

On protective immunization against gastroenteritis (rotaviruses) of infants and small children

Rotaviruses are worldwide in distribution and the most common cause of diarrhea (gastroenteritis) in infancy and early childhood. The viruses reproduce in the patients' small intestine and are excreted in large quantities with the stool. Rotaviruses are highly contagious. They are transmitted chiefly by contact and smear infection, less often through food and water. It only takes a few pathogens to cause an infection.

Because the viruses are very stable in the environment, it is almost impossible to prevent a rotavirus infection in small children through hygienic measures alone. Hence a large percentage of children succumb to violent rotavirus diarrhea during their early years, often repeatedly.

Very young children in particular can have severe symptoms. The main symptoms are watery diarrhea (often as much as 20 times a day), vomiting, and fever, usually associated with abdominal pain. The symptoms usually persist for 2 to 6 days. Dehydration frequently occurs due to the severe diarrhea and can be life-threatening in small patients. As a rule it requires treatment in a hospital setting. Fatal outcomes are rare in Germany, but nearly every day a child dies from rotavirus-induced gastroenteritis somewhere in the European Union.

Vaccine

Rotavirus vaccines contain weakened live viruses. There are different vaccines and high efficacy against rotavirus infections has been demonstrated for both. Depending on the vaccine, the vaccination is given by mouth (oral administration) to the child being immunized 2 or 3 times at intervals of at least 4 weeks in each case. Your doctor can tell you about the beginning and duration of the immune protection. Booster vaccinations after the basic immunization has been completed are not recommended.

Who should get vaccinated and when?

The Standing Committee on Immunization (STIKO) has been recommending that all infants in Germany be immunized against rotaviruses since July of 2013. The rotavirus oral vaccination is recommended from an age of 6 weeks and should be started as soon as possible after this point in time, by 12 weeks of age at the latest. It is strongly recommended that the vaccination series be completed at the age of 24 to 32 weeks (depending on the vaccine).

The vaccination can be administered simultaneously with a multiple vaccination recommended for this age group against diphtheria, whooping cough, tetanus, polio, hepatitis B, and Hib infection (5- or 6-valent vaccines). The pneumococcal conjugate vaccine recommended for infants can be administered simultaneously.

Who should not get vaccinated?

Persons suffering from an acute disease with a fever requiring treatment should not be vaccinated. As a rule, children with an immune deficiency disease (congenital, acquired, medication-induced) should also not be vaccinated. Infants with a history of intestinal obstruction (ileus) and children with congenital malformations of the digestive tract should not be vaccinated. The vaccination should be postponed in infants who are currently suffering from diarrhea and/or vomiting.

Behavior after the vaccination

The vaccine recipient does not need any special care. The vaccination can be administered regardless of the consumption of food, beverages, or breast milk.

In isolated cases the vaccine viruses can be transmitted to unprotected contact persons. Although healthy contact persons do not get sick as a rule, as a precaution people with weakened immune systems (e.g., cancer patients, patients under immunosuppressant therapy) should avoid contact with a freshly vaccinated infant for ca. 14 days.

Persons caring for recently vaccinated infants should practice meticulous hygiene while changing diapers. There are no risks associated with the immunization of a child, not even for a pregnant woman living in the vicinity.

Possible general post-vaccinal reactions

After the vaccination, fever, diarrhea, vomiting, appetite loss, and other gastrointestinal complaints occur frequently to very frequently (in up to 10% or more of the vaccine recipients) as an expression of the body's normal reaction to the vaccine. Acute respiratory tract symptoms occur occasionally to frequently (0.1 to 1% and 1 to 10%, respectively), whereas inflammation of the middle ear (otitis media) occurs only in isolated cases. Irritability is very common, whereas crying, sleep disorders, fatigue, and drowsiness are reported occasionally. A skin rash will occasionally occur after immunization with rotavirus oral vaccine.

As a rule these events are of a temporary nature and subside quickly with no further consequences. They do not occur any more frequently after the 2nd vaccine dose than after the first one. A serious progression has been reported in rare cases; in the studies the symptoms described above were observed with more or less equal frequency in the vaccinated children and the children in the control group, who did not receive the vaccination.

Are post-vaccinal complications possible?

Post-vaccinal complications are very rare consequences of immunization that exceed the normal extent of a post-vaccinal reaction. They have significant adverse impacts the health of the vaccine recipient. A slightly higher risk of an intestinal obstruction occurring within 31 days, mainly within 7 days after administration of the 1st dose of the rotavirus vaccine (and also after the 2nd dose in exceptional cases) cannot be ruled out. Severe abdominal pain, persistent vomiting, bloody stool, a bloated stomach and/or high fever are symptoms that may indicate an intestinal obstruction. Should such symptoms occur during the aforementioned period, promptly inform the doctor accordingly. Hypersensitivity reactions (for example on the skin (hives)) or bronchial muscle spasms have been reported on rare occasions. Other complications with the currently approved modern rotavirus vaccines have not been reported thus far.

Advice on possible side effects by the vaccinator

As a supplement to this information leaflet, your doctor will propose an information discussion.

The vaccinator is also at your disposal for advice should you experience any symptoms more severe than the rapidly subsiding local and general reactions mentioned above.

You can contact the vaccinator at:

Disclaimer

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Name _____

Name

Protective immunization against rotavirus diseases*Schutzimpfung gegen Rotavirus-Erkrankungen*

Enclosed is an information leaflet on the administration of the vaccination against rotavirus diseases. It contains the essential details on the disease that can be prevented by the vaccination, the vaccine, the vaccination, behavior after the vaccination, and on post-vaccinal reactions and possible post-vaccinal complications.

Anliegend erhalten Sie ein Merkblatt über die Durchführung der Schutzimpfung gegen Rotavirus-Erkrankungen. Darin sind die wesentlichen Angaben über die durch die Impfung vermeidbare Krankheit, den Impfstoff, die Impfung, das Verhalten nach der Impfung sowie über Impfreaktionen und mögliche Impfkomplicationen enthalten.

Before the vaccination is administered, the following additional details are requested:

Vor der Durchführung der Impfung wird zusätzlich um folgende Angaben gebeten:

1. Does the vaccine recipient have an immune deficiency disease (acquired, congenital, medication-induced)?

Besteht bei dem Impfling eine Immundefizienzkrankheit (erworben, angeboren, durch Medikamente bedingt)?

Yes (*Ja*)

No (*Nein*)

2. In the past 6 weeks, did the vaccine recipient receive immunoglobulin (gamma globulin) or a blood transfusion?

Hat der Impfling in den vergangenen 6 Wochen Immunglobulin (Gammaglobulin) erhalten oder wurde eine Bluttransfusion vorgenommen?

Yes (*Ja*)

No (*Nein*)

3. Has the vaccine recipient had an intestinal obstruction (ileus) in the past?

Hatte der Impfling in der Vergangenheit einen Darmverschluss?

Yes (*Ja*)

No (*Nein*)

4. Is the vaccine recipient currently suffering from diarrhea and/or vomiting?

Leidet der Impfling zurzeit unter Durchfall und/oder Erbrechen?

Yes (*Ja*)

No (*Nein*)

Ask the vaccinator if you wish to know more about protective immunization against rotavirus diseases!

Falls Sie noch mehr über die Schutzimpfung gegen Rotavirus-Erkrankungen wissen wollen, fragen Sie den Impfarzt!

Please bring your immunization record with you when you come for the vaccination appointment!

Zum Impftermin bringen Sie bitte das Impfbuch mit!

Declaration of consent*Einverständniserklärung***to protective immunization against infectious gastroenteritis (rotaviruses) in infants and small children***zur Durchführung der Schutzimpfung gegen infektiöse Durchfallerkrankung der Säuglinge und Kleinkinder (Rotaviren)*Name of the vaccine recipient _____
*Name des Impflings*D.O.B. _____
geb. am

I have read and understood the contents of the information leaflet and was informed in detail about the vaccination in the discussion with my doctor.

Ich habe den Inhalt des Merkblatts zur Kenntnis genommen und bin von meinem Arzt/meiner Ärztin im Gespräch ausführlich über die Impfung aufgeklärt worden. I have no further questions.*Ich habe keine weiteren Fragen.* I consent to the proposed vaccination against rotavirus diseases.*Ich willige in die vorgeschlagene Impfung gegen Rotavirus-Erkrankungen ein.* I do not wish to be vaccinated. I was informed of the possible disadvantages of not getting vaccinated.*Ich lehne die Impfung ab. Über mögliche Nachteile der Ablehnung dieser Impfung wurde ich informiert.*Comments _____
*Vermerke*Place, Date _____
*Ort, Datum*_____
Vaccine recipient's
or guardian's signature
*Unterschrift des Impflings bzw. des Sorgeberechtigten*_____
Doctor's signature
Unterschrift des Arztes/der Ärztin