

Summary of risk management plan for RotaTeq™ (rotavirus vaccine, live, oral, pentavalent)

This is a summary of the risk management plan (RMP) for RotaTeq™. The RMP details important risks of RotaTeq™, and how more information will be obtained about RotaTeq™'s risks and uncertainties (missing information).

RotaTeq™'s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how RotaTeq™ should be used.

This summary of the RMP for RotaTeq™ should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of RotaTeq™'s RMP.

I. The Medicine and What it is Used for

RotaTeq™ is authorised for active immunisation of infants from the age of 6 weeks to 32 weeks for prevention of gastroenteritis due to rotavirus infection (see SmPC for the full indication). It contains Rotavirus vaccine (live) as the active substance in a 2 ml oral solution in a tube and is for oral administration only.

Further information about the evaluation of RotaTeq™'s benefits can be found in RotaTeq™'s EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage [https://www.ema.europa.eu/en/documents/overview/rotateq-epar-summary-public_en.pdf]

II. Risks Associated With the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of RotaTeq™, together with measures to minimise such risks and the proposed studies for learning more about RotaTeq™'s risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;

- The medicine’s legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of Important Risks and Missing Information

Important risks of RotaTeq™ are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of RotaTeq™. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

Table II.A.1: List of Important Risks and Missing Information

List of Important Risks and Missing Information*	
Important identified risks	None
Important potential risks	None
Missing information	None
* The important identified or potential risks included in prior versions of the RMP have been removed based the review of accumulating clinical data and the guidance in GVP module 5 (Rev 2), as per routine updates of the RMP during the life cycle of the product.	

II.B Summary of Important Risks

The safety information in the Prescribing Information is aligned to the reference medicinal product. There are no identified risks, potential risks, or missing information in this RMP.

II.C Post-Authorisation Development Plan

II.C.1 Studies Which are Conditions of the Marketing Authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of RotaTeq™.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for RotaTeq™.