



## Rotavirus Vaccines

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### Drug Levels and Effects

#### Summary of Use during Lactation

Rotavirus vaccines are used only in infants and are not indicated for use in women of childbearing age. Breastfeeding protects infants against acute gastroenteritis caused by rotavirus.[1,2] However, breastfeeding can reduce the immune response of an infant to rotavirus vaccines in low- and middle-income countries.[3-9] Maternal antibodies are probably an important cause of the lower response rate, but lactadherin, a milk glycoprotein, and infant genetics may also be factors.[8-10] Breastfeeding might also reduce viral shedding in the stool by the vaccinated infants.[6] The extent of the effect depends on the maternal anti-rotavirus antibody titer in breastmilk with higher titers found in less developed areas.[11-15] Withholding breastfeeding for up to 2 hours before and after vaccine administration has been recommended to minimize the interference.[11,16,17] However, other studies found that withholding breastfeeding for either one hour before and after immunization, [18,19] or for 30 minutes before vaccination had no effect on seroconversion.[20] Reviews have concluded that withholding of breastfeeding at the time of vaccination has no effect on seroconversion of infants.[8,21]

A European study found no difference in rotavirus infection rates during the first season between infants who were breastfed and formula-fed when they received rotavirus vaccination. In the second season, protection against infection was slightly less in breastfed infants.[4] A German study found that exclusive or partial breastfeeding increased the risk of breakthrough infection fourfold.[5] A study in Indonesia found that rotavirus vaccine was cost-effective for the health system, even with improved breastfeeding rates.[22]

Studies have found that breastfeeding decreases the risk of intestinal intussusception caused by rotavirus vaccine by about half.[23,24]

#### Drug Levels

*Maternal Levels.* Relevant published information was not found as of the revision date.

*Infant Levels.* Relevant published information was not found as of the revision date.

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## Effects in Breastfed Infants

A subset of 300 infants in a multicenter European rotavirus efficacy trial had antirotavirus IgA titers measured 1 to 2 months after the second rotavirus dose (Rotarix - GSK). Breast-fed infants had an 85.5% conversion rate compared with 89.2% rate in exclusively formula-fed infants, which was not statistically different. The serum antirotavirus IgA concentrations were 185.8 units/mL and 231.5 units/mL in the breastfed and exclusively formula-fed infants, respectively.[4]

Two hundred fifty breastfed infants were randomized to receive their routine rotavirus vaccination (Rotarix) with either unrestricted breastfeeding or withholding breastfeeding from 1 hour before to 1 hour after the vaccination. No difference were found in the rate of seroconversion between the two groups of infants.[19]

Four hundred infants in India were randomized to either be breastfed before receiving rotavirus vaccine (Rotarix) or to not be breastfed within 30 minutes of their vaccination. Vaccinations were given at 6 to 7 weeks and at 10 to 14 weeks of age. Of the 388 infants with evaluable information, no difference was found in the seroconversion rate between the two groups.[20]

Among 45 breastfed (at least 4 times daily) Nicaraguan infants who were given a rotavirus vaccination (Rotateq-MSD), 31 infants seroconverted and 14 infants did not. The seroconversion failures were mostly in infants who had high preimmunization IgA levels and whose mothers had high serum IgG antibody levels against rotavirus. No correlation was found between breastmilk IgA or neutralizing antibodies and seroconversion, although the sample size was small.[25]

In a monovalent G1P[8] rotavirus vaccine (Rotarix) trial in Bangladesh, rotavirus-specific plasma IgA antibody seroconversion rates were higher among infants of maternal non-secretors of antibodies (39%) compared to mothers who secreted anti-rotavirus antibodies (23%). Maternal secretor status was a significant predictor of infant response to the vaccine.[15]

## Effects on Lactation and Breastmilk

Relevant published information was not found as of the revision date.

## References

1. Plenge-Bönig A, Soto-Ramírez N, Karmaus W, et al. Breastfeeding protects against acute gastroenteritis due to rotavirus in infants. *Eur J Pediatr*. 2010;169:1471–6. PubMed PMID: 20617343.
2. Das S, Sahoo GC, Das P, et al. Evaluating the impact of breastfeeding on rotavirus antigenemia and disease severity in Indian children. *PLoS One*. 2016;11:e0146243. PubMed PMID: 26828823.
3. Goveia MG, Dinubile MJ, Dallas MJ, et al. Efficacy of pentavalent human-bovine (WC3) reassortant rotavirus vaccine based on breastfeeding frequency. *Pediatr Infect Dis J*. 2008;27:656–8. PubMed PMID: 18520448.
4. Vesikari T, Prymula R, Schuster V, et al. Efficacy and immunogenicity of live-attenuated human rotavirus vaccine in breast-fed and formula-fed European infants. *Pediatr Infect Dis J*. 2012;31:509–13. PubMed PMID: 22228235.
5. Adlhoch C, Hoehne M, Littmann M, et al. Rotavirus vaccine effectiveness and case-control study on risk factors for breakthrough infections in Germany, 2010-2011. *Pediatr Infect Dis J*. 2013;32:e82–9. PubMed PMID: 23334342.
6. Bautista-Marquez A, Velasquez DE, Esparza-Aguilar M, et al. Breastfeeding linked to the reduction of both rotavirus shedding and IgA levels after Rotarix(R) immunization in Mexican infants. *Vaccine*. 2016;34:5284–9. PubMed PMID: 27663670.
7. Parker EP, Ramani S, Lopman BA, et al. Causes of impaired oral vaccine efficacy in developing countries. *Future Microbiol*. 2018;13:97–118. PubMed PMID: 29218997.

8. Otero CE, Langel SN, Blasi M, et al. Maternal antibody interference contributes to reduced rotavirus vaccine efficacy in developing countries. *PLoS Pathog.* 2020;16:e1009010. PubMed PMID: 33211756.
9. Hitchings MDT, Cummings DAT, Grais RF, et al. A mixture model to assess the immunogenicity of an oral rotavirus vaccine among healthy infants in Niger. *Vaccine.* 2020;38:8161–6. PubMed PMID: 33162202.
10. Mwila-Kazimbaya K, García MP, Bosomprah S, et al. Effect of innate antiviral glycoproteins in breast milk on seroconversion to rotavirus vaccine (Rotarix) in children in Lusaka, Zambia. *PLoS One.* 2017;12:e0189351. PubMed PMID: 29284036.
11. Moon SS, Wang Y, Shane AL, et al. Inhibitory effect of breast milk on infectivity of live oral rotavirus vaccines. *Pediatr Infect Dis J.* 2010;29:919–23. PubMed PMID: 20442687.
12. Chan J, Nirwati H, Triasih R, et al. Maternal antibodies to rotavirus: Could they interfere with live rotavirus vaccines in developing countries? *Vaccine.* 2011;29:1242–7. PubMed PMID: 21147127.
13. Moon SS, Groome MJ, Velasquez DE, et al. Pre vaccination rotavirus serum IgG and IgA are associated with lower immunogenicity of live, oral human rotavirus vaccine in South African infants. *Clin Infect Dis.* 2016;62:157–65. PubMed PMID: 26400993.
14. Trang NV, Braeckman T, Lernout T, et al. Prevalence of rotavirus antibodies in breast milk and inhibitory effects to rotavirus vaccines. *Hum Vaccin Immunother.* 2014;10:3681–7. PubMed PMID: 25668672.
15. Williams FB, Kader A, Colgate ER, et al. Maternal secretor status affects oral rotavirus vaccine response in breastfed infants in Bangladesh. *J Infect Dis.* 2021;224:1147–51. PubMed PMID: 32157282.
16. Foster RH, Wagstaff AJ. Tetravalent human-rhesus reassortant rotavirus vaccine: a review of its immunogenicity, tolerability and protective efficacy against paediatric rotavirus gastroenteritis. *BioDrugs.* 1998;9:155–78. PubMed PMID: 18020551.
17. Danchin MH, Bines JE, Watts E, et al. Rotavirus specific maternal antibodies and immune response to RV3-BB rotavirus vaccine in central java and yogyakarta, Indonesia. *Vaccine.* 2020;38:3235–42. PubMed PMID: 32160948.
18. Ali A, Kazi AM, Cortese MM, et al. Impact of withholding breastfeeding at the time of vaccination on the immunogenicity of oral rotavirus vaccine—a randomized trial. *PLoS One.* 2015;10:e0127622. PubMed PMID: 26035743.
19. Groome MJ, Moon SS, Velasquez D, et al. Effect of breastfeeding on immunogenicity of oral live-attenuated human rotavirus vaccine: a randomized trial in HIV-uninfected infants in Soweto, South Africa. *Bull World Health Organ.* 2014;92:238–45. PubMed PMID: 24700991.
20. Rongsen-Chandola T, Strand TA, Goyal N, et al. Effect of withholding breastfeeding on the immune response to a live oral rotavirus vaccine in North Indian infants. *Vaccine.* 2014;32 Suppl 1:A134–9. PubMed PMID: 25091668.
21. Mwila K, Chilengi R, Simuyandi M, et al. Contribution of maternal immunity to decreased rotavirus vaccine performance in low and middle income countries. *Clin Vaccine Immunol.* 2017;24:e00405–16. PubMed PMID: 27847365.
22. Suwantika AA, Postma MJ. Effect of breastfeeding promotion interventions on cost-effectiveness of rotavirus immunization in Indonesia. *BMC Public Health.* 2013;13:1106. PubMed PMID: 24289227.
23. Oberle D, Hoffelner M, Pavel J, et al. Retrospective multicenter matched case-control study on the risk factors for intussusception in infants less than 1 year of age with a special focus on rotavirus vaccines - the German Intussusception Study. *Hum Vaccin Immunother.* 2020;16:2481–94. PubMed PMID: 32271647.
24. Restivo V, Costantino C, Giorgianni G, et al. Case-control study on intestinal intussusception: Implications for anti-rotavirus vaccination. *Expert Rev Vaccines.* 2018;17:1135–41. PubMed PMID: 30407079.
25. Becker-Dreps S, Vilchez S, Velasquez D, et al. Rotavirus-specific IgG antibodies from mothers' serum may inhibit infant immune responses to the pentavalent rotavirus vaccine. *Pediatr Infect Dis J.* 2015;34:115–6. PubMed PMID: 25741808.

## Substance Identification

### Substance Name

Rotavirus Vaccines

### Drug Class

Breast Feeding

Lactation

Vaccines

Viral Vaccines