### BOOSTRIX®-POLIO: Diphtheria-Tetanus-Acellular Pertussis-Polio Combined Vaccine Biological Page (dTap-IPV)

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<th>Section 7: Biological Product Information</th>
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### Manufacturers
- **GlaxoSmithKline Inc.**

### Biological Classification
- Inactivated

### Indications for Provincially Funded Vaccine
- **Children 4 years up to and including 6 years of age who have received 4 previous doses of DTaP-IPV±Hib vaccine:**
  - Reinforcing dose of diphtheria, tetanus, pertussis and polio vaccine routinely given as the preschool booster.
  - **Note:** For children who are delayed in their immunization schedule refer to Diphtheria-Tetanus-Acellular Pertussis-Polio-Haemophilus Influenzae type B Conjugate Combined Vaccine Biological Page #07.211 and Diphtheria Tetanus-Acellular Pertussis-Polio Combined Vaccine Biological Page #07.212.

- **Children 7 years up to and including 17 years of age:**
  - Initiating or completing a primary immunization series for tetanus, diphtheria, pertussis and polio.

- **Individuals 18 years of age and older:**
  - When immunization with tetanus, diphtheria, pertussis and polio antigens are indicated (primary or reinforcing dose). Refer to Polio and Tetanus-Diphtheria-Pertussis vaccine biological pages.

### Notes:
- Recipients of hematopoietic stem cell transplant (HSCT) and candidates/recipient of solid organ transplant (SOT), see *Standard for Immunization of Transplant Candidates and Recipients* for recommended vaccine and schedule information.
- Individuals who sustain a tetanus prone wound need to have their tetanus immunization history assessed (Tetanus Prevention, Prophylaxis and Wound/Injury Management Standard #08.400).
- Individuals who have had pertussis infection should continue to receive pertussis-containing vaccines.
- Individuals travelling to countries currently exporting and/or infected with polio may need special immunization documentation verifying polio immunization. These individuals should consult with a Travel Clinic to determine what documentation is required.

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*Note: For questions related to Travel and/or For Sale vaccine refer to AHS Travel Health and Contracted Immunization Services resources.*
## Serology

Pre-Immunization and Post-Immunization

- There are no serological tests available for pertussis or polio.
- Serological testing is not typically recommended to assess levels of immunity to diphtheria or tetanus. For additional information see the Alberta Health DAT/TAT Interpretation tables at: [https://open.alberta.ca/dataset/715eb289-53b2-4c69-a17e-60717b9e6eb8/resource/f91417df-26c0-435f-b3da-fea0b031617a/download/AIP-Adverse-Events-Following-Immunization-DAT-TAT-Levels.pdf](https://open.alberta.ca/dataset/715eb289-53b2-4c69-a17e-60717b9e6eb8/resource/f91417df-26c0-435f-b3da-fea0b031617a/download/AIP-Adverse-Events-Following-Immunization-DAT-TAT-Levels.pdf)

## Schedule

**Children 4 years up to and including 6 years of age:**

- Reinforcing preschool booster given a minimum of 6 months from previous dose of tetanus, diphtheria, pertussis and polio containing vaccine.

**Individuals 7 years up to and including 17 years of age initiating or completing a primary immunization series:**

- Dose 1 – day 0
- Dose 2 – 4 to 8 weeks after dose 1
- Dose 3 – 6 to 12 months after dose 2

**Note:**

For children with delayed immunization see # 03.110 Standard for Recommended Immunization Schedules, Section 2 and 3 to determine number of doses and correct spacing.

**Individuals 18 years of age and older:**

- One dose as part of a primary immunization series or a reinforcing dose where all 4 antigens are indicated. When additional doses of tetanus, diphtheria and polio vaccine are required see the corresponding vaccine biological pages for more information.

## Preferred Use

N/A

## Dose

0.5 mL

## Route

IM

## Contraindications/Precautions

### Contraindications:

- Known severe hypersensitivity to any component of the vaccine
- Anaphylactic or other allergic reaction to a previous dose of a vaccine containing tetanus, diphtheria, pertussis, or polio.
- Encephalopathy of unknown etiology (e. g., coma, decreased level of consciousness, prolonged seizures) within 7 days of a previous dose of a pertussis-containing vaccine.
- Should not be administered to individuals who have experienced transient thrombocytopenia following a previous dose of diphtheria/tetanus containing vaccine. Consult with MOH on a case-by-case basis to determine immunization recommendations.

### Precautions:

- Frequent booster doses of tetanus and diphtheria toxoids may lead to severe local and systemic reactions and may be associated with high levels of circulating antitoxin.
### POSSIBLE REACTIONS

**Common:**
- Tenderness, pain, redness and swelling at the injection site, usually mild and transient in duration
- The most frequent systemic reactions are headache, fatigue, fever, loss of appetite, gastro-intestinal symptoms, drowsiness, irritability.

**Rare:**
- Dizziness, arthralgia, myalgia, pruritus, rash and lymphadenopathy
- The following additional adverse events have been reported from post-marketing surveillance: allergic reactions including anaphylactoid reactions have been very rarely reported
- As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.

### PREGNANCY

Adequate data is not available for the use of dTap-IPV vaccine during pregnancy and therefore will not routinely be recommended in Alberta for pregnant women. However, this vaccine may be offered to pregnant women 26 weeks gestation or greater if indicated in specific situations and in consultation with the MOH where there is high risk of pertussis and polio disease (see Indications Section). Immunization during pregnancy requires careful consideration of the risks from disease versus the benefits of the vaccine and should only be offered in consultation with the zone MOH.

### LACTATION

Can be administered to eligible breastfeeding women.

### COMPOSITION

**Active Ingredients:**
- Diphtheria toxoid – 2.5 Lf
- Tetanus toxoid - 5 Lf
- Acellular pertussis:
  - Pertussis toxoid (PT) – 8 mcg
  - Filamentous haemagglutinin (FHA) – 8 mcg
  - Pertactin (PRN) – 2.5 mcg
- Inactivated poliomyelitis vaccine
  - Type 1 (Mahoney) – 40 DU
  - Type 2 (MEF1) – 8 DU
  - Type 3 (Saukett) – 32 DU

**Non-medical Ingredients:**
- Sodium chloride
- Aluminum salts
- Medium 199
- Water for injection
- Trace amounts of:
  - Formaldehyde
  - Neomycin
  - Polymixin

### BLOOD/BLOOD PRODUCTS

Animal blood (including equine-derived blood) is used as a raw material in the manufacturing process. Does not contain human blood or blood products.
| **Ingredients of animal origin, including bovine, equine and porcine derived materials, are used as raw materials in the manufacturing process.** |
| **Latex** | Does not contain latex. |
| **Interchangeability** | Individuals who begin their immunization with a different combined product may complete immunization using dTap-IPV. |
| **Administration with Other Products** | • May be given at the same time as other inactivated and live vaccines using a separate needle and syringe for each vaccine.  
• The same limb may be used if necessary, but different sites on the limb must be chosen. |
| **Appearance** | Uniform, cloudy white suspension. |
| **Storage** | • Store at +2°C to +8°C  
• Do not freeze  
• Do not use beyond the labeled expiry date  
• Store in original packaging when possible to protect from light |
| **Vaccine Code** | dTap-IPV |
| **Antigen Code** | Tetanus – T  
Diphtheria – D  
Acellular pertussis – P  
Inactivated polio vaccine – POL |
| **Licensed for** | • Licensed for booster immunization of individuals 4 years of age and older.  
• Currently off label use is recommended, per Alberta Health Immunization Policy, for primary immunization of individuals 7 years of age and older who need all of the antigens contained in the vaccine. |
| **Notes:** | In September 2012, BOOSTRIX®-POLIO replaced Quadracel® as the preschool booster in the routine immunization program in Alberta and for primary immunization for individuals 7 years up to and including 17 years of age who require tetanus, diphtheria, pertussis and polio vaccine. |
| **Related Resources:** | • Diphtheria, Tetanus, Acellular Pertussis and Polio Vaccine Information Sheet (104503). |
References:


