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**EPAR summary for the public**

# RotaTeq

rotavirus vaccine, live, oral

This document is a summary of the European public assessment report (EPAR) for RotaTeq. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for RotaTeq.

## What is RotaTeq?

RotaTeq is a vaccine that is taken by mouth. It is available as a solution in a single-dose tube. It contains five live rotavirus strains, each carrying a different antigen (G1, G2, G3, G4 and P1[8]).

## What is RotaTeq used for?

RotaTeq is used in babies from six to 26 weeks of age to protect against gastroenteritis (diarrhoea and vomiting) caused by rotavirus infections. RotaTeq is given according to official recommendations.

The vaccine can only be obtained with a prescription.

## How is RotaTeq used?

RotaTeq is given as three doses, with at least four weeks between each dose. The contents of the tube of RotaTeq are given directly into the baby's mouth. The first dose is given when the baby is between six and 12 weeks of age. It is recommended that the last dose be given before the child is aged 20 to 22 weeks, and in any case, all three doses should be given by the time the child is 26 weeks (six months) old. RotaTeq can be given at the same time as other vaccinations (except the oral polio vaccine, when a two-week interval is needed between the two vaccines).

RotaTeq can be given to premature babies, as long as the pregnancy lasted at least 25 weeks. The first dose should be given six weeks after birth at the earliest.

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## How does RotaTeq work?

There are various types of rotaviruses that cause gastroenteritis. They vary in that they may carry different antigens. An antigen is a specific structure that the body can recognise as ‘foreign’ and against which the body can make an antibody, a special protein that can neutralise or destroy the antigen. RotaTeq contains viruses that carry the antigens for some of the most commonly occurring types of rotaviruses. When a baby is given the vaccine, the immune system (the system that fights diseases) makes antibodies against these antigens, which help prevent infections caused by rotaviruses that occur naturally and carry the same or very similar antigens.

## How has RotaTeq been studied?

Overall, the studies of RotaTeq involved over 72,000 babies aged six to 12 weeks, including about 2,000 premature babies. About half of the babies received RotaTeq, and the others received placebo (a dummy vaccine). The main study was very large (over 70,000 babies) because it was designed to see if the vaccine caused a very rare, serious side effect called intussusception, a condition in which part of the bowel becomes enfolded within another part of the bowel, leading to a blockage. The main measure of effectiveness, which was studied in 6,000 babies, was the number of babies who developed rotavirus gastroenteritis during the following rotavirus season (the time of the year when rotaviruses are known to circulate and cause infection, generally during the cooler months in winter to early spring).

## What benefit has RotaTeq shown during the studies?

The number of cases of rotavirus gastroenteritis due to viruses with the same antigens as in the vaccine decreased following vaccination with RotaTeq. Among the almost 6,000 babies in whom the main measure of effectiveness was studied, 82 of the babies vaccinated with RotaTeq developed rotavirus gastroenteritis (one with severe gastroenteritis) compared with 315 of the babies who received placebo (51 severe cases). The study also showed that there were fewer hospital admissions or visits to emergency clinics for rotavirus gastroenteritis in babies vaccinated with RotaTeq.

## What is the risk associated with RotaTeq?

The most common side effects with RotaTeq (seen in more than 1 patient in 10) are pyrexia (fever), diarrhoea and vomiting. For the full list of all side effects reported with RotaTeq, see the package leaflet.

RotaTeq should not be used in babies who may be hypersensitive (allergic) to the active substance or any of the other ingredients, or who showed signs of allergy after receiving a dose of RotaTeq or another vaccine against rotavirus in the past. RotaTeq must not be given to babies who have had intussusception in the past or who have problems with their bowel that could put them at risk of intussusception. It must also not be used in babies whose immune system is weakened. For the full list of restrictions, see the package leaflet.

RotaTeq should never be injected under any circumstances.

## Why has RotaTeq been approved?

The CHMP decided that RotaTeq’s benefits are greater than its risks and recommended that it be given marketing authorisation.

## Other information about RotaTeq:

The European Commission granted a marketing authorisation valid throughout the European Union for RotaTeq to Sanofi Pasteur MSD, SNC, on 27 June 2006. The marketing authorisation is valid for an unlimited period.

The full EPAR for RotaTeq can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with RotaTeq, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 05-2011.