Vaxelis (DTaP-IPV-Hib-HepB) Fact Sheet

Vaxelis is a hexavalent combination vaccine approved to prevent diphtheria, tetanus, pertussis, polio, *Haemophilus influenzae* type b, and hepatitis B.

### Storage
- Between 2°C to 8°C (36°F to 46°F)
- Protect from light
- Do NOT freeze

### Preparation
- Presentations: Single dose vial or manufacturer-filled syringe
- Do NOT reconstitute

### Administration
- Dosage: 0.5 mL
- Route: IM Injection
- Ages: 6 weeks through 4 years

### Considerations
Vaxelis (DTaP-IPV-Hib-HepB) is approved for:
- Any dose in the hepatitis B series EXCEPT the dose at birth
- Doses 1 through 3 in the DTaP, Polio and Hib series

A combination vaccine generally is preferred over separate injections of the equivalent component vaccines and may be used when any of the components are indicated and none are contraindicated. However, efforts should be made to avoid giving extra vaccine doses when another option is available.

- Administering 4 doses of HepB is acceptable when a combination vaccine containing HepB is used after the birth dose.

Switching between combination and single-component vaccine products is acceptable IF the minimum intervals for all the components are maintained and follow age indications. The minimum interval between doses is the greatest interval between doses of any of the individual antigens. See Table 3.1 in *General Best Practice Guidelines for Immunization*: [www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html](http://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html)

Combination vaccines can be used to catch-up children who have fallen behind (note: product age indications apply).

DTaP-IPV-Hib-HepB may be administered to an infant born to a woman who is HBsAg-negative, HBsAg-positive or whose HBsAg status is unknown.

For additional information, please refer to the 2021 Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger: [www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html](http://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html)

### Contraindications
- A severe, anaphylactic reaction to a previous dose of Vaxelis, any ingredient of Vaxelis, or any other diphtheria toxoid, tetanus toxoid, pertussis-containing vaccine, inactivated poliovirus vaccine, hepatitis B vaccine, or *Haemophilus influenzae* type b vaccine
- Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not due to another cause occurring within 7 days after vaccination with a pertussis-containing vaccine

### Precautions
- Progressive or unstable neurologic disorder, including infantile spasms, uncontrolled seizures or progressive encephalopathy; defer DTaP until neurologic status clarified and stabilized
- Moderate to severe acute illness with or without fever
- Guillain-Barré syndrome within 6 weeks of a prior vaccine containing tetanus toxoid
- History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria-toxoid—containing or tetanus-toxoid-containing vaccine
### SAMPLE IMMUNIZATION SCHEDULES

#### Completing HepB, DTaP, IPV, and Hib (through 18 months) using all single-component vaccines

<table>
<thead>
<tr>
<th>Birth¹</th>
<th>2 months</th>
<th>4 months</th>
<th>6 months²</th>
<th>12–15 months</th>
<th>15–18 months</th>
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</thead>
<tbody>
<tr>
<td>HepB</td>
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<td>HepB</td>
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<td>DTaP</td>
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<td>DTaP</td>
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<td>DTaP³</td>
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<td>IPV</td>
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<td>Hib</td>
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<td>Hib</td>
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</table>

#### Using Vaxelis

<table>
<thead>
<tr>
<th>Birth¹</th>
<th>2 months</th>
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<th>15–18 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>HepB</td>
<td>Vaxelis (DTaP-IPV-Hib-HepB)</td>
<td>Vaxelis (DTaP-IPV-Hib-HepB)</td>
<td>Vaxelis (DTaP-IPV-Hib-HepB)</td>
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<td>DTaP³</td>
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<td>Hib</td>
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</table>

#### Using Vaxelis to complete the vaccine series started with PediariX

<table>
<thead>
<tr>
<th>Birth¹</th>
<th>2 months</th>
<th>4 months</th>
<th>6 months²</th>
<th>12–15 months</th>
<th>15–18 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>HepB</td>
<td>PediariX (DTaP-HepB-IPV)</td>
<td>Vaxelis (DTaP-IPV-Hib-HepB)</td>
<td>Vaxelis (DTaP-IPV-Hib-HepB)</td>
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<td>DTaP³</td>
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<td>Hib</td>
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</table>

<table>
<thead>
<tr>
<th>Birth¹</th>
<th>2 months</th>
<th>4 months</th>
<th>6 months²</th>
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<th>15–18 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>HepB</td>
<td>PediariX (DTaP-HepB-IPV)</td>
<td>PediariX (DTaP-HepB-IPV)</td>
<td>Vaxelis (DTaP-IPV-Hib-HepB)</td>
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<td>DTaP³</td>
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<td>Hib</td>
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</tbody>
</table>

#### Using Vaxelis to complete the vaccine series started with Pentacel

<table>
<thead>
<tr>
<th>Birth¹</th>
<th>2 months</th>
<th>4 months</th>
<th>6 months²</th>
<th>12–15 months</th>
<th>15–18 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>HepB</td>
<td></td>
<td></td>
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<td>HepB</td>
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<tr>
<td></td>
<td>Pentacel (DTaP-IPV/Hib)</td>
<td>Vaxelis (DTaP-IPV-Hib-HepB)</td>
<td>Vaxelis (DTaP-IPV-Hib-HepB)</td>
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<td>DTaP³</td>
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<td>Hib</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Birth¹</th>
<th>2 months</th>
<th>4 months</th>
<th>6 months²</th>
<th>12–15 months</th>
<th>15–18 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>HepB</td>
<td></td>
<td></td>
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<td>HepB</td>
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</tr>
<tr>
<td></td>
<td>Pentacel (DTaP-IPV/Hib)</td>
<td>Pentacel (DTaP-IPV/Hib)</td>
<td>Vaxelis (DTaP-IPV-Hib-HepB)</td>
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<td>DTaP³</td>
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<td>Hib</td>
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</tbody>
</table>
**SAMPLE IMMUNIZATION SCHEDULES (continued)**

**Using single-component vaccines to complete the vaccine series started with Vaxelis**

<table>
<thead>
<tr>
<th>Birth¹</th>
<th>2 months</th>
<th>4 months</th>
<th>6 months²</th>
<th>12–15 months</th>
<th>15–18 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>HepB</td>
<td>Vaxelis (DTaP-IPV-Hib-HepB)</td>
<td>DTaP</td>
<td>DTaP³</td>
<td>Hib</td>
<td>Hib</td>
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<tr>
<td></td>
<td></td>
<td>IPV</td>
<td>IPV</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Birth¹</th>
<th>2 months</th>
<th>4 months</th>
<th>6 months²</th>
<th>12–15 months</th>
<th>15–18 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>HepB</td>
<td>Vaxelis (DTaP-IPV-Hib-HepB)</td>
<td>Vaxelis (DTaP-IPV-Hib-HepB)</td>
<td>HepB</td>
<td>DTaP³</td>
<td>Hib</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>IPV</td>
<td>Hib</td>
</tr>
</tbody>
</table>

¹ Only single-component HepB vaccine (Engerix-B or Recombivax HB) should be used for any dose administered BEFORE 6 weeks of age, including the birth dose. Combination products containing hepatitis B should NOT be administered before 6 weeks of age. See additional recommendations for infants born to hepatitis B surface antigen-positive or unknown mothers, or for infants weighing less than 2,000 grams at birth: [www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hepb.html](http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hepb.html)

² The minimum age for the final (3rd or 4th) dose of HepB vaccine is 6 months (24 weeks) of age. In populations with high rates of childhood HBV infection (e.g., Alaska Natives, Pacific Islanders, and immigrant families from Asia, Africa, and countries with intermediate or high endemic rates of infection), the final HepB dose should be administered at age 6–12 months. Infants born to mothers who are hepatitis B surface antigen-positive or mothers with unknown hepatitis B status should complete the series within the first 6 months of life.

³ The same manufacturer’s DTaP vaccine should be used for all doses in a series. If this is not possible, or if the manufacturer of previous doses is not known, administer any comparable vaccine that is available. The 4th dose of DTaP may be administered as early as age 12 months, provided at least 6 months have elapsed since the 3rd dose.

⁴ When PedvaxHIB is used for all doses, a dose at 6 months is not necessary.
<table>
<thead>
<tr>
<th>ACIP Abbreviation</th>
<th>Product Name/Manufacturer</th>
<th>Age Indications</th>
<th>Includes</th>
<th>Can Be Used For:</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTaP-IPV-Hib-HepB</td>
<td>Vaxelis/MCM Vaccine Company</td>
<td>6 weeks through 4 years of age (prior to the 5th birthday)</td>
<td>DTaP</td>
<td>Doses 1 through 3 in the DTaP series</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>IPV</td>
<td>Doses 1 through 3 in the IPV series</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>HepB</td>
<td>Any dose in the HepB series except the dose administered at birth</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Hib</td>
<td>Any dose in the Hib series except the final dose</td>
</tr>
<tr>
<td>DTaP-IPV-Hib</td>
<td>Pediarix/GSK</td>
<td>6 weeks through 6 years of age (prior to the 7th birthday)</td>
<td>DTaP</td>
<td>Doses 1 through 3 in the DTaP series</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>IPV</td>
<td>Doses 1 through 3 in the IPV series</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>HepB</td>
<td>Any dose in the HepB series except the dose administered at birth</td>
</tr>
<tr>
<td>DTaP-IPV/Hib</td>
<td>Pentacel/Sanofi Pasteur</td>
<td>6 weeks through 4 years of age (prior to the 5th birthday)</td>
<td>DTaP</td>
<td>Doses 1 through 4 in the DTaP series</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>IPV</td>
<td>Doses 1 through 4 in the IPV series</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Hib</td>
<td>Any dose in the Hib series</td>
</tr>
<tr>
<td>DTaP-IPV</td>
<td>Kinrix/GSK</td>
<td>4 years through 6 years of age (prior to the 7th birthday)</td>
<td>DTaP</td>
<td>Dose 5 in the DTaP series</td>
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<td></td>
<td>IPV</td>
<td>Dose 4 in the IPV series</td>
</tr>
<tr>
<td>DTaP-IPV</td>
<td>Quadracel/Sanofi Pasteur</td>
<td>4 years through 6 years of age (prior to the 7th birthday)</td>
<td>DTaP</td>
<td>Dose 5 in the DTaP series</td>
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<td></td>
<td></td>
<td></td>
<td>IPV</td>
<td>Dose 4 or 5 in the IPV series</td>
</tr>
</tbody>
</table>

1 The Advisory Committee on Immunization Practices prefers that doses of DTaP in a series come from the same manufacturer; however, if this is not possible or if the manufacturer of doses given previously is unknown, providers should administer the vaccine that they have available.