



EUROPEAN MEDICINES AGENCY  
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## **EPAR summary for the public**

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# Rotarix

rotavirus vaccine, live

This document is a summary of the European Public Assessment Report (EPAR) for Rotarix. 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 Rotarix.

## **What is Rotarix?**

Rotarix is a vaccine that is given by mouth. It is available in three forms:

- a powder and solvent that are made up into an oral suspension in an oral applicator;
- an oral suspension in a prefilled oral applicator;
- an oral suspension in a squeezable tube.

Rotarix contains a live attenuated (weakened) form of the human rotavirus (RIX4414 strain).

## **What is Rotarix used for?**

Rotarix is used in babies aged from 6 to 24 weeks to protect against gastroenteritis (diarrhoea and vomiting) caused by rotavirus infections. Rotarix is given according to official recommendations.

The vaccine can only be obtained with a prescription.

## **How is Rotarix used?**

Rotarix is given as two doses, at least four weeks apart. The first dose is given when the baby is older than six weeks. Ideally, both doses should be given before the baby is aged 16 weeks and they must be given by the time the baby is 24 weeks old. The same vaccination course can be used in babies born up to 13 weeks prematurely (from 27 weeks gestational age).



If the powder and solvent are used, they should be mixed together just before the vaccine is given, and the resulting suspension given directly into the mouth of the baby using the oral applicator provided. If the ready-made oral suspension is used, the contents of the prefilled oral applicator or tube should be given into the mouth of the baby. Rotarix can be given at the same time as other vaccines.

### **How does Rotarix work?**

Rotarix contains small amounts of rotavirus, a virus that causes gastroenteritis. The virus is alive, but it has been weakened so that it does not cause the disease, which makes it suitable for use in a vaccine. When an infant is given the vaccine, the immune system (the system that fights diseases) recognises the weakened virus as 'foreign' and makes defences against it. After vaccination, the immune system is able to respond more quickly when it is exposed to the virus again. This helps to protect against gastroenteritis caused by rotavirus.

### **How has Rotarix been studied?**

Overall, the clinical studies of Rotarix involved over 75,000 babies and took place in various countries worldwide. The main study compared Rotarix with placebo (a dummy vaccine) in over 63,000 babies who were born at full term (after a pregnancy of at least 36 weeks). The benefit of the vaccine was measured by looking at how many babies developed severe rotavirus gastroenteritis in the months after they had been vaccinated and before they had reached one year of age.

A further study looked at the safety of Rotarix and its ability to stimulate the production of antibodies in 1,009 babies born up to 13 weeks prematurely. These results were compared with the findings of a study in babies born at full term who were vaccinated with Rotarix.

Four additional studies were carried out in over 3,000 infants, to confirm that the ready-for-use forms of the vaccine were as safe and as effective as the powder and solvent formulation in stimulating the production of antibodies against rotavirus.

### **What benefit has Rotarix shown during the studies?**

Rotarix was more effective than placebo in preventing severe gastroenteritis due to rotavirus. In the main study, the number of cases of severe rotavirus gastroenteritis was lower following vaccination with Rotarix: 0.1% of the babies vaccinated with Rotarix in whom effectiveness was assessed developed severe rotavirus gastroenteritis (12 out of over 9,000) compared with 0.9% of the babies who received placebo (77 out of almost 9,000).

The study in premature babies showed that Rotarix was well tolerated and produced similar levels of antibodies as in infants born at full term.

### **What is the risk associated with Rotarix?**

The most common side effects with Rotarix (seen in between 1 and 10 patients in 100) are diarrhoea and irritability. Very rarely (seen in less than 1 patient in 10,000), a serious condition called intussusception (in which part of the bowel becomes enfolded within another part of the bowel, leading to a blockage) has been reported after the use of rotavirus vaccines. For the full list of all side effects reported with Rotarix, see the package leaflet.

Rotarix must not be used in babies who are hypersensitive (allergic) to any of the ingredients of the vaccine or those who showed signs of allergy after receiving a dose of rotavirus vaccine in the past. It must also not be given to patients who have disorders that cause severe abnormalities of the immune system called 'severe combined immunodeficiency', who have had intussusception in the past, or who have problems with their bowel that could put them at risk of intussusception. Vaccination with Rotarix should be postponed in babies who have a sudden high fever, diarrhoea or vomiting.

Rotarix should never be injected under any circumstances.

### **Why has Rotarix been approved?**

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

### **What measures are being taken to ensure the safe and effective use of Rotarix?**

A risk management plan has been developed to ensure that Rotarix is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Rotarix, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that markets Rotarix is developing a vaccine free of porcine circovirus type 1 (PCV-1) after a very small amount of viral particles was found in the vaccine in 2010. PCV-1 is not known to cause any disease.

### **Other information about Rotarix:**

The European Commission granted a marketing authorisation valid throughout the European Union for Rotarix on 21 February 2006.

The full EPAR for Rotarix can be found on the Agency's website: [ema.europa.eu/Find\\_medicine/Human\\_medicines/European\\_Public\\_Assessment\\_Reports](http://ema.europa.eu/Find_medicine/Human_medicines/European_Public_Assessment_Reports). For more information about treatment with Rotarix, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2016.