

For persons wishing to receive vaccination with rotavirus vaccine (RotaTeq[®] oral solution)

To parents

Before having your child vaccinated with the rotavirus vaccine, it is necessary to know the physical condition of your child. Please thoroughly read the following information about rotavirus vaccine (RotaTeq[®] oral solution) and fill in the screening questionnaire as completely as possible.

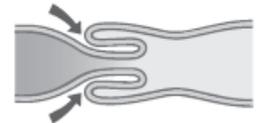
○ Outline and effect of RotaTeq[®] oral solution

1. Rotavirus is a cause of gastroenteritis observed in infants and children aged 5 years or less. Its infectivity is strong, and it is difficult to prevent rotavirus infection merely by washing of the hands. Severe gastroenteritis due to rotavirus increases the stress and burden on the infant and his/her family, with some infected children even requiring hospital admission. It rarely causes convulsion or encephalitis.
2. RotaTeq[®] oral solution is a pentavalent attenuated live rotavirus vaccine to immunize 6- to 32-week-old infants by oral administration 3 times. (it is recommended that initial vaccination be performed before 14 weeks and 6 days after birth).
3. The vaccination of RotaTeq[®] oral solution is expected to prevent rotavirus gastroenteritis accompanied by diarrhea, vomiting, and fever. Furthermore, it is confirmed that the use of this vaccine has restrained the frequency of visit to medical organ in association with rotavirus gastroenteritis.

○ Adverse reactions of RotaTeq[®] oral solution

In a clinical study in Japan, adverse reactions such as diarrhea (5.5%), vomiting (4.2%), gastroenteritis (3.4%), and fever (1.3%) were observed (reported within 14 days after vaccination). According to an international post-marketing survey, the risk of intussusception may be slightly higher during the 21 days after vaccination (primarily for 7 days). If you have any concerns, please consult a physician.

Intussusception*: It is a condition in which a part of the intestine invades into another section of intestine to occlude the intestine. Major symptoms are repeated vomiting, repetition of crying and ill temper (the patient cries hard or becomes sullen due to the abdominal ache but due to the repeated cycles of pain and no pain, there is no symptom sometimes), looking tired-out, ill-temper with unknown cause (different from everyday condition), and bloody stools like strawberry jelly.



○ The following infants should not receive vaccination:

1. Infants with fever (temperature higher than 37.5°C)
2. Those with severe acute diseases
3. Those with a history of hypersensitivity (including severe allergic responses with dyspnea or systemic urticaria appearing within 30 minutes after vaccination) to the components of RotaTeq[®] oral solution (please ask a physician for details)
4. Those with a history of intussusception
5. Untreated infants with congenital gastrointestinal tract disorder that may increase the risk of intussusception
6. Infants with severe combined immunodeficiency (SCID)
7. Others whose parents have been instructed to avoid vaccination by attending physicians

○ Consult a physician before vaccinating the following infants:

1. Infants with underlying diseases such as cardiovascular/kidney/liver/blood diseases and development disorder
2. Those with a history of fever within 2 days after vaccination, or those with symptoms such as systemic exanthema, suggesting allergy
3. Those with a history of convulsion
4. Those with diseases associated with the abnormal immune function, those with risks for diseases associated with the abnormal immune function, those receiving immunosuppressive therapy, and those with a family history of congenital immunodeficiency
5. Those with gastrointestinal disorder (e.g., active gastrointestinal diseases, chronic diarrhea)

[Please see the reverse side.]

○ Precautions for vaccination with RotaTeq[®] oral solution

1. The first vaccination dose should be given 6 or more weeks after birth*. The second and third doses should be given at more than 4-week intervals. The third vaccination dose should be given and vaccination thus completed before 32 weeks of age*. Vaccination is not possible after the prescribed vaccination time point. (It is recommended to receive the initial vaccination by 14 weeks and 6 days after birth.)
2. If you have any questions about rotavirus vaccine or adverse reactions, please consult a physician before using the vaccination.
3. On the day of vaccination, please check the physical condition of your child to confirm the health of your child.
4. The screening questionnaire provides important information for the physician who performs the vaccination. Please fill in the form accurately.

* X weeks after birth = the same weekday after X weeks counting from the date of birth. Example: 32 weeks old refers to Day 0 (first day) of the 32nd week of birth.

○ Precautions after vaccination with RotaTeq[®] oral solution

1. As severe allergic symptoms may occur, please rest your child for at least 30 minutes after vaccination.
2. If changes in the condition or abnormal symptoms are observed in your child after vaccination, please promptly consult a physician. After vaccination, adverse reactions such as diarrhea, vomiting, gastroenteritis, and fever may occur.
3. If the symptoms assumed to indicate intussusception such as “repeated vomiting”, “repetition of crying and ill temper”, “looking tired-out”, “ill-temper with unknown cause”, “bloody stools like strawberry jelly” are observed, immediately consult the family doctor. According to an international post-marketing survey, the risk of intussusception may be slightly higher during the 21 days after vaccination (primarily for 7 days). During this period, caution is needed.

The symptoms of intussusception will improve after prompt treatment, avoid protracting the symptoms by keeping the patient long at home while observing the condition. If you visit other medical organ for the treatment, also notify the medical organ where vaccination was given.

4. Please avoid high-intensity exercise for the child on the day of vaccination.
5. Your child can bathe on the day of vaccination.
6. There is no restriction on the solid food and liquid food including mother’s milk before and after vaccination.
7. After vaccination, the virus may infect the child’s family or close persons through stools. Wash your hands carefully after changing your child’s diaper. Caution is needed when the persons who have an impaired immune system (patients with malignant tumors or immune disorder or those receiving immunosuppressive therapy) are in close contact with your child.
8. If the baby spits out immediately after vaccination of RotaTeq[®] oral solution, additional vaccination that time is not necessary. Advisory Committee on Immunization Practices (ACIP) recommends that additional vaccination should not be conducted if the baby has spit out because there is no data related to additional vaccination. The efficacy and safety were confirmed in the clinical studies in Japan and abroad by the test method that did not conduct additional vaccination if spitting occurs.

Vaccination of other vaccine

1. It is necessary to provide an interval of 27 days or more for other vaccination after the RotaTeq[®] oral solution vaccination. If you wish to receive other vaccine at the same time, please consult the doctor.
2. Since the data related to the compatibility with other rotavirus vaccine is not available, cross vaccination with other rotavirus vaccine should be avoided.

Scheduled day for vaccination	Date / / () Time	Hospital	
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[Reference]

When vaccination with rotavirus vaccine causes health damage, medical expenses are covered for some patients based on the “The Relief System for Sufferers from Adverse Drug Reactions.” Please refer to the homepage of the Pharmaceuticals and Medical Devices Agency for details.

[The Relief System for Sufferers from Adverse Drug Reactions]

This system provides coverage for medical expenses, medical benefit, and disability pension to relieve persons suffering from side effect-related health damage, such as diseases/disturbance requiring hospital admission/treatment despite the adequate use of drugs. To claim coverage, a medical certificate issued by a physician or medication certificate is required. When requesting relief payment, please consult the Pharmaceuticals and Medical Devices Agency.

<Contact for inquiries>

Relief System-Consulting Counter, Pharmaceuticals and Medical Devices Agency

Telephone: 0120-149-931 (free dial) URL: <http://www.pmda.go.jp/>

Screening questionnaire for vaccination with rotavirus vaccine (RotaTeq® oral solution)

*Please fill in the blanks inside the bold frame, or select your answer by circling your option.

Frequency of vaccination	First · Second · Third	Body temperature before consultation	°C
Address	〒	Phone number	() -
Infant's name	M / F	Date of birth	/ / (d/m/y)
Parent's name			(weeks and days after birth)

Questionnaire	Answer		Physician's comment
With respect to the vaccination that your child will receive today, have you read and understood the explanatory note ["For persons wishing to receive vaccination with rotavirus vaccine (RotaTeq® oral solution)"]?	No	Yes	
Let us know about your child's development history. Birth weight	() g		
Were there any abnormalities at delivery?	Yes	No	
Were there any abnormalities after birth?	Yes	No	
Have you ever been informed of the presence of an abnormality on a health checkup for your child?	Yes	No	
Does your child have any unfavorable condition today? ○ Symptom ()	Yes	No	
Has your child been ill within the past 1 month? ○ Disease ()	Yes	No	
Has any family member or friend who has been in contact with your child developed measles, rubella, varicella, or mumps within the past 1 month? ○ Disease ()	Yes	No	
Has your child received any vaccination within the past 1 month? ○ Vaccine ()	Yes	No	
Has your child ever received vaccination with another rotavirus vaccine (Rotarix)? ○ Frequency and timing of vaccination (times, *First vaccination / *Second vaccination /)	Yes	No	
Has your child ever undergone treatment because of a diagnosis of a special disease (congenital anomalies, heart/kidney/liver/blood/cranial nerve diseases, immunodeficiency, or other diseases) ○ Disease () ○ Attending physician's comments ()	Yes	No	
Has your child ever experienced repeated fever/diarrhea/white pimples on the cheek/tongue or a persistent common cold? ○ Symptoms ()	Yes	No	
Has your child ever developed convulsion? Age: months ○ Was fever observed at that time?	Yes	No	
Has your child ever developed drug-/food-related exanthema/urticaria or showed an unfavorable condition? ○ Drug/food name ()	Yes	No	
Is there any close relative who was diagnosed with congenital immunodeficiency?	Yes	No	
Has your child ever become sick after vaccination? ○ Vaccine ()	Yes	No	
Is there any close relative who became sick after vaccination?	Yes	No	
Has your child received blood transfusion or immunoglobulin injection within the last 6 months?	Yes	No	
Do you have any questions regarding today's vaccination?	Yes	No	

Physician's comments

Based on the above answers and the results of the interview, I have decided that the patient (can/should not) receive a vaccination today.
I have explained to the parent the information concerning the efficacy and adverse reaction of vaccination and the support provided by Pharmaceuticals and Medical Devices Agency Law.

Physician's signature []

Parent's comments

I have understood the efficacy of vaccination and adverse reactions through a physician's consultation/explanation.

Do you consent to the above contents and wish for your child to receive vaccination with this vaccine? (Yes/No)

Parent's signature []

Vaccine name	Dosage and method	Place, physician's name, and date of vaccination
Name: Rotavirus Vaccine, Live, Oral, Pentavalent <input type="checkbox"/> RotaTeq® oral solution Manufacturer: MSD Co., Ltd. Lot number:	Oral vaccination, 2 mL	Hospital: Physician's name: Date of vaccination: (/ / o'clock)

Remarks

This screening questionnaire is used to improve the safety of vaccination. Personal information that you described will only be used for pre-vaccination consultation.