



Rotavirus Vaccine, Live, Oral, Pentavalent

For RotaTeq[®] recipient

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For RotaTeq[®] recipient

(What you should know before having your baby vaccinated)



Precautions and adverse reactions

- As severe allergic symptoms may occur, please rest your baby for at least 30 minutes after vaccination.
- If you notice any changes in your baby condition or abnormal symptoms after vaccinating with RotaTeq[®] Oral Solution, consult your doctor immediately.
- Adverse reactions such as diarrhea, vomiting, gastroenteritis and fever may occur after vaccination.

* Common adverse reactions reported in the clinical study in Japan within 14 days after vaccination were diarrhea (5.5%), vomiting (4.2%), gastroenteritis (3.4%), and fever (1.3%).

Your baby may have intussusception if he/she has any of the following symptoms.

Consult your doctor promptly if you notice any unusual symptoms that may not be prolonged.

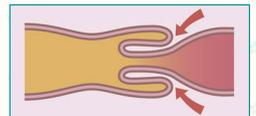
Major symptoms of intussusception

- Repeated vomiting
- Repetition of crying and ill temper
- Looking tired out, lack of energy
- Bloody stools (stools mixed with mucus and blood)

● According to an overseas survey, the risk of intussusception may increase during the 21 days after vaccination with RotaTeq[®] (primarily for 7 days). Please pay special attention to the above symptoms during this period.

What is intussusception?

- A condition in which part of the intestine enters other parts of the intestine to obstruct the intestine.
- Regardless of whether or not a child is vaccinated against rotavirus, the disease mainly affects children aged 0 years (about 1000 children per year in Japan at the age of 0 years develop this disease*).
- Intussusception is usually treated with fluid or air from the anus to restore the intestine. As the time elapses from the onset (>12 hours), the bowel in the blocked area necroses and the rate of surgery increases, so a doctor should be consulted promptly if any suspicious symptoms occur.



* Citation: From the 4th Meeting of the Immunization and Vaccination Committee of the Health Sciences Council, Sectional Meeting of Immunization Basic Policy Subcommittee on Vaccine Evaluation, Document 1-2 Recent findings on rotavirus vaccine

Actions to be taken after vaccination

- Your baby can bathe on the day of vaccination.
- After your baby is vaccinated with RotaTeq® Oral Solution, a vaccine-derived virus may infect your family or close persons through your baby's stools, etc. Pay attention to washing your hands after changing diapers. Be careful when your baby has close contact with a person who has a weakened immune system as follows:
 - Patients with malignant tumors or immune disorders
 - Those receiving immunosuppressive therapy

If RotaTeq® Oral Solution is exhaled after vaccination, it does not require an additional dose.

The guidelines for routine vaccination recommend that additional vaccination is not necessary even if the baby has spat out the vaccine solution after receiving oral vaccination.

The efficacy was confirmed in the clinical studies in Japan and overseas by the test method that did not conduct additional vaccination if spitting occurred.



Vaccination schedule for RotaTeq® Oral Solution

- The first vaccination dose should be given at 6 weeks after birth.
- It is recommended to receive the first vaccination by 14 weeks and 6 days after birth.
- The second and third doses should be given at more than 4-week intervals and vaccination thus completed before 32 weeks of age (about 8 months).
- If the vaccination period has passed, your baby cannot be vaccinated.
 - *○ weeks after birth = ○ times on the same day of the week counted from the date of birth
- If the doctor considers it necessary, your baby can receive other vaccines at the same time. This solution cannot be mixed with other vaccines.



- If you visit another medical institution for any changes in your baby's physical condition or symptoms suggestive of intussusception, you should bring your maternity health handbook (vaccination record) and also say that your baby has been vaccinated with RotaTeq® Oral Solution.
- If you visit another medical institution for intussusception, please also inform the medical institution at which your baby has received RotaTeq® Oral Solution.