



California  
Department of  
Health Services

**SANDRA SHEWRY**  
Director

State of California—Health and Human Services Agency  
**Department of Health Services**

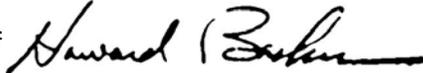


Governor

June 15, 2006

IZB-FY0506-20

TO: California Vaccines for Children (VFC) Program Providers

FROM: Howard Backer, M.D., M.P.H., Chief Immunization Branch 

SUBJECT: PENTAVALENT, BOVINE-HUMAN REASSORTANT ROTAVIRUS VACCINE (RV) IS NOW AVAILABLE FROM VFC

This memo is divided into sections to enable you to quickly access the information you need:

<b>Section</b>	<b>Page(s)</b>
Summary	1
Background and Composition	2
Recommendations for Vaccine Use	2-3
How Supplied	3
Ordering and Billing	3-4
Potential Vaccine Reactions	4
Contraindications	4
Precautions	4-5
Special Situations	5
Documentation	5-6

## **SUMMARY**

In February 2006, United States Food and Drug Administration (FDA) licensed a new, live rotavirus vaccine, RotaTeq™ (Merck & Co., Inc.), for use in infants. The Advisory Committee on Immunization Practices (ACIP) voted at their February 2006 meeting to recommend the routine use of the new rotavirus vaccine as a three dose series in infants six weeks to 32 weeks of age. The new rotavirus vaccine is now available from VFC. This letter summarizes information about use of RotaTeq™ in the VFC program. The Immunization Branch is following ACIP's provisional recommendations for RV. When available, ACIP's final recommendations will be provided as well as any updated vaccine information.

## **BACKGROUND AND COMPOSITION**

Rotavirus infection is the leading cause of severe diarrhea in infants and young children. Most rotavirus infections occur in children younger than five years old. The most severe cases occur among infants and young children between six months and 24 months of age. In the United States, rotavirus disease occurs in annual winter epidemics and causes about 20-60 deaths, >50,000 hospitalizations, >550,000 emergency department or outpatient visits, and leads to approximately one billion dollars of health care and lost productivity costs each year.

In 1998, a previous rotavirus vaccine, Rotashield™, was licensed by the FDA in the United States. However, it was removed from the market in 1999 because of its association with intussusception. Consequently, the new rotavirus vaccine, RotaTeq™, was evaluated in a very large scale, placebo-controlled trial of over 70,000 children who were monitored for intussusception and other complications. In this study, the vaccine was not associated with an increased risk of intussusception when compared to placebo. Safety of this vaccine will continue to be closely monitored in additional studies conducted after licensure.

RotaTeq™ is a live, oral, pentavalent, bovine-human reassortant rotavirus vaccine (RV). Each of the five reassortant viruses in the vaccine contains a mix or “reassortant” of strains that infect humans and cows.

In studies of the vaccine, efficacy of RV against rotavirus gastroenteritis was 74 percent, and efficacy against severe rotavirus gastroenteritis was 98 percent. In addition, RV reduced hospitalizations for rotavirus gastroenteritis by 96 percent.

Additional rotavirus vaccines may be licensed in the future.

## **RECOMMENDATIONS FOR VACCINE USE**

### **Eligible Groups for receipt of VFC Supplies of RV**

VFC supplies of RV may be given to VFC eligible infants aged six weeks through 32 weeks.

### **Dosing Schedule and Administration**

RV is recommended for routine immunization to be given as a three dose series administered orally at two months, four months and six months of age. The first dose should be given between six and 12 weeks of age. The last dose of RV should be administered by 32 weeks of age. There should be a four to ten week interval between doses. Preterm infants should receive the vaccine according to their age in weeks since birth (see SPECIAL SITUATIONS for further information).

The vaccine is provided in ready to use, plastic, latex free liquid tubes; RV should not be mixed with other vaccines or solutions. RV should be administered as soon as possible after being removed from refrigeration.

To administer RV:

- Tear open the RV pouch and remove the dosing tube.
- Clear any vaccine from the dispensing tip by holding the tube vertically and tapping the cap.
- Puncture the dispensing tip by screwing the cap clockwise until it becomes tight then remove the cap by turning it counterclockwise.
- Administer the dose by gently squeezing the vaccine into the infant's mouth toward the inner cheek until the dosing tube is empty.

The used dosing tube and cap are considered biowaste because RV is a live virus vaccine. They should be disposed of appropriately in hard sided biowaste containers.

Readministration of any RV dose to an infant who regurgitates, spits out, or vomits during or after administration of vaccine is not recommended. The infant should receive the remaining doses of RV at appropriate intervals.

### **Administration with other vaccines**

Rotavirus vaccine may be given at the same visit as other childhood vaccines, including Hib, IPV, hepatitis B, pneumococcal conjugate vaccines, and DTaP. RV has been shown to be safe and effective in trials when given together with routine vaccines during infancy.

### **HOW SUPPLIED:**

RotaTeq™ (RV):

- Each 2 mL dose is supplied as a suspension in a container consisting of a squeezable plastic, latex free dosing tube with a twist-off cap, allowing for direct oral administration.
- The dosing tube is contained in a pouch and supplied as a:
  - Package of ten individually pouched single-dose tubes
- The suspension is a pale yellow clear liquid that may have a pink tint.
- Should be refrigerated at 2°-8°C during transportation and storage.
- Should be protected from light.
- Does not contain thimerosal or other preservatives.

### **ORDERING AND BILLING**

#### **How to order**

VFC Providers may order RV using the attached revised order form (DHS 8501 (6/06)). Remember to complete all the boxes in the four columns of the order form, even if you are ordering only RV. Maintain a copy of your order forms for your office files. Please be aware that your orders of RV may be adjusted, especially during this introductory phase.

#### **Billing Information**

Child Health and Disability Program (CHDP): Claims may be submitted for doses of RV administered on or after June 1, 2006.

- The CHDP administration fee is \$9.00 using CHDP code **75**. However, providers should wait until notified by CHDP to submit claims. CHDP Provider Information Notices can be found at <http://www.dhs.ca.gov/pcfh/cms/onlinearchive/chdppl.htm>.

Other codes for the use of the rotavirus vaccine that is not supplied by VFC:

The CPT code for the rotavirus vaccine is **90680**.

The CPT code for administration of the rotavirus vaccine is:

**90467** when the physician performs face-to-face vaccine counseling associated with the administration and the patient is under eight years old.

The ICD-9-CM code for the rotavirus vaccine is **V04.89**.

## POTENTIAL VACCINE REACTIONS

Serious Adverse Events: During the studies, there was no increase in rates of intussusception and other serious adverse events in infants receiving RV compared to those infants who did not receive RV.

Minor Adverse Events: The following were reported more often in infants who received RV when compared to those who received placebo:

Event	RV recipients	Placebo recipients
Diarrhea	24.1%	21.3%
Vomiting	15.2%	13.6%
Ear Infection	14.5%	13.0%
Runny nose and sore throat	6.9%	5.8%
Wheezing and coughing	1.1%	0.7%

Report suspected reactions to RV or other vaccines to the Vaccine Adverse Events Reporting System (VAERS) at (800) 822-7967 (toll-free) or <http://vaers.hhs.gov>.

## CONTRAINDICATIONS

- History of severe hypersensitivity to any component of the vaccine
- History of serious allergic reaction to a previous dose of vaccine

## PRECAUTIONS

- Previous history of intussusception—CURRENTLY, IT IS RECOMMENDED TO WITHHOLD IMMUNIZATION UNTIL THERE IS FURTHER POST LICENSURE DATA ON SAFETY.
- Altered immunocompetence
  - a) Infants with blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic system.

- b) Infants on immunosuppressive therapy (including high dose systemic corticosteroids).
  - c) Infants with primary and acquired immunodeficiency states, including Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS) or other clinical manifestations of infection with human immunodeficiency viruses; cellular immune deficiencies, and hypogammaglobulinemic and dysgammaglobulinemic states. Infants with indeterminate HIV status who are born to mothers with HIV/AIDS.
  - d) Infants who have received a blood transfusion or blood products, including immunoglobulins, within 42 days.
- Moderate to severe illness, including acute gastroenteritis
  - Preexisting chronic gastrointestinal disease

### SPECIAL SITUATIONS

- **Premature infants (<37 weeks gestation)** can be immunized if all the following apply:
  - a) they are at least six weeks of age,
  - b) are being or have been discharged from the hospital nursery,
  - c) and, are clinically stable.
- **Exposure of Immunocompromised Persons to Vaccinated Infants:** Infants living in households with persons who have or are suspected of having an immunodeficiency disorder or impaired immune status can be vaccinated.
- **Exposure of Pregnant Women to Vaccinated Infants:** Infants in households with pregnant women can be vaccinated.
- **Hospitalization after Vaccination:** If a recently vaccinated child is hospitalized, no precautions other than routine universal precautions need to be taken to prevent the spread of vaccine virus.
- **Breastfed Infants:** RV can be given to breastfed infants.

### DOCUMENTATION

Vaccine Information Statement (VIS) and fact sheet: An interim VIS (4/12/06) that can be used with the rotavirus vaccine can be found at <http://www.cdc.gov/nip/publications/VIS/vis-rotavirus.pdf>. A question and answer sheet on rotavirus disease and the vaccine can be found at: <http://www.cdc.gov/nip/diseases/rota/rota-faqs.htm>.

Product Insert: Refer to the product package insert for RV for additional vaccine information. This may be found at <http://www.fda.gov/cber/label/rotamer020306LB.pdf>.

VFC resolution No. 2/06-2: The VFC resolution on the rotavirus vaccine may be found at: [http://www.cdc.gov/nip/vfc/acip\\_vfc\\_resolutions.htm](http://www.cdc.gov/nip/vfc/acip_vfc_resolutions.htm).

ACIP and AAP recommendations: ACIP recommendations for RV will later be published at <http://www.cdc.gov/mmwr>. The provisional ACIP recommendations may be found at: [http://www.cdc.gov/nip/recs/provisional\\_rec/rotavirus-child.pdf](http://www.cdc.gov/nip/recs/provisional_rec/rotavirus-child.pdf). AAP recommendations and other information about RV will be available to AAP members at <http://www.cispimmunize.org/>.

Vaccine Injury Compensation Program (VICP): Rotavirus vaccine is covered by the federal VICP. Information on the federal VICP and the rotavirus vaccine may be found at: <http://www.hrsa.gov/vaccinecompensation/>.

Enclosures: Order Form (6/06), Interim VIS (4/06)

cc: CDHS Immunization Branch Field Representatives  
Local Health Officers  
Local Health Department Immunization Coordinators  
Local Health Department CHDP Program Directors  
Vanessa Baird, Chief, Medi-Cal Managed Care Division, CDHS  
Marian Dalsey, M.D., Acting Chief, Children Medical Services Branch, CDHS  
Michael Farber, M.D., Chief Medical Officer, Medi-Cal Managed Care, CDHS  
Susann Steinberg, M.D., Chief, Maternal, Child and Adolescent Health/Office of Family Planning Branch, CDHS  
Villita Lewis, Deputy Director, Benefits and Quality Monitoring, MRMIB  
Marcia Ehinger, M.D., Medi-Cal Benefits Branch, CDHS  
Kathy Chance, M.D., Children Medical Services Branch, CDHS

# ROTAVIRUS VACCINE

## WHAT YOU NEED TO KNOW

### 1 What is rotavirus?

Rotavirus is a virus that causes severe diarrhea, mostly in babies and young children. It is often accompanied by vomiting and fever.

Rotavirus is not the only cause of severe diarrhea, but it is one of the most serious. Each year in the United States rotavirus is responsible for:

- more than 400,000 doctor visits
- more than 200,000 emergency room visits
- 55,000 to 70,000 hospitalizations
- 20-60 deaths

Almost all children in the U.S. are infected with rotavirus before their 5th birthday.

Children are most likely to get rotavirus disease between November and May, depending on the part of the country.

Your child can get rotavirus infection by being around other children who are already infected.

### 2 Rotavirus vaccine

Better hygiene and sanitation have not been very good at reducing rotavirus disease. Rotavirus vaccine is the best way to protect children against rotavirus disease.

Rotavirus vaccine is an oral (swallowed) vaccine; it is not given by injection.

Rotavirus vaccine will not prevent diarrhea or vomiting caused by other germs, but it is very good at preventing diarrhea and vomiting caused by rotavirus. About 98% of children who get the vaccine are protected from *severe* rotavirus diarrhea, and about 74% do not get rotavirus diarrhea at all.

Children who get the vaccine are also much less likely to be hospitalized or to see a doctor because of rotavirus infection.



### 3 Who should get rotavirus vaccine and when?

Children should get 3 doses of rotavirus vaccine. They are recommended at these ages:

- First Dose: 2 months of age
- Second Dose: 4 months of age
- Third Dose: 6 months of age

- The first dose should be given between 6 and 12 weeks of age. The vaccine has not been studied when started among children outside that age range.
- Children should have gotten all 3 doses by 32 weeks of age.

Rotavirus vaccine may be given at the same time as other childhood vaccines.

Children who get the vaccine may be fed normally afterward.

### 4 Some children should not get rotavirus vaccine or should wait

- A child who has had a severe (life-threatening) allergic reaction to a dose of rotavirus vaccine should not get another dose. A child who has a severe (life threatening) allergy to any component of rotavirus vaccine should not get the vaccine. Tell your doctor if your child has any severe allergies that you know of.
- Children who are moderately or severely ill at the time the vaccination is scheduled should probably wait until they recover. This includes children who have diarrhea or vomiting. Ask your doctor or nurse. Children with mild illnesses should usually get the vaccine.
- Check with your doctor if your child has any ongoing digestive problems.

- Check with your doctor if your child's immune system is weakened because of:
  - HIV/AIDS, or any other disease that affects the immune system
  - treatment with drugs such as long-term steroids
  - cancer, or cancer treatment with x-rays or drugs
- Check with your doctor if your child recently had a blood transfusion or received any other blood product (such as immune globulin).

In the late 1990s a different type of rotavirus vaccine was used. This vaccine was found to be associated with an uncommon type of bowel obstruction called "intussusception," and was taken off the market.

The new rotavirus vaccine has been tested with more than 70,000 children and has not been associated with intussusception.

However, once a person has had intussusception, from any cause, they are at higher risk for getting it again. So as a precaution, it is suggested that if a child has had intussusception they should not get rotavirus vaccine.

## 5 What are the risks from rotavirus vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of rotavirus vaccine causing serious harm, or death, is extremely small.

Getting rotavirus vaccine is much safer than getting the disease.

### Mild problems

Children are slightly (1-3%) more likely to have mild, temporary diarrhea or vomiting within 7 days after getting a dose of rotavirus vaccine than children who have not gotten the vaccine.

**Moderate or severe reactions** have not been associated with this vaccine.

If rare reactions occur with any new product, they may not be identified until thousands, or millions, of people have used it. Like all vaccines, rotavirus vaccine will continue to be monitored for unusual or severe problems.

Vaccine Information Statement (Interim)		
Rotavirus	IMM-661E	(4/12/06)

## 6 What if there is a moderate or severe reaction?

### What should I look for?

- Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

### What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS web site at [www.vaers.hhs.gov](http://www.vaers.hhs.gov), or by calling **1-800-822-7967**.

*VAERS does not provide medical advice.*

## 7 The National Vaccine Injury Compensation Program

In the rare event that you or your child has a serious reaction to a vaccine, a federal program has been created to help pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call **1-800-338-2382** or visit their website at [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation).

## 8 How can I learn more?

- Ask your doctor or nurse. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)**
  - Visit CDC's National Immunization Program website at: [www.cdc.gov/nip](http://www.cdc.gov/nip)



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**CENTERS FOR DISEASE CONTROL AND PREVENTION**  
 NATIONAL IMMUNIZATION PROGRAM

# VACCINES FOR CHILDREN (VFC) PROGRAM VACCINE ORDER FORM

PIN (6 digit)

COUNTY

NAME OF PHYSICIAN'S OFFICE, PRACTICE, CLINIC, ETC. DATE CHDP MEDI-CAL PROVIDER  
 Yes  No

DELIVERY ADDRESS (Number and Street—No P.O. Boxes)  CHECK HERE IF THIS IS A NEW ADDRESS. CITY ZIP CODE

**DELIVERY:** Please specify all days and times you may receive vaccine.  DAY AND TIME DAY AND TIME DAY AND TIME DAY AND TIME  
 Tue.  Wed.  Thu.  Fri.

CONTACT PERSON TELEPHONE FAX

<b>Vaccines<sup>1</sup></b> Write in the name of the manufacturer you prefer (if any) for DTaP, hepatitis A, hepatitis B, Hib, and Tdap vaccines in the indicated spaces below.	<b>YOU MUST COMPLETE ALL THE BOXES IN THE FOUR COLUMNS BELOW FOR VFC TO PROCESS YOUR ORDER. (EVEN IF YOU ARE ONLY ORDERING ONE VACCINE)</b>			Vaccine Shipped in Vials of the Following Sizes	<b>New Vaccine Order</b> (Minimum 10 doses) Order in multiple of 10 doses
	Number of Doses (VFC Only) Used Since Last Order Enter "0" if None	<b>VACCINE INVENTORY</b>			
	Number of Doses (VFC Only) On-Hand	Lot Number	Expiration Date		

**REGULAR ORDER VFC VACCINES**

<b>DTaP</b> (Preferred Mfr.: _____)				10 x 1 dose vial	doses
<b>DTaP/Hepatitis B/IPV Combination</b>				10 x 1 dose vial	doses
<b>Hepatitis A</b> (Age 12 months–18 years) (Preferred Mfr.: _____)				10 x 1 dose vial	doses
<b>Hepatitis B</b> (Pediatric/Adolescent) (Preferred Mfr.: _____)				10 x 1 dose vial	doses
<b>Hepatitis B/Hib Combination</b>				10 x 1 dose vial	doses
<b>Hib</b> (Preferred Mfr.: _____)				10 x 1 dose vial 5 x 1 dose vial	doses
<b>IPV</b> (Inactivated Polio Vaccine)				10 dose vial	doses
<b>Meningococcal Conjugate</b> (ONLY for adolescents 11–18 years of age)				5 x 1 dose vial	doses
<b>Pneumococcal Conjugate</b>				5 x 1 dose vial	doses
<b>Rotavirus</b> (Live, Oral Vaccine) (ONLY for infants ages 6 - 32 weeks)				10 x 1 dose in 2mL tubes	doses
<b>Td–Preservative Free</b> (Age 7–18 years)				10 x 1 dose syringe no needle	doses
<b>Tdap</b> (Adolescent Td with acellular pertussis [booster] ages 10-18 years) <sup>2</sup> (Preferred Mfr.: _____)				10 x 1 dose vial	doses

**REGULAR VFC VACCINES STORED IN THE FREEZER**

<b>MMR</b> (Combined Measles, Mumps, and Rubella)				10 x 1 dose vial	doses
<b>Varicella</b> (Chickenpox)				10 x 1 dose vials	doses
<b>MMRV</b> (Combined Measles, Mumps, Rubella, and Varicella [Chickenpox] vaccines for children 12 mos to 12 years)				10 x 1 dose vial	doses

**IMPORTANT**  **IF THE SPECIFIC VACCINE MANUFACTURERS I HAVE INDICATED ABOVE ARE NOT AVAILABLE:**  
 Send another manufacturer's vaccine.  Send the manufacturer's vaccine I requested when it is available.

**Notes #1:** Toxoids and vaccines not available through the VFC Program: DT-Pediatric, DTaP-Hib, OPV, tetanus, measles, MR (measles-rubella), mumps, and rubella vaccines, HBIG, and PPD.  
**Notes #2:** Read the package insert to see if the product selected can be given at 10 years of age.

**Instructions:** 1. Please Print or Type.  
 2. Order no more than once every two months (i.e., no more than six times per year). Place your order with sufficient stock on hand to allow at least 30 days for delivery. (It should not take 30 days to deliver vaccine, but this will prevent you from running out of vaccine if there is a delay in filling your order.)  
 3. Fax your order to the VFC Program.  
**Questions:** Toll-free: 877-2Get-VFC (877-243-8832)  
**FAX orders to:** Toll-free: 877-FAXX-VFC (877-329-9832)



**STATE USE ONLY**

ASSIGNED		
APPROVED		
ASSIGNED		
ENTERED		
SHIPPED		