

**OREGON STATE PUBLIC HEALTH DIVISION, DHS  
IMMUNIZATION PROGRAM**

**PENTAVALENT ROTAVIRUS VACCINE (PRV)  
Live Virus Vaccine**

**I. ORDER:**

1. Screen for contraindications.
2. Provide the current Vaccine Information Statement (VIS), answering any questions.
3. Obtain a signed Vaccine Administration Record (VAR).
4. Instructions for **oral administration** of vaccine:
  - Administer as soon as possible after removing vaccine from refrigerator and protect from light.
  - Tear open the pouch and remove dosing tube.
  - Clear fluid from dispensing tip by taping cap.
  - Puncture dispensing tip by screwing cap clockwise.
  - Remove cap by turning it counterclockwise.
  - Administer the 2 ml suspension of oral rotavirus vaccine into the patient's mouth by gently squeezing the liquid toward the inner cheek until dosing tube is empty. (A residual drop may remain in the tip of the tube).
  - Discard the empty tube and cap in approved biological waste containers.
5. If an infant regurgitates, spits out, or vomits during or after administration of vaccine, re-administration is **not** recommended.
6. There are no restrictions on the infant's consumption of food or liquid, including breast milk, either before or after vaccination with PRV.
7. PRV can be administered simultaneously with other childhood vaccines indicated at the same visits, including HIB, IPV, Hepatitis B, PCV, and DTaP vaccines.

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Signature

Health Officer or Medical Provider

Date

July 2006

## II. LICENSED PENTAVALENT ROTAVIRUS VACCINE (PRV)<sup>1,2</sup>

Product Name	Vaccine components	Acceptable Age Range	Thimerosal
RotaTeq®	5 reassortant virus strains G1, G2, G3, G4, and P1[8] <sup>3</sup>	6–32 weeks	none

<sup>1</sup>RotaTeq® is a live viral vaccine that replicates in the small intestine and induces immunity.

<sup>2</sup>Store and transport refrigerated at 2–8°C (36–46°F).

<sup>3</sup> Human–bovine reassortants.

## III. RECOMMENDATIONS FOR USE

### Infants

- Indicated for the prevention of rotavirus gastroenteritis in infants and children caused by serotypes G1, G2, G3, and G4.
- All infants should be immunized with 3 doses of PRV starting no earlier than 6 weeks of age and finishing no later than 32 weeks of age. The first dose should never be given after 12 weeks of age.

### Special Situations

- Premature Infants (i.e., those born at <37 weeks' gestation) can be immunized if they:
  1. are at least 6 weeks of age,
  2. are being or have been discharged from the hospital nursery, and
  3. are clinically stable.
- Infants living in households with persons who have or are suspected of having an immunodeficiency disorder or impaired immune status may be vaccinated.
- Infants living in households with pregnant women may be vaccinated.

#### IV. PENTAVALENT ROTAVIRUS VACCINE SCHEDULE<sup>1</sup>

**DOSE AND ROUTE:** 2 ml oral suspension administered into the infants mouth

<b>Dose</b>	<b>Minimum Age<sup>2</sup></b>	<b>Recommended Age</b>	<b>Minimum Spacing<sup>2</sup></b>	<b>Maximum Age</b>
1	6 weeks	8 weeks (2 months)		12 weeks <sup>3</sup>
2	10 weeks	16 weeks (4 months)	4 weeks from dose #1 to dose #2	32 weeks <sup>3</sup>
3	14 weeks	24 weeks (6 months)	4 weeks from dose #2 to dose #3	32 weeks <sup>4</sup>

<sup>1</sup> Premature Infants (i.e., those born at <37 weeks' gestation) can be immunized if they

- a) are 6 weeks of age,
- b) are being or have been discharged from the hospital nursery, and
- c) are clinically stable.

<sup>2</sup> For retrospective checking, doses that violate the minimum spacing or age by 4 or fewer days do not need to be repeated. (per Bill Atkinson-CDC)

<sup>3</sup> Don't start the PRV series if the child is >12 weeks old. If the 1<sup>st</sup> dose is inadvertently administered to an infant >12 weeks of age, the 2<sup>nd</sup> dose should be given 4-10 weeks later as long as the child is ≤ 32 weeks of age.

<sup>4</sup> No PRV should be administered >32 weeks of age.

<p><b>V. CONTRAINDICATIONS</b></p> <p>A. History of severe hypersensitivity to any component of the vaccine</p> <p>B. History of serious allergic reaction to a previous dose of vaccine</p>	<p><b>VI. PRECAUTIONS</b></p> <p>A. Altered immunocompetence<sup>1</sup></p> <ul style="list-style-type: none"><li>○ Infants with blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic system</li><li>○ Infants on immunosuppressive therapy (including high-dose systemic corticosteroids)</li><li>○ Infants with primary and acquired immunodeficiency states, including HIV/AIDS or other clinical manifestations of infection with human immunodeficiency viruses; cellular immune deficiencies; and hypogammaglobulinemic and dysgammaglobulinemic states.</li><li>○ Infants with indeterminant HIV status who are born to mothers with HIV/AIDS</li><li>○ Infants who have received a blood transfusion or blood products, including immunoglobulins, within 42 days</li></ul> <p>B. Moderate or severe illness, including acute gastroenteritis</p> <p>C. Preexisting chronic gastrointestinal disease</p> <p>D. Previous history of intussusception</p> <p><sup>1</sup>No safety or efficacy data are available for the administration of RotaTeq® to infants who are potentially immunocompromised.</p>
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## VII. SIDE EFFECTS AND ADVERSE REACTIONS

**Table 1:** Adverse events that occurred within 42 days of any dose among recipients of RotaTeq® as compared with placebo recipients (package insert)

<b>Adverse Event</b>	<b>RotaTeq® (n=6,138)</b>	<b>Placebo (n=5,573)</b>
	<b>n (%)</b>	<b>n (%)</b>
Fever	(42.6%)	(42.8%)
Diarrhea*	479 (24.1%)	1,186 (21.3%)
Vomiting*	929 (15.2%)	758 (13.6%)
Otitis media*	887 (14.5%)	724 (13.0%)
Nasopharyngitis*	422 (6.9%)	325 (5.8%)
Bronchospasm*	66 (1.1%)	40 (0.7%)

\* These events occurred at a statistically higher incidence among recipients of RotaTeq® as compared with placebo recipients.

**Table 2:** Serious adverse events and confirmed cases of intussusception in recipients of RotaTeq® as compared with placebo recipients (package insert)

<b>Adverse Event</b>	<b>RotaTeq® (n= 34,837)</b>	<b>Placebo (n=34,788)</b>
	<b>n(%)</b>	<b>n(%)</b>
Serious Events <sup>1</sup>	803 (2.4%)	859(2.6%)
Bronchiolitis	(0.6%)	(0.7%)
Gastroenteritis	(0.2%)	(0.3%)
Pneumonia	(0.2%)	(0.2%)
Urinary tract infection	(0.1%)	(0.1%)
Confirmed intussusception within 42 days of any dose	6	5
Confirmed intussusception within 365 days of dose 1	13	15
Death <sup>2</sup>	25	27

<sup>1</sup>Reported within 42 days of receiving a single dose in phase 3 trials.

<sup>2</sup>Not attributable to vaccine per “blinded” reviewers (Vesikari T. NEJM 2006;354:28).

## VIII. OTHER CONSIDERATIONS

- A Hospitalization after Vaccination:** If a recently vaccinated child is hospitalized for any reason, no precautions beyond the routine universal precautions need be taken to prevent the spread of vaccine virus in the hospital setting.
- B Post-exposure prophylaxis:** No clinical data are available for PRV when administered after exposure to rotavirus.
- C Immunosuppressive therapies** including irradiation, antimetabolites, alkylating agents, cytotoxic drugs and corticosteroids may reduce the immune response to vaccine.
- D One or two- dose protection** of RotaTeq® was not reported in clinical trials.

## IX. ADVERSE EVENT REPORTING

Adverse events following immunization should be reported by public providers to the State Public Health Immunization Program, DHS, using a Vaccine Adverse Events Reporting System form (VAERS), according to state guidelines. Private providers should report all adverse events directly to VAERS.

VAERS phone number: (800) 822-7967, and the website address is [www.vaers.org](http://www.vaers.org).

## X. REFERENCES

1. ACIP. Prevention of rotavirus gastroenteritis among Infants and children: provisional recommendations for use of rotavirus vaccine (PRV). Available at: [http://www.cdc.gov/nip/recs/provisional\\_rec/rotavirus-child.pdf](http://www.cdc.gov/nip/recs/provisional_rec/rotavirus-child.pdf).
2. RotaTeq® package insert. Available at: [www.merck.com/product/usa/pi\\_circulars/r/rotateq/rotateq\\_pi.pdf](http://www.merck.com/product/usa/pi_circulars/r/rotateq/rotateq_pi.pdf).

For more information or to clarify any part of the above order, consult with your health officer or call the Oregon State Public Health Division Immunization Program at (971) 673-0300.

Visit our website at <http://oregon.gov/dhs/ph/imm/index.shtml>.

To request this material in an alternate format (e.g., Braille), please call 971-673-0300.