

PRODUCT MONOGRAPH

BOOSTRIX[®]

Combined diphtheria, tetanus, acellular pertussis (adsorbed) vaccine for booster
vaccination

Active immunizing agent against infection by diphtheria, tetanus and whooping cough

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BOOSTRIX[®]

Combined diphtheria, tetanus, acellular pertussis (adsorbed) vaccine for
booster vaccination

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
Intramuscular	Suspension for injection/ not less than 2.5 limit of flocculation ('Lf'), or 2 IU ('International Units') of diphtheria toxoid; not less than 5 Lf (20 IU) of tetanus toxoid; 8 µg of pertussis toxoid, 8 µg of filamentous hemagglutinin and 2.5 µg of pertactin (69 kDa outer membrane protein).	Aluminum adjuvant (as aluminum hydroxide and aluminum phosphate), sodium chloride and water for injection.

DESCRIPTION

BOOSTRIX[®] (combined diphtheria, tetanus, acellular pertussis (adsorbed) vaccine) is presented as a turbid white suspension in a single dose vial or prefilled syringe. Upon storage, a white deposit and clear supernatant can be observed.

INDICATIONS AND CLINICAL USE

BOOSTRIX[®] (combined diphtheria, tetanus, acellular pertussis (adsorbed) vaccine) is indicated for:

- Booster vaccination against diphtheria, tetanus and pertussis of individuals from the age of four years onwards.

BOOSTRIX[®] is not intended for primary immunization.

CONTRAINDICATIONS

- BOOSTRIX[®] (combined diphtheria, tetanus, acellular pertussis (adsorbed) vaccine) is contraindicated in patients who are hypersensitive to any component of the vaccine or subjects having shown signs of hypersensitivity after previous administration of diphtheria, tetanus, or pertussis vaccines. For a complete listing, see the DOSAGE FORMS, COMPOSITION AND PACKAGING section of the product monograph.
- BOOSTRIX[®] is contraindicated if the subject has experienced an encephalopathy of unknown etiology, occurring within 7 days following previous vaccination with pertussis containing vaccine. In these circumstances, adult-type combined diphtheria tetanus vaccine should be used.
- BOOSTRIX[®] should not be administered to subjects who have experienced transient thrombocytopenia or neurological complications following an earlier immunization against diphtheria and/or tetanus.

WARNINGS AND PRECAUTIONS

General

It is good clinical practice that immunization should be preceded by a review of the medical history (especially with regard to previous immunization and possible occurrence of undesirable events) and a clinical examination.

As with any other vaccine, BOOSTRIX[®] (combined diphtheria, tetanus, acellular pertussis (adsorbed) vaccine) may not protect 100% of individuals receiving the vaccine.

BOOSTRIX[®] should under no circumstances be administered intravenously.

As with other vaccines, the administration of BOOSTRIX[®] should be postponed in subjects suffering from acute severe febrile illness. The presence of a minor infection is not a contraindication.

If any of the following events occur in temporal relation to administration of whole-cell DTP or acellular DTP vaccine, the decision to give subsequent doses of vaccine containing the pertussis component should be carefully considered. There may be circumstances, such as high incidence of pertussis, in which the potential benefits outweigh possible risks, particularly since these events have not been proven to cause permanent sequelae.

- Temperature of $\geq 40.5^{\circ}\text{C}$ within 48 hours of vaccination, not due to another identifiable cause.
- Collapse or shock like state (hypotonic hyporesponsive episode) within 48 hours of vaccination.
- Persistent, inconsolable crying lasting ≥ 3 hours, occurring within 48 hours of vaccination.
- Convulsions with or without fever, occurring within 3 days of vaccination.

Neurologic

In children with progressive neurological disorders, including infantile spasms, uncontrolled epilepsy or progressive encephalopathy, it is better to defer pertussis (Pa or Pw) immunization until the condition is corrected or stable. However, the decision to give pertussis vaccine must be made on an individual basis after careful consideration of the risks and benefits.

A history or a family history of convulsions and a family history of an adverse event following DTP vaccination do not constitute contraindications.

Hematologic

BOOSTRIX[®] should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects. Firm pressure should be applied to the injection site (without rubbing) for at least 2 minutes.

Immune

HIV infection is not considered as a contraindication for diphtheria, tetanus and pertussis vaccination. The expected immunological response may not be obtained after vaccination.

Sensitivity

As with other injectable vaccines, appropriate medication (eg. Epinephrine 1:1000) should be readily available for immediate use in case of anaphylaxis or anaphylactoid reactions following administration of the vaccine. For this reason, the vaccinee should remain under medical supervision for 30 minutes after immunization.

Special Populations

Pregnant Women:

Adequate human data on the use of BOOSTRIX[®] during pregnancy are not available.

As with other inactivated vaccines, one does not expect vaccination with BOOSTRIX[®] to be harmful to the fetus. However, the vaccine should be used during pregnancy only when clearly needed, and when the possible advantages outweigh the possible risks for the fetus.

Nursing Women:

Adequate human data on the use during lactation and adequate animal reproductive studies are not available.

ADVERSE REACTIONS**Clinical Trial Adverse Drug Reactions**

Because clinical trials are conducted under very specific conditions the adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse drug reaction information from clinical trials is useful for identifying drug-related adverse events and for approximating rates.

A total of 1,243 vaccinees have received a dose of BOOSTRIX[®] (combined diphtheria, tetanus, acellular pertussis (adsorbed) vaccine) in clinical studies of which 1,032 were over 10 years of age.

During controlled clinical studies, diary cards were used to monitor signs and symptoms in all vaccinees following administration of a dose of BOOSTRIX[®]. Table 1 below summarizes data from two pivotal studies for solicited local and general symptoms reported during a 15 day follow up period after vaccination. Onset of the majority of local and general symptoms occurred within 48 hours of vaccination. All symptoms resolved without sequelae. A causal relationship between these events and vaccination has not necessarily been established.

Table 1 Summary data from 2 pivotal studies for solicited local and general symptoms reported during a 15 day follow up period vaccination.

Solicited Symptoms	Incidence (%)					
	BOOSTRIX [®] administered to adolescent subjects aged 10-17 years	Adolescent comparator group who received separate Td and aP (ap) vaccines		BOOSTRIX [®] administered to adult subjects aged 18 years	Adult comparator group who received separate Td and aP (ap) vaccines	
	BOOSTRIX [®] N=448	Td N=60	aP N=59	BOOSTRIX [®] N=438	Td* N=54	aP* N=55
Local reactions						
Pain (All)	79.0	83.3	67.8	72.6	85.2	56.4
(Grade 3)	3.8	10.0	8.5	0.7	0	3.65
Redness (All)	33.0	53.3	15.3	32	38.9	20.0
(≥ 50 mm)	5.8	16.7	0	2.5	7.4	0
Swelling (All)	35.0	46.7	15.3	20.8	29.6	10.9
(≥ 50 mm)	7.8	10.0	1.7	2.5	5.6	0
General Symptoms						
Fever (≥ 37.5°C)	8.9	8.3	5.1	18.5	33.3	12.7
Fever (≥ 39.1°C)	0.4	0	0	0.2	0	0
Malaise	27.7	26.7	20.3	19.2	20.4	14.5
Fatigue	56.2	50.0	40.7	27.2	25.9	23.6
Vomiting	4.0	5.0	3.4	3.4	3.7	5.5
Headache	51.3	51.7	35.6	37.0	44.4	47.3
Dizziness	20.5	26.7	13.6	10.0	3.7	9.1

Td – Tetanus + diphtheria toxoid

aP – acellular pertussis

* These data are from the first vaccination of either of these comparator vaccine.

Clinical Studies in Children, Adolescents and Adults

In controlled clinical studies, the most commonly reported solicited reactions were those at the site of injection. They included pain, redness and swelling. In a study which involved children, in which parents who spontaneously contacted the investigator to report swelling were asked to bring in their child for examination, notable swellings (as judged by the investigator) were observed with a frequency of 0.5% following dTpa vaccination. None of these cases were considered to correspond to the phenomenon of whole limb swelling as previously reported following DT and DTP vaccination. All local symptoms resolved without any sequelae.

Systemic adverse events, considered to be probably or suspected to be related to vaccination, very commonly reported in adolescents and adults, were malaise, fatigue and headache. Commonly reported symptoms in children included diarrhea. Irritability, loss of appetite and vomiting were reported only for 4-6 year old children.

Fever > 39.0°C, considered as probably or suspected to be related to vaccination, was infrequently reported in adolescents and adults and commonly reported in children 4-6 years of age.

All unsolicited symptoms were very rarely reported. These included increased sweating, hypertonia, arthrosis, myalgia, pruritus and lymphadenopathy.

Very rare allergic reactions including anaphylactoid reactions, have been reported following vaccination with DTPa-containing vaccines.

Extremely rare cases of collapse or shock-like state (hypotonic hyporesponsive episode) and convulsions within 2 to 3 days of vaccination have been reported in DTPa and DTPa combination vaccines. All of the subjects recovered totally and spontaneously without sequelae. At the present time, there have been no collapse or shock-like episodes reported following administration of BOOSTRIX[®].

DRUG INTERACTIONS

Drug-Drug Interactions

Concomitant use with other inactivated vaccines or with immunoglobulin has not been studied. It is unlikely the coadministration will result in interference with the immune responses. When considered necessary, BOOSTRIX[®] (combined diphtheria, tetanus, acellular pertussis (adsorbed) vaccine) can be administered simultaneously with other vaccines or immunoglobulin, at a different injection site.

As with other vaccines, patients receiving immunosuppressive therapy or patients with immunodeficiency may not achieve an adequate response.

Drug-Lifestyle Interactions

The vaccine is unlikely to produce an effect on the ability to drive and use machines.

DOSAGE AND ADMINISTRATION

Recommended Dose

A single 0.5 mL dose of the vaccine is recommended.

Tetanus Prophylaxis in Wound Management

The following table summarizes the recommended use of immunizing agents in wound management. It is important to ascertain the number of doses of toxoid previously given and the interval since the last dose. When a tetanus booster dose is required, the combined preparation of tetanus and diphtheria toxoid formulated for adults (Td) is preferred. Appropriate cleansing and debridement of wounds is imperative, and use of antibiotics may be considered.

Some individuals with humoral immune deficiency, including those with HIV infection, may not respond adequately to tetanus toxoid. Therefore, tetanus immune globulin (TIG) should be used in addition to tetanus toxoid if a wound occurs that is not clean, regardless of the time elapsed since the last booster.

Table 2 Guide to Tetanus Prophylaxis in Wound Management

History of Tetanus Immunization	Clean, minor wounds		All other wounds	
	Td or Tdap*	Tig**	Td or Tdap*	Tig
Uncertain of < 3 doses of an immunization series†	Yes	No	Yes	Yes
≥ 3 doses received in an immunization series†	No‡	No	No§	No¶

*Adult type combined tetanus and diphtheria toxoids or a combined preparation of diphtheria, tetanus and acellular pertussis. If the patient is < 7 years old a tetanus toxoid-containing vaccine is given as part of the routine childhood immunization.

**Tetanus immune globulin, given at a separate site from Td (or Tdap).

† The immunization series for tetanus is described in the text (Schedule and Dosage).

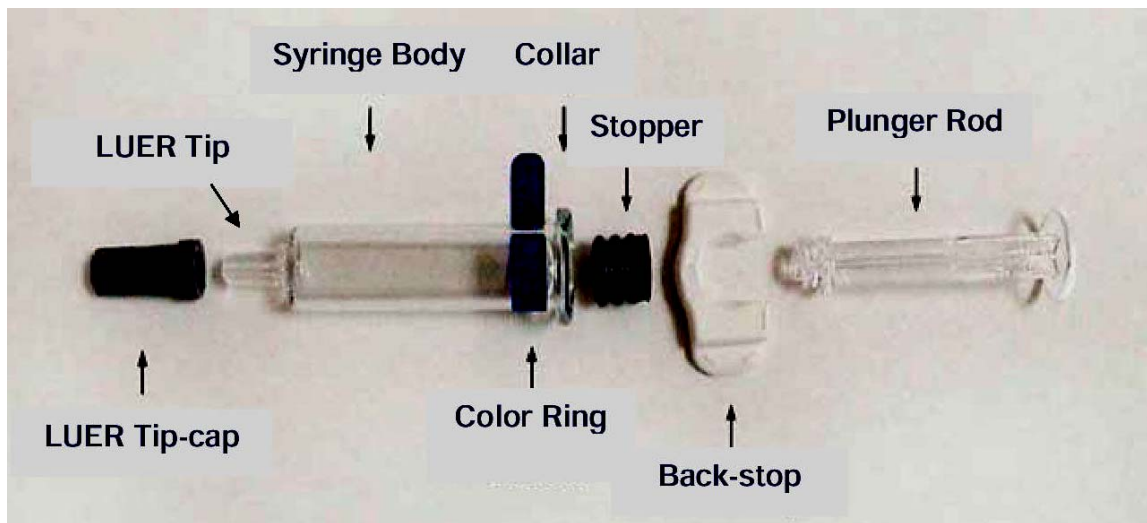
‡Yes, if > 10 years since last booster.

§Yes, if > 5 years since last booster. More frequent boosters not required and can be associated with increased adverse events. The bivalent toxoid, Td, is not considered to be significantly more reactogenic than T alone and is recommended for use in this circumstance. The patient should be informed that Td (or Tdap) has never been given.

¶Yes, if individuals are known to have a significant humoral immune deficiency state (e.g. HIV, agammaglobulinemia) since immune response to tetanus toxoid may be suboptimal.

Administration

Do not remove the white back-stop from the syringe. Prior to administration, ensure that the plunger rod is firmly attached to the rubber stopper by turning the plunger clockwise until slight resistance is felt. **Do not** over tighten. Remove syringe LUER Tip-cap and needle cap. Attach needle by pressing and twisting in a clockwise rotation until secured to the syringe.



Prior to vaccination, the vaccine should be well shaken in order to obtain a homogeneous turbid white suspension and visually inspected for any foreign particulate matter and/or variation of physical aspect prior to administration. In the event of either being observed, discard the vaccine.

BOOSTRIX[®] (combined diphtheria, tetanus, acellular pertussis (adsorbed) vaccine) should not be mixed with other vaccines in the same syringe.

BOOSTRIX[®] is for deep muscular injection.

Repeat vaccination against diphtheria and tetanus should be performed at intervals as per official recommendations (generally 10 years). It is not necessary to recommence primary vaccination, should the officially recommended interbooster interval be exceeded.

OVERDOSAGE

No case of overdose has been reported.

ACTION AND CLINICAL PHARMACOLOGY

Diphtheria

Diphtheria is a serious communicable disease, primarily a localized and generalized intoxication caused by diphtheria toxin, an extracellular protein metabolite of toxigenic strains of *Corynebacterium diphtheriae*. The disease occurs most frequently in unimmunized or partially immunized individuals. The incidence of diphtheria in Canada has decreased from 9,000 cases reported in 1924 to extremely low levels. Only one or two cases have been reported annually in recent years. The case fatality rate remains 5 to 10%, with the highest death rates in the very young and elderly. If immunization levels are allowed to fall and adults do not receive booster doses, disease re-emergence may appear as demonstrated in the Commonwealth of Independent States (former Soviet Union), where tens of thousands of cases with substantial mortality have been reported. Protection against disease is due to the development of neutralizing antibodies to the diphtheria toxin. Following adequate immunization with diphtheria toxoid, it is generally accepted that protection persists for at least 10 years. Serum antitoxin levels of at least 0.01 antitoxin units per mL are generally regarded as protective. This significantly reduces both the risk of developing diphtheria and the severity of clinical illness. Immunization with diphtheria toxoid does not, however, eliminate carriage of *C. diphtheriae* in the pharynx or nose or on the skin.

Tetanus

Tetanus is an intoxication manifested primarily by neuromuscular dysfunction caused by a potent exotoxin released by *Clostridium tetani*. Immunization is highly effective, provides long lasting protection and is recommended for the entire population. Only 1 to 7 with an average of 5 cases of tetanus are reported annually in Canada while no deaths have been recorded since 1995. The disease continues to occur almost exclusively among persons who are unvaccinated or inadequately vaccinated or whose vaccination histories are unknown or uncertain.

Spores of *C. tetani* are ubiquitous. Naturally acquired immunity to tetanus toxin does not occur. Thus, universal primary immunization and timed booster doses to maintain adequate tetanus antitoxin levels are necessary to protect all age groups. Protection against disease is due to the development of neutralizing antibodies to the tetanus toxin. Tetanus toxoid is a highly effective antigen and a completed primary series generally induces serum antitoxin levels of at least 0.01 antitoxin units per mL, a level which has been reported to be protective. It is generally accepted that protection persists for at least 10 years. To maintain immunity to tetanus following completion of primary immunization, booster doses administered as Td are recommended at 10 yearly intervals.

Pertussis

Pertussis (whooping cough) is a disease of the respiratory tract caused by *Bordetella pertussis*. Pertussis is highly communicable (attack rates in unimmunized household contacts of up to 90% have been reported) and can affect individuals of any age; however, severity is greatest among young infants. Precise epidemiologic data do not exist, since bacteriological confirmation of pertussis can be obtained in less than half of the suspected cases. Most reported illness from *B. pertussis* occurs in infants and young children in whom complications can be severe. Older children, adolescents and adults, in whom classic signs of pertussis infection are often absent, may go undiagnosed, and may serve as reservoirs of disease and may act as the primary source of transmission of the bacillus to infants.

Pertussis epidemics are cyclic, occur every 3 to 4 years, and outbreaks continue to occur due to 1) the decline in immunity in individuals who received the whole cell vaccine during childhood; 2) a decline in the population that may have acquired natural infection with longer lasting immunity; 3) improvements in diagnosis and surveillance; and 4) possible genetic changes in current strains compared with the strains of *B. pertussis* from which the original whole cell vaccine was prepared. With the licensure of acellular pertussis vaccines, which have better safety and efficacy profiles, the use of whole cell pertussis vaccines is no longer recommended in Canada.

During the 1980s pertussis incidence was low, but has increased since 1990 in spite of high vaccine coverage. Over the past 10 years, the annual number of reported cases of pertussis in Canada has ranged from 2,400 to 10,000 although these figures likely under represent the true incidence because of incomplete reporting.

Active surveillance for pertussis has found that 1 to 25% of patients with prolonged cough had *B. pertussis* infection. Using a combination of laboratory methods, the Sentinel Health Unit Surveillance System has documented pertussis infection in 9 to 20% of non improving cough illness of 7 days or more in adolescents and adults.

Canadian studies have estimated that the secondary attack rate of pertussis in adolescents and adults by household contact ranged between 12 and 14% in contacts aged 12 to 17 years, 11 to 18% for those 18 to 29 years of age and 8 to 33% in those 30 years of age or older. It can be concluded that between 10 to 25% of adolescents and adults are susceptible to pertussis and thus play a role in its transmission.

Antigenic components of *B. pertussis* believed to contribute to protective immunity include: pertussis toxin; filamentous hemagglutinin; and pertactin (69kDa). Although the role of these antigens in providing protective immunity in humans is not well understood, clinical trials which evaluated candidate acellular DTP vaccines manufactured by GlaxoSmithKline supported the efficacy of three component INFANRIX™ (DTPa). Recently published data suggests a higher importance of the PT and pertactin (69kDa) components in providing protection against pertussis.

Protective efficacy of pertussis

There is currently no correlate of protection defined for pertussis; however, the protective efficacy of GlaxoSmithKline DTPa (INFANRIX™) vaccine against WHO defined typical pertussis (≥ 21 days of paroxysmal cough with laboratory confirmation) was demonstrated in the following 3 dose primary studies:

A prospective blinded household contact study performed in Germany (3, 4, 5 months schedule). Based on data collected from secondary contacts in households where there was an index case with typical pertussis, the protective efficacy of the vaccine was 88.7%. Protection against laboratory confirmed mild disease, defined as 14 days or more of cough of any type was 73 and 67% when defined as 7 days or more of cough of any type.

An NIH sponsored efficacy study performed in Italy (2, 4, 6 months schedule). The vaccine efficacy was found to be 84%. When the definition of pertussis was expanded to include clinically milder cases with respect to type and duration of cough, the efficacy of INFANRIX™ was calculated to be 71% against > 7 days of any cough and 73% against > 14 days of any cough. In a follow up of the same cohort, the efficacy was confirmed up to 5 years after completion of primary vaccination without administration of a booster dose of pertussis.

As infants cannot begin their pertussis vaccination course until they are at least 6 weeks old and three doses of vaccine need to be given, vaccination does not confer complete protection until infants have received all 3 doses. Several studies have shown that adults are a significant source of pertussis in the first week of life. It could be expected that immunization of immediate close contacts of newborn infants, such as parents, grandparents and healthcare workers, would reduce exposure of pertussis to infants not

yet adequately protected through immunization. Booster immunization with BOOSTRIX[®], an acellular pertussis vaccine with reduced antigen content of diphtheria toxoids and pertussis, has demonstrated that the vaccine was immunogenic and well tolerated in clinical studies in which adolescents and adults have received BOOSTRIX[®].

STORAGE AND STABILITY

BOOSTRIX[®] (combined diphtheria, tetanus, acellular pertussis (adsorbed) vaccine) must be stored at +2 to +8°C. Do not use beyond the expiry date printed on the label and packaging.

Upon removal from the refrigerator, the vaccine is stable for 8 hours at 21°C.

DO NOT FREEZE; discard if vaccine has been frozen.

DOSAGE FORMS, COMPOSITION AND PACKAGING

The vaccine is available in prefilled syringes (in packages of 1 and 10).

BOOSTRIX[®] (combined diphtheria, tetanus, acellular pertussis (adsorbed) vaccine) contains diphtheria toxoid, tetanus toxoid, three purified pertussis antigens [pertussis toxoid (PT), filamentous haemagglutinin (FHA) and pertactin (69 kDalton outer membrane protein)] adsorbed onto aluminum salts. The final vaccine is formulated in saline.

BOOSTRIX[®] meets the World Health Organization requirements for manufacture of biological substances and for diphtheria and tetanus vaccines.

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

Drug Substance:

Proper name: Combined diphtheria, tetanus, acellular pertussis (adsorbed)
vaccine for booster vaccination

Product Characteristics:

BOOSTRIX[®] (combined diphtheria, tetanus, acellular pertussis (adsorbed) vaccine) contains diphtheria toxoid, tetanus toxoid, three purified pertussis antigens [pertussis toxoid (PT), filamentous hemagglutinin (FHA) and pertactin (69 kDalton outer membrane protein)] adsorbed onto aluminum salts. The final vaccine is formulated in saline.

CLINICAL TRIALS

Immune response results to the diphtheria, tetanus, and acellular pertussis components in the comparative studies (dTpa versus dT) of booster vaccination with BOOSTRIX[®] (combined diphtheria, tetanus, acellular pertussis (adsorbed) vaccine) in different age groups are presented in Table 3 below.

Table 3 Percent Seroconversion following vaccination with BOOSTRIX[®]

Age at booster	Previous vaccinations	Results following vaccination with dTpa				
		Anti-PT*	Anti-FHA*	Anti-69kDa OMP*	Anti diphtheria [†]	Anti tetanus [†]
4-6 yrs	4 doses DTPa (primary plus booster)	98.3%	91.1%	94.8%	100%	100%
10-13 yrs	4 doses DTPw (primary plus booster)	92.1%	96.8%	98.9%	100%	100%
11-17 yrs	4 doses DTPw (primary plus booster)	100%	95.0%	100%	100%	100%
≥ 18 yrs**	Variable vaccination histories	95.0%	99.2%	98.5%	92.7%	99.8%

[†]Percentage of vaccinees having anti-diphtheria and anti-tetanus antibody titres > 0.1 IU/mL post vaccination.

*Percentage of vaccinees having anti-PT, anti-FHA, anti-69 kDa OMP antibody titres > cut off (i.e. 5 EL/mL) post vaccination for initially seronegative subjects; or the percentage of vaccinees having a 2 fold increase in anti-PT, anti-FHA, anti-69kDaOMP antibody titres post vaccination for initially seropositive subjects.

**Pooled results from 2 pivotal studies in adults.

Results of the comparative studies with commercial dT vaccines containing the same antigen content indicates that the degree and duration of protection with BOOSTRIX[®] would not be different from those obtained with these vaccines.

Pertussis

One month post vaccination, the overall response rate for each of the three individual pertussis antigens (pertussis toxoid, filamentous hemagglutinin, pertactin) was between 92.1 – 100%, 95.0 – 99.8% and 97.9 – 100%, respectively.

The pertussis antigens contained in BOOSTRIX[®] are an integral part of the pediatric acellular pertussis combination vaccine (INFANRIX[™]), for which efficacy after primary vaccination has been demonstrated in a household contact efficacy study. The antibody titres to all 3 pertussis components following vaccination with BOOSTRIX[®] are higher than those observed during the household contact efficacy trial. Based on these comparisons, BOOSTRIX[®] provides protection against pertussis, however the degree and duration of protection afforded by the vaccine are undetermined.

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PART III: CONSUMER INFORMATION

BOOSTRIX®

Combined diphtheria, tetanus, acellular pertussis (adsorbed) vaccine for booster vaccination

This leaflet is part III of a three-part "Product Monograph" published when BOOSTRIX® (Combined diphtheria, tetanus, acellular pertussis (adsorbed) vaccine for booster vaccination) was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about BOOSTRIX®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

BOOSTRIX® is a vaccine used in adults and children 4 years of age and above for protection against diphtheria, tetanus (lockjaw) and pertussis (whooping cough).

Vaccination is the best way to protect against these diseases.

What it does:

The vaccine works by causing the body to produce its own protection (antibodies) against these diseases.

When it should not be used:

Do not use BOOSTRIX® if:

- you or your child has previously had any allergic reaction to BOOSTRIX®, or any ingredient contained in this vaccine. The active substances and other ingredients in BOOSTRIX® are listed below. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.
- you or your child has previously had an allergic reaction to any vaccine against diphtheria, tetanus or pertussis diseases.
- you or your child experienced problems of the nervous system within 7 days after previous vaccination with a vaccine against pertussis (whooping cough) disease.
- you or your child has a severe infection with a high temperature (over 40°C). A minor infection such as a cold should not be a problem, but talk to your doctor first.
- you are pregnant.

What the medicinal ingredient is:

The active substances contained in BOOSTRIX® are: combined diphtheria and tetanus toxoids, three purified pertussis toxoids [pertussis toxoid, filamentous haemagglutinin and pertactin (69 kiloDalton outer membrane protein)].

None of the components in the vaccine are infectious.

What the important nonmedicinal ingredients are:

Aluminum salts, sodium chloride, and water for injection.

What dosage form it comes in:

BOOSTRIX® is presented as a cloudy white sterile suspension in a single dose prefilled syringe.

WARNINGS AND PRECAUTIONS

BEFORE you use BOOSTRIX® talk to your doctor or pharmacist if:

- you or your child have a family history of convulsions.
- your child is suffering from neurological disorders, including infantile spasms, uncontrolled epilepsy or progressive encephalopathy (disease of brain).
- you or your child has a bleeding problem or bruises easily. BOOSTRIX® should be given with caution since bleeding may occur following vaccination.
- you or your child has a high temperature (over 38°C).
- you or your child has any known allergies.
- you or your child is taking any other medicine or has recently received any other vaccine.
- you or your child has any serious health problem.
- your child is younger than 4 years of age.
- you are pregnant or breastfeeding.

INTERACTIONS WITH THIS MEDICATION

Patients receiving immunosuppressive therapy or patients with immunodeficiency may not be fully protected against disease after receiving BOOSTRIX®.

PROPER USE OF THIS MEDICATION

Usual dose:

The dose of BOOSTRIX® (combined diphtheria, tetanus, acellular pertussis (adsorbed) vaccine) is 0.5 mL.

The doctor will give BOOSTRIX® as an injection into the muscle.

The vaccine should never be given into a vein.

Missed Dose:

If you or your child misses a scheduled injection, talk to your doctor and arrange another visit.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all vaccines, BOOSTRIX® may occasionally cause unwanted effects.

As with other vaccines, you or your child may feel pain at the injection site, or you may see some redness and swelling at this site. However, these reactions usually clear up within a few days.

Other side effects which can occur are:

- dizziness
- fever more than 38°C
- headache
- ill feeling
- sleepiness
- vomiting
- diarrhea

If these symptoms continue or become severe, tell the doctor or nurse.

As with all injectable vaccines, there is an extremely small risk of a severe allergic reaction. This can be recognized by symptoms such as itchy rash of the hands and feet, swelling of the eyes and face and difficulty in breathing or swallowing. Such reactions will usually occur before leaving the doctor's office, but in any event you should seek immediate treatment.

If you or your child develop any other symptom within days following the vaccination, tell your doctor as soon as possible.

Do not be alarmed by this list of possible side effects. It is possible that you or your child will have no side effects from vaccination.

This is not a complete list of side effects. For any unexpected effects while taking BOOSTRIX®, contact your doctor or pharmacist.

HOW TO STORE IT

Store BOOSTRIX® in a refrigerator at 2°C to 8°C.

Store in the original package in order to protect from light.
Do not freeze. Freezing destroys the vaccine.

Keep out of the reach and sight of children.

Do not use after the expiry date which is stated on the carton. The date for last use corresponds to the last day of that month mentioned.

REPORTING SUSPECTED SIDE EFFECTS

To monitor vaccine safety, the Public Health Agency of Canada collects information on serious and unexpected adverse events following vaccination. If you suspect you have had a serious or unexpected event following receipt of a vaccine you may notify the Public Health Agency of Canada:

By toll-free telephone: 1-866-844-0018

By toll-free fax: 1-866-844-5931

By email: caefi@phac-aspc.gc.ca

By regular mail:

Vaccine Safety

130 Colonnade Road

Ottawa, Ontario

K1A 0K9 Address Locator 6502A

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying the Public Health Agency of Canada. The Public Health Agency of Canada does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.gsk.ca>

or by contacting the sponsor,

GlaxoSmithKline Inc.

7333 Mississauga Road

Mississauga, Ontario

L5N 6L4

1-800-387-7374

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