
4.	Congo	May 2014
5.	Côte d'Ivoire	July 2014
6.	Dominican Republic	March 2012
7.	El Salvador	June 2011

8. Guyana	January 2012
9. Jamaica	January 2011
10. Malawi	April 2014
11. Malaysia	December 2013
12. Mauritania	March 2014
13. Senegal	February 2014

14. South Africa	December 2013
15. Tajikistan	August 2011
16. Tanzania, U. Rep. of	December 2014
17. Uganda	February 2014
18. Vietnam	February 2014

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Pending Submission

1. Afghanistan	19. Kenya
2. Algeria	20. Lesotho
3. Angola	21. Liberia
4. Benin	22. Libya
5. Botswana	23. Madagascar
6. Burundi	24. Maldives
7. Cape Verde	25. Mauritius
8. Comoros	26. Montenegro
9. Congo, Dem. Rep. of the	27. Morocco
10. Djibouti	28. Mozambique
11. Equatorial Guinea	29. Nicaragua
12. Eritrea	30. Nigeria
13. Gambia	31. Papua New Guinea
14. Ghana	32. Rwanda
15. Guinea-Bissau	33. São Tomé and Príncipe
16. Indonesia	34. Seychelles
17. Iraq	35. Sierra Leone
18. Jordan	

36. Somalia
37. South Sudan
38. Sri Lanka
39. Sudan
40. Suriname
41. Swaziland
42. Togo
43. Trinidad and Tobago
44. Tunisia
45. Yemen
46. Zambia

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).

Asterisk (*): Product available through distributor.

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.

