
ロタウイルス胃腸炎予防ワクチン (ロタリックス[®] 内用液) 接種予診票

Rotavirus Vaccine
Rotarix[®] Pre-vaccination Screening Questionnaire

『ロタウイルス胃腸炎予防ワクチン(ロタリックス®内用液) 接種予診票』の使い方

接種説明書(「保護者の方へ」)および予診票で1セットとなります。

接種説明書

Explanation before Rotarix® Vaccination for Rotavirus Gastroenteritis

For the parents/guardians:

Please be sure to read this document.

1 About Rotavirus Gastroenteritis

- Rotavirus gastroenteritis is a common viral gastroenteritis in children. Rotavirus, the cause of rotavirus gastroenteritis, is ubiquitous; regardless of hygiene, the infection is found worldwide.
- The illness often begins with explosive vomiting and leads to whitish watery diarrhoea. It can be accompanied by fever and such symptoms may last one week. Most patients are cared for at home and recover, but some children become dehydrated due to severe vomiting and diarrhoea. In more serious cases, the illness may lead to kidney failure, brain inflammation or encephalopathy. Hospitalisation is required for patients with severe cases.
- In Japan, rotavirus gastroenteritis peaks from the late winter to spring. The incidence of clinical illness peaks among children aged 3-24 months – the highest peak is at 7-15 months. Until the age of three months, infants are protected by maternal immunity and thus, if infected, the illness will be asymptomatic or only mild. However, the first infection after the age of three months is usually the most severe. In fact, rotavirus infection is the most common cause of severe acute gastroenteritis in infants and young children, and there is a report that one in ten children requiring an outpatient visit will ultimately require an inpatient visit.
- Children can be protected from severe rotavirus gastroenteritis by vaccination.

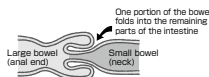
2 Indications for Rotarix®

- Rotarix® is a live, oral vaccine indicated for the prevention of rotavirus gastroenteritis (For oral use only. Not for injection).
- Rotarix® was developed by the attenuation of a common human rotavirus strain in cell culture, reducing pathogenicity and is made as a syrupy liquid agent.
- Five major rotavirus strains, G1, G2, G3, G4, and G9, are responsible for most of the rotavirus gastroenteritis episodes worldwide. Rotarix® is based on the G1 type, the most common human strain.
- The vaccine mimics natural infection and typically provides effective protection against the other four main strains.

3 The following infants should not receive vaccination:

- Infants with fever (temperature higher than 37.5°C).
- Those with severe acute diseases (Postpone when there is symptoms of diarrhea and vomiting).
- Those with a history of hypersensitivity to Rotarix®.
- Untreated infants with congenital gastrointestinal tract disorder that may increase the risk of intussusception* (such as Meckel's diverticulum).
- Those with a history of intussusception.
- Infants with severe combined immunodeficiency (SCID).
- Infants under all other inappropriate conditions for vaccination.

*Intussusception (IS): A condition occurring when one portion of the bowel folds into the remaining parts of the intestine that should be treated urgently. Regardless of vaccination, this condition is often observed in children less than 1 year old. IS causes a blockage of the intestine and the blood supply, which can lead to the death of intestinal tissues (necrosis). If IS is observed, the obstruction is typically cleared by flushing fluid, such as contrast agents and water, or air through the intestine from the anus. However, the more time passes from the start of the symptoms (e.g. 12 hours or longer), the higher the possibility that surgery will become necessary to remove the necrotized tissue.



4 Consult a physician before vaccinating the following infants:

- Infants with underlying diseases such as cardiovascular/kidney/liver/blood diseases and development disorder.
- Those with a history of fever within 2 days after vaccination, or those with symptoms such as systemic exanthema, suggesting allergy.

保護者にお渡しください

予診票

(Rotavirus Vaccine, Live, Oral) Screening Questionnaire

parts surrounded by thick solid lines, or enclose with ○. Body Temperature before interview: / / (d/m/y) Degrees (°C)

1st: / / 2nd (Previous Time: / / (d/m/y))

TEL: () - () - ()

Birth Date: / / (d/m/y) Born on / / (d/m/y) Age (weeks days)

| Vaccination Questionnaire | Answer | Doctor's Comment |
|--|--------|------------------|
| the document (For the Parents/Guardians of a Child for Vaccination) explaining if administered today? | Yes No | |
| the following questions about the child: Weight at birth (g) | Yes No | |
| ave any abnormal findings at delivery? | Yes No | |
| ave any abnormal findings after birth? | Yes No | |
| mainly identified at an infant health check? | Yes No | |
| today? the nature of the illness. (Details:) | Yes No | |
| have diarrhoea today? | Yes No | |
| seen ill within the last month? (Disease Name:) | Yes No | |
| member or neighbor of the child had a disease such as measles, rubella, mumps within the last month? (Disease Name:) | Yes No | |
| been vaccinated within the last month? (Vaccine Name:) | Yes No | |
| have a congenital anomaly, heart, kidney, liver, digestive system, central nerve system, or any other diseases for which you have consulted a doctor? (Disease Name:) | Yes No | |
| did the doctor who manages the above disease agree with today's vaccination? | Yes No | |
| repeatedly had an obvious fever, diarrhoea or other symptoms such as white spots inside the cheeks, or a prolonged recovery from illness? | Yes No | |
| ever had a seizure (spasm or fit) in the past? (When: / /) If "yes" to the preceding question, did the child have a fever at that time? (Yes / No) | Yes No | |
| ever had a rash or urticaria as a reaction to medications or food or become ill after foods or receiving certain medications? (Food Name:) | Yes No | |
| have a family member or relative with a congenital immunodeficiency? | Yes No | |
| had a serious reaction to a vaccine in the past? | Yes No | |
| member or relative of the child had a serious reaction to a vaccine in the past? | Yes No | |
| received a transfusion of blood or blood products or been given a medicine called () in the past 6 months? | Yes No | |
| any questions about today's vaccination? | Yes No | |

Signature or Name and Seal of Doctor: _____

For the Parent/Guardian

I fully understand all of the above, including the benefits, aim and side effects of vaccination (especially the risk and management of intussusception), having consulted with the doctor and having read the explanatory document. I (do / do not) agree to have the child vaccinated, taking into consideration past illnesses and present condition. * Please circle your choice.

Signature of Parent / Guardian: _____

| Vaccine Name | Dosage | Institution / Doctor's Name / Date Administered |
|--|--|--|
| Vaccine Name: Live Attenuated Human Rotavirus Vaccine, Oral Manufacturer: GlaxoSmithKline K.K. Lot Number: _____ | Oral administration at a specified dose of 1.5 mL. | Institution: _____ Doctor's Name: _____ Date Administered: / / (d/m/y) |

This screening questionnaire is intended to ensure vaccination safety. Personal information is used only for the preliminary examination for immunization.

販売提携(資料請求先)

ジャパンワクチン株式会社
東京都千代田区四番町6
【製品に関するお問い合わせ・資料請求先】 ジャパンワクチン株式会社 お客様相談室
Tel: 0120-289-373 (平日9:00~17:30 土、日、祝祭、当社休日除く)

販売元

第一三共株式会社
Daichi-Sankyo
東京都中央区日本橋本町3-5-1

製造販売元(輸入)

グラクソ・スミスクライン株式会社
東京都渋谷区千駄ヶ谷4-6-15

Explanation before Rotarix[®] Vaccination for Rotavirus Gastroenteritis

For the parents/guardians:

Please be sure to read
this document.

1 About Rotavirus Gastroenteritis

- Rotavirus gastroenteritis is a common viral gastroenteritis in children. Rotavirus, the cause of rotavirus gastroenteritis, is ubiquitous; regardless of hygiene, the infection is found worldwide.
- The illness often begins with explosive vomiting and leads to whitish watery diarrhoea. It can be accompanied by fever and such symptoms may last one week. Most patients are cared for at home and recover, but some children become dehydrated due to severe vomiting and diarrhoea. In more serious cases, the illness may lead to kidney failure, brain inflammation or encephalopathy. Hospitalisation is required for patients with severe cases.
- In Japan, rotavirus gastroenteritis peaks from the late winter to spring. The incidence of clinical illness peaks among children aged 3-24 months - the highest peak is at 7-15 months. Until the age of three months, infants are protected by maternal immunity and thus, if infected, the illness will be asymptomatic or only mild. However, the first infection after the age of three months is usually the most severe. In fact, rotavirus infection is the most common causes of severe acute gastroenteritis in infants and young children, and there is a report that one in ten children requiring an outpatient visit will ultimately require an inpatient visit.
- Children can be protected from severe rotavirus gastroenteritis by vaccination.

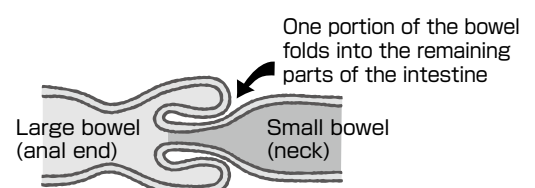
2 Indications for Rotarix[®]

- Rotarix[®] is a live, oral vaccine indicated for the prevention of rotavirus gastroenteritis (For oral use only. Not for injection).
- Rotarix[®] was developed by the attenuation of a common human rotavirus strain in cell culture, reducing pathogenicity and is made as a syrupy liquid agent.
- Five major rotavirus strains, G1, G2, G3, G4, and G9, are responsible for most of the rotavirus gastroenteritis episodes worldwide. Rotarix[®] is based on the G1 type, the most common human strain.
- The vaccine mimics natural infection and typically provides effective protection against the other four main strains.

3 The following infants should not receive vaccination:

- Infants with fever (temperature higher than 37.5°C).
- Those with severe acute diseases (Postpone when there is symptoms of diarrhea and vomiting).
- Those with a history of hypersensitivity to Rotarix[®].
- Untreated infants with congenital gastrointestinal tract disorder that may increase the risk of intussusception* (such as Meckel's diverticulum).
- Those with a history of intussusception.
- Infants with severe combined immunodeficiency (SCID).
- Infants under all other inappropriate conditions for vaccination.

*Intussusception (IS): A condition occurring when one portion of the bowel folds into the remaining parts of the intestine that should be treated urgently. Regardless of vaccination, this condition is often observed in children less than 1 year old. IS causes a blockage of the intestine and the blood supply, which can lead to the death of intestinal tissues (necrosis). If IS is observed, the obstruction is typically cleared by flushing fluid, such as contrast agents and water, or air through the intestine from the anus. However, the more time passes from the start of the symptoms (e.g. 12 hours or longer), the higher the possibility that surgery will become necessary to remove the necrotized tissue.



4 Consult a physician before vaccinating the following infants:

- Infants with underlying diseases such as cardiovascular/kidney/liver/blood diseases and development disorder.
- Those with a history of fever within 2 days after vaccination, or those with symptoms such as systemic exanthema, suggesting allergy.

- Those with a history of convulsion.
- Those with diseases associated with the abnormal immune function, those receiving immunosuppressive therapy, and those with a family history of congenital immunodeficiency (Vaccination in those immunocompromised may lead to viral proliferation and development of infection).
- Those with gastrointestinal disorder.

5 Dosage and Administration of Rotarix®

- Rotarix® is an oral, sweetened syrupy liquid vaccine.
- The vaccine is administered by directly inserting a tube with 1.5 ml dose into the mouth of the child*.
- The first dose should be administered to infants beginning at 6 weeks of age (it is recommended that the maximum age for the first dose is 14 weeks and 6 days). The 2-dose series should be completed by 24 weeks of age.
- There should be an interval of at least 27 days (4 weeks) between the first and second dose.

*Refrain from breastfeeding immediately prior (approximately 30 minutes) to vaccination with Rotarix®.

6 Efficacy of Rotarix®

- Rotarix® mimics natural infection and provides effective protection against rotavirus gastroenteritis after two doses. Clinical trials have demonstrated efficacy against gastroenteritis caused by strains other than one contained in Rotarix®.
- An overseas clinical trial showed that the vaccine's efficacy lasts at least three years.
- Protection against gastroenteritis caused by any organisms other than rotavirus is unknown. As with other vaccines, Rotarix® does not work for all infants.

7 Adverse reactions of Rotarix®

- Reported main adverse reactions within 30 days after administration from a clinical trial conducted in Japan were irritability (7.3%), diarrhoea (3.5%), cough/runny nose (3.3%). Other adverse reactions such as fever, anorexia, vomiting were also reported.
- Some overseas clinical trials reported irritability, diarrhoea (1 - below 10%), aerenterectasia (distended bowel) abdominal pains, and dermatitis (0.1 - below 1%). Overseas post-marketing surveys reported intussusception, bloody stool, and viral shedding from patients with severe combined immunodeficiency disease (SCID).
- **Relief System for Sufferers from Adverse Reactions to Vaccination**

Despite proper use of Rotarix®, if an adverse reaction occurs that causes disease that requires hospitalisation, or if disorders occur, you will be provided assistance under the Relief System for Sufferers from Adverse Drug Reactions.

Depending on the severity of injury, fees for medical treatment, medical allowances, disability pension, survivor pension, lump-sum benefit for a bereaved family, will be paid after Food and Pharmaceutical Council deliberation. If your child shows any signs of distress or suspect symptoms, immediately seek medical attention.

8 Post-Vaccination Warnings

- As severe allergic symptoms may occur, please rest your child for at least 30 minutes after vaccination without returning home.
- On the day of vaccination, prevent the child from excessive activities.
- Monitor the child's health status and look carefully for any changes. If any abnormalities such as high fever or seizures appear, visit a doctor immediately.
- If symptoms of intussusception (IS) appear, including repetitive cycles of crying and crankiness, repeated vomiting, weakness and pale complexion, and bloody stools, visit a doctor immediately. In post-marketing surveys conducted in Japan and overseas, the possibility of a slight increase in the risk of developing IS was reported after rotavirus vaccinations. Therefore, attention should be paid to the appearance of symptoms of IS after vaccination (especially the week after the vaccination), regardless of the number of vaccinations administered.

Even if you visit another medical institution due to symptoms of IS, please inform the medical institution that administered Rotarix®.

- Approximately one week after vaccination, shedding of vaccine virus in stools will occur, but the excreted virus is unlikely to cause gastroenteritis. However, for safety's sake, always wash your hands after contacting with children who have been vaccinated, e.g. after changing nappies. In particular, if you have a family with dysfunction of immune system, do wash your hands after contacting children who have been vaccinated.
- Rotavirus vaccine series should be completed with the same product. Safety and effectiveness have not been evaluated when Rotarix® is administered as the first dose and another rotavirus vaccine is administered as the second dose, or vice versa.

| | |
|---|---------------------|
| Planned Date of Vaccination: | Institution/Clinic: |
| / / (d/m/y) | Doctor's Name: |
| Time Administered ____ : ____ (a.m./p.m.) | |

Rotarix® (Rotavirus Vaccine, Live, Oral) Screening Questionnaire

Please fill out the parts surrounded by thick solid lines, or enclose with ○ .

| | | | | | |
|------------------------|-----|------------------------------------|------------|---------------------|--|
| | | Body Temperature before interview | | Degrees (°C) | |
| Times | 1st | 2nd [Previous Time: / / / (d/m/y)] | | | |
| Address | 〒 | | TEL | () - | |
| Child's Name | () | M F | Birth Date | Born on / / (d/m/y) | |
| Parent/Guardian's Name | | | | Age (weeks days) | |

| Vaccination Questionnaire | Answer | | Doctor's Comment |
|--|--------|----|------------------|
| Have you read the document (For the Parents/Guardians of a Child for Vaccination) explaining Rotarix® that will be administered today? | Yes | No | |
| Please answer the following questions about the child. Weight at birth (g) | | | |
| Did the child have any abnormal findings at delivery? | Yes | No | |
| Did the child have any abnormal findings after birth? | Yes | No | |
| Was any abnormality identified at an infant health check? | Yes | No | |
| Is the child sick today? If so, describe the nature of the illness. (Details:) | Yes | No | |
| Does the child have diarrhoea today? | Yes | No | |
| Has the child been ill within the last month? (When: / ~ /) (Disease Name:) | Yes | No | |
| Has any family member or neighbor of the child had a disease such as measles, rubella, chickenpox or mumps within the last month? (Disease Name:) | Yes | No | |
| Has the child been vaccinated within the last month? (When: / ~ /) (Vaccine Name:) | Yes | No | |
| Does the child have a congenital anomaly, heart, kidney, liver, digestive system, central nerve disease, immune deficiency, or any other diseases for which you have consulted a doctor? (Disease Name:) | Yes | No | |
| Where relevant, did the doctor who manages the above disease agree with today's vaccination? | Yes | No | |
| Has the child repeatedly had an obvious fever, diarrhoea or other symptoms such as white spots on the tongue inside the cheeks, or a prolonged recovery from illness? | Yes | No | |
| Has the child ever had a seizure (spasm or fit) in the past? (When: /) If you answered "yes" to the preceding question, did the child have a fever at that time? (Yes / No) | Yes | No | |
| Has the child ever had a rash or urticaria as a reaction to medications or food or become ill after eating certain foods or receiving certain medications? (Medicine Name:) (Food Name:) | Yes | No | |
| Does the child have a family member or relative with a congenital immunodeficiency? | Yes | No | |
| Has the child had a serious reaction to a vaccine in the past? (Vaccine Name:) | Yes | No | |
| Has any family member or relative of the child had a serious reaction to a vaccine in the past? | Yes | No | |
| Has the child received a transfusion of blood or blood products or been given a medicine called gamma globulin in the past 6 months? | Yes | No | |
| Do you have any questions about today's vaccination? | Yes | No | |

| |
|---|
| <p>Doctor's Comment</p> <p>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 the information regarding the benefits and side effects of vaccination (especially the risk and management of intussusception) and the support provided to people who experience adverse events associated with the vaccination to the parents/legal guardians.</p> <p style="text-align: right;">Signature or Name and Seal of Doctor: _____</p> |
|---|

| |
|---|
| <p>For the Parent/Guardian</p> <p>I fully understand all of the above, including the benefits, aim and side effects of vaccination (especially the risk and management of intussusception), having consulted with the doctor and having read the explanatory document. I (do / do not)* agree to have the child vaccinated, taking into consideration past illnesses and present condition. * Please circle your choice.</p> <p style="text-align: right;">Signature of Parent / Guardian: _____</p> |
|---|

| Vaccine Name | Dosage | Institution / Doctor's Name / Date Administered |
|--|---|--|
| Vaccine Name: Live Attenuated Human Rotavirus Vaccine, Oral Manufacturer: GlaxoSmithKline K.K. Lot Number: | Oral administration at a specified dose of 1.5 mL | Institution: Doctor's Name: Date Administered: / / (d/m/y) |

This screening questionnaire is intended to ensure vaccination safety. Personal information is used only for the preliminary examination for immunization.