NEW ZEALAND DATA SHEET

1. PRODUCT NAME

BOOSTRIX-IPV Combined diphtheria-tetanus-acellular pertussis (dTpa) and enhanced inactivated polio suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

BOOSTRIX-IPV contains diphtheria toxoid, tetanus toxoid, and three purified pertussis antigens [pertussis toxoid (PT), filamentous hemagglutinin (FHA) and pertactin (PRN/69 kiloDalton outer membrane protein)] adsorbed on aluminium salts. It also contains three types of inactivated polio viruses (type 1: Mahoney strain; type 2: MEF-1 strain; type 3: Saukett strain).

1 dose (0.5 mL) contains:

Diphtheria toxoid[1]	not less than 2 International Units (IU) (2.5 Lf)
Tetanus toxoid[1]	not less than 20 International Units (IU) (5 Lf)
Bordetella pertussis antigens	
Pertussis toxoid[1]	8 micrograms
Filamentous Haemagglutinin[1]	8 micrograms
Pertactin[1]	2.5 micrograms
Inactivated poliovirus	
type 1 (Mahoney strain)[2]	40 D-antigen unit
type 2 (MEF-1 strain)[2]	8 D-antigen unit
type 3 (Saukett strain)[2]	32 D-antigen unit
[1]adsorbed on aluminium hydroxide, hydrated ($Al(OH)_3$)	0.3 milligrams Al^{3+}
and aluminium phosphate ($AlPO_4$)	0.2 milligrams Al^{3+}

[2] propagated in VERO cells

The final vaccine also contains aluminium hydroxide and aluminium phosphate as adjuvants, sodium chloride, Medium 199, water for injections, and traces of neomycin sulfate and polymyxin sulfate.

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

For the full list of excipients, see section 6.1 List of excipients.

3. PHARMACEUTICAL FORM

Suspension for injection.

BOOSTRIX-IPV is a turbid white suspension presented in a prefilled syringe. Upon storage, a white deposit and clear supernatant can be observed. This is a normal finding.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BOOSTRIX-IPV is indicated for booster vaccination against diphtheria, tetanus, pertussis and poliomyelitis of individuals from the age of four years onwards (see section 4.2 Dose and method of administration).

BOOSTRIX-IPV is also indicated for passive protection against pertussis in early infancy following maternal immunisation during pregnancy (see Section 4.2 Dose and method of administration, Section 4.6 Fertility, pregnancy and lactation and 5.1 Pharmacodynamic properties).

BOOSTRIX-IPV is not intended for primary immunisation.

4.2 Dose and method of administration

Dose

A single 0.5 mL dose of the vaccine is recommended.

BOOSTRIX-IPV may be administered from the age of four years onwards. BOOSTRIX-IPV should be administered in accordance with official recommendations and/or local practice regarding the use of vaccines that provide low (adult) dose diphtheria toxoid plus tetanus toxoid in combination with pertussis and poliomyelitis antigens.

BOOSTRIX-IPV can be administered to pregnant women during the second or the third trimester in accordance with official recommendations (see Section 4.1 Indications, Section 4.6 Fertility, pregnancy and lactation and 5.1 Pharmacodynamic properties)

BOOSTRIX-IPV can be used in the management of tetanus prone injuries in persons who have previously received a primary vaccination series of tetanus toxoid vaccine. Tetanus immunoglobulin should be administered concomitantly in accordance with official recommendations.

Repeat vaccination against diphtheria, tetanus and poliomyelitis should be performed at intervals as per official recommendations.

Method of administration

BOOSTRIX-IPV is for deep intramuscular injection preferably in the deltoid region (see Section 4.4 Special warnings and precautions for use).

4.3 Contraindications

BOOSTRIX-IPV should not be administered to subjects with known hypersensitivity to any component of the vaccine (see section 6.1 List of excipients) or to subjects having shown signs of hypersensitivity after previous administration of diphtheria, tetanus, pertussis or poliomyelitis vaccines.

BOOSTRIX-IPV contains traces of neomycin and polymyxin. The vaccine should not be used in subjects with known hypersensitivity to neomycin and polymyxin.

BOOSTRIX-IPV is contraindicated if the subject has experienced an encephalopathy of unknown aetiology, occurring within 7 days following previous vaccination with pertussis-containing vaccine. In these circumstances, pertussis vaccination should be discontinued and the vaccination course should be continued with diphtheria, tetanus and poliomyelitis vaccines.

BOOSTRIX-IPV should not be administered to subjects who have experienced neurological complications following an earlier immunisation against diphtheria and/or tetanus (for convulsions or hypotonic-hyporesponsive episodes, see section 4.4 Special warnings and precautions for use).

4.4 Special warnings and precautions for use

Vaccination should be preceded by a review of the medical history (especially with regard to previous vaccination and possible occurrence of undesirable events).

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic reaction following the administration of the vaccine.

As with other vaccines, administration of BOOSTRIX-IPV 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 are known to have occurred in temporal relation to receipt of pertussis-containing vaccine in infancy, the decision to give subsequent doses of pertussis-containing vaccines should be carefully considered:

- Temperature of ≥ 40.0°C within 48 hours of vaccination, not due to another identifiable cause.
- Collapse or shock-like state (hypotonic-hyporesponsiveness 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.

There may be circumstances, such as a high incidence of pertussis, when the potential benefits outweigh possible risks.

In children with progressive neurological disorders, including infantile spasms, uncontrolled epilepsy or progressive encephalopathy, it is better to defer pertussis (Pa or Pw) immunisation 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.

BOOSTRIX-IPV should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects. If in accordance with official recommendations, the vaccine may need to be administered subcutaneously to these subjects. With both routes of administration, firm pressure should be applied to the injection site (without rubbing) for at least two minutes.

BOOSTRIX-IPV should in no circumstances be administered intravascularly.

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

Human Immunodeficiency Virus (HIV) infection is not considered as a contraindication.

The expected immunological response may not be obtained after vaccination of immunosuppressed patients.

Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. It is important that procedures are in place to avoid injury from faints.

As with any vaccine, a protective immune response may not be elicited in all vaccines.

4.5 Interaction with other medicines and other forms of interaction

Concomitant use with other inactivated vaccines and with immunoglobulin is unlikely to result in interference with the immune responses.

When considered necessary, BOOSTRIX-IPV can be given concomitantly with other vaccines or immunoglobulins.

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

4.6 Fertility, pregnancy and lactation

Pregnancy

BOOSTRIX-IPV can be used during the second or third trimester of pregnancy in accordance with official recommendations.

For data relating to the prevention of pertussis disease in infants born to women vaccinated during pregnancy, see section 5.1 Pharmacodynamic properties.

Safety data from a randomised controlled clinical trial (341 pregnancy outcomes) and from a prospective observational study (793 pregnancy outcomes) where BOOSTRIX (dTpa component of BOOSTRIX-IPV) was administered to pregnant women during the third trimester have shown no vaccine related adverse effect on pregnancy or on the health of the foetus/newborn child.

Safety data from prospective clinical studies on the use of BOOSTRIX-IPV or BOOSTRIX during the first and second trimester of pregnancy are not available.

Data from post-marketing surveillance where pregnant women were exposed to BOOSTRIX-IPV or to BOOSTRIX in the second or the third trimester have shown no vaccine related adverse effect on pregnancy or on the health of the foetus/newborn child.

As with other inactivated vaccines, it is not expected that vaccination with BOOSTRIX-IPV harms the foetus at any trimester of pregnancy.

Non-clinical data obtained with BOOSTRIX-IPV reveal no specific hazard for humans based on conventional studies of embryo-foetal development in rats and rabbits, and also of parturition and postnatal toxicity in rats (up to the end of the lactation period).

Breast-feeding

The safety of BOOSTRIX-IPV when administered to breast-feeding women has not been evaluated.

It is unknown whether BOOSTRIX-IPV is excreted in human breast milk.

BOOSTRIX-IPV should only be used during breast-feeding when the possible advantages outweigh the potential risks.

Fertility

No human data available. Non-clinical data obtained with BOOSTRIX-IPV reveal no specific hazard for humans based on conventional studies of female fertility in rats and rabbits.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Summary of the safety profile

The safety profile presented below is based on data from clinical trials where BOOSTRIX-IPV was administered to 908 children (from 4 to 9 years of age) and 955 adults, adolescents and children (above 10 years of age).

The most common events occurring after vaccine administration were local injection site reactions (pain, redness and swelling) reported by 31.3 – 82.3% of subjects overall. These had their onset within the first day after vaccination. All resolved without sequelae.

Tabulated list of adverse reactions

Adverse reactions reported are listed according to the following frequency:

Very common ≥1/10

Common ≥1/100 and <1/10

Uncommon ≥1/1000 and <1/100

Rare ≥1/10,000 and <1/1000

Very rare <1/10,000

Children from 4 to 9 years of age

Blood and lymphatic system disorders

Uncommon: lymphadenopathy

Metabolism and nutrition disorders

Common: anorexia

Psychiatric disorders

Common: irritability

Uncommon: sleep disorder, apathy

Nervous system disorders

Very common: somnolence

Common: headache

Respiratory, thoracic and mediastinal disorders

Uncommon: dry throat

Gastrointestinal disorders

Uncommon: diarrhoea, vomiting, abdominal pain, nausea

General disorders and administration site conditions

Very common: injection site reactions (including pain, redness and swelling)

Common: fever ≥ 37.5 °C (including fever > 39°C), injection site reactions (such as haemorrhage)

Uncommon: fatigue

Adults, adolescents and children from the age of 10 years onwards

Infections and infestations

Uncommon: oral herpes

Blood and lymphatic system disorders

Uncommon: lymphadenopathy

Metabolism and nutrition disorders

Uncommon: decreased appetite

Nervous system disorders

Very common: headache

Uncommon: paraesthesia, somnolence, dizziness

Respiratory, thoracic and mediastinal disorders

Uncommon: asthma

Gastrointestinal disorders

Common: gastrointestinal disorders

Skin and subcutaneous tissue disorders

Uncommon: pruritus

Musculoskeletal and connective tissue disorders

Uncommon: myalgia, arthralgia

General disorders and administration site conditions

Very common: injection site reactions (including pain, redness and swelling), fatigue

Common: fever ≥ 37.5 °C, injection site reactions (such as haematoma)

Uncommon: fever > 39 °C, chills, pain

The following adverse reactions were additionally reported during clinical trials with GlaxoSmithKline's other reduced-antigen content diphtheria-tetanus-acellular pertussis

vaccine (BOOSTRIX) where BOOSTRIX was administered to 839 children (from 4 to 9 years of age) and 1931 adults, adolescents and children (above 10 years of age):

Children from 4 to 9 years of age

Infections and infestations

Uncommon: upper respiratory tract infection

Nervous system disorders

Uncommon: disturbances in attention

Eye disorders

Uncommon: conjunctivitis

Gastrointestinal disorders

Common: gastrointestinal disorders

Skin and subcutaneous tissue disorders

Uncommon: rash

General disorders and administration site conditions

Uncommon: injection site reactions (such as induration), pain

Adults, adolescents and children from the age of 10 years onwards

Infections and infestations

Uncommon: upper respiratory tract infection, pharyngitis

Nervous system disorders

Uncommon: syncope

Respiratory, thoracic and mediastinal disorders

Uncommon: cough

Gastrointestinal disorders

Common: nausea

Uncommon: diarrhoea, vomiting

Skin and subcutaneous tissue disorders

Uncommon: hyperhidrosis, rash

Musculoskeletal and connective tissue disorders

Uncommon: joint stiffness, musculoskeletal stiffness

General disorders and administration site conditions

Very common: malaise

Common: injection site reactions (such as injection site mass and injection site abscess sterile)

Uncommon: influenza like illness

Reactogenicity after a repeat dose of BOOSTRIX-IPV or BOOSTRIX

Subjects fully primed with 4 doses of DTPa followed by BOOSTRIX-IPV at around 4-8 years of age show no increased reactogenicity after the second BOOSTRIX-IPV dose administered 5 years later.

Subjects fully primed with 4 doses of DTPw followed by a BOOSTRIX-IPV around 10 years of age show an increase of local reactogenicity after an additional Boostrix dose administered 10 years later.

Post Marketing Data

Immune system disorders

Very rare: allergic reactions, including anaphylactic and anaphylactoid reactions

General disorders and administration site conditions

Rare: injection site induration

The following adverse reactions were additionally reported during post marketing surveillance after vaccination with GlaxoSmithKline's other reduced-antigen content diphtheria-tetanus-acellular pertussis vaccine (BOOSTRIX):

Blood and lymphatic system disorders

Rare: angioedema

Nervous system disorders

Rare: convulsions (with or without fever)

Skin and subcutaneous tissue disorders

Rare: urticaria

General disorders and administration site conditions

Rare: extensive swelling of the vaccinated limb, asthenia

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions via: https://nzphvc.otago.ac.nz/reporting.

4.9 Overdose

Cases of overdose have been reported during post-marketing surveillance. Adverse events following overdosage, when reported, were similar to those reported with normal vaccine administration.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Bacterial vaccines combined, ATC code: J07CA.

Mechanism of action

Not applicable.

Clinical efficacy and safety

Immune response

One month post vaccination with BOOSTRIX-IPV, immune responses in 1608 subjects were the following:

Antigen	Response (% vaccinees)	Adults, adolescents and children from the age of 4 years onwards*
Diphtheria	≥ 0.1 IU/ml	83.5 – 100%
Tetanus	≥ 0.1 IU/ml	99.6 – 100%
Pertussis		
Pertussis toxoid	Vaccine response	84.0 – 94.0%
Filamentous haemagglutinin	Vaccine response	90.1 – 97.2%
Pertactin	Vaccine response	90.4 – 96.7%
Inactivated poliomyelitis		
Type 1	Seroprotection ≥ 8	99.6 – 100%
Type 2	Seroprotection ≥ 8	99.6 – 100%
Type 3	Seroprotection ≥ 8	99.1 – 100%

*In clinical studies, seroprotection and vaccine response rates to all antigens after a booster dose of BOOSTRIX-IPV were similar to the licensed controlled vaccines studied.

As with other adult-type Td vaccines, BOOSTRIX-IPV induces higher seroprotection rates and higher titres of both anti-D and anti-T antibodies in children and adolescents as compared to adults.

The pertussis antigens contained in BOOSTRIX-IPV are an integral part of the paediatric acellular pertussis combination vaccine (INFANRIX), for which efficacy after primary vaccination has been 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%.

- an NIH sponsored efficacy study performed in Italy (2, 4, 6 months schedule).

The vaccine efficacy was found to be 84%. In a follow-up of the same cohort, efficacy persisted undiminished up to 5 years after completion of primary vaccination without administration of a booster dose against pertussis.

This study assessed duration of protection of INFANRIX given in a 3-dose schedule to infants. A similar duration of protection cannot be assumed to apply to older children or adults given a single dose of BOOSTRIX-IPV, regardless of previous vaccination against pertussis.

Although the protective efficacy of BOOSTRIX-IPV has not been demonstrated in adolescents and adult age groups, vaccinees in these age groups who received BOOSTRIX-IPV achieved anti-pertussis antibody titres greater than those in the German household contact study where the protective efficacy of INFANRIX was 88.7%.

There are currently no data which demonstrate a reduction of transmission of pertussis after immunisation with BOOSTRIX-IPV. However, it could be expected that immunisation of immediate close contacts of newborn infants, such as parents, grandparents healthcare workers and childcare workers would reduce exposure of pertussis to infants not yet adequately protected through immunisation.

Passive protection against pertussis in infants (below 3 months of age) born to mothers vaccinated during pregnancy

In a randomised, cross-over, placebo-controlled study, higher pertussis antibody concentrations were demonstrated at delivery in the cord blood of babies born to mothers vaccinated with BOOSTRIX (N=291) versus placebo (N=292) during the third trimester of pregnancy. The concentrations of antibodies against the pertussis antigens PT, FHA and PRN were respectively 8, 16 and 21 times higher in the cord blood of babies born to vaccinated mothers versus controls. These antibody titres may provide passive protection against pertussis, as shown by observational effectiveness studies.

Immunogenicity in infants and toddlers born to mothers vaccinated during pregnancy

In follow-up trials in more than 500 infants and toddlers born to vaccinated mothers, clinical data did not show clinically relevant interference between maternal vaccination with BOOSTRIX and the infant and toddler response to diphtheria, tetanus, hepatitis B, inactivated polio virus, *Haemophilus influenzae* type b or pneumococcal antigens. Although lower concentrations of antibodies against some pertussis antigens were observed post primary and post booster vaccination, 92.1 - 98.1% of subjects born to vaccinated mothers showed a booster response against all pertussis antigens. Current epidemiological data on pertussis disease do not suggest any clinical relevance of this immune interference.

Effectiveness in the protection against pertussis disease in infants born to women vaccinated during pregnancy

BOOSTRIX or BOOSTRIX-IPV vaccine effectiveness (VE) was evaluated in three observational studies, in UK, Spain and Australia. The vaccine was used during the third trimester of pregnancy to protect infants below 3 months of age against pertussis disease, as part of a maternal vaccination programme.

Details of each study design and results are provided below.

Study location	**Vaccine**	**Study design**	**Vaccination Effectiveness (VE)**
UK	BOOSTRIX-IPV	Retrospective, screening method	88% (95% CI: 79, 93)
Spain	BOOSTRIX	Prospective, matched case-control	90.9% (95% CI: 56.6, 98.1)

Study location	Vaccine	Study design	Vaccination Effectiveness (VE)
Australia	BOOSTRIX	Prospective, matched case-control	69% (95% CI: 13, 89)

CI: confidence interval

If maternal vaccination occurs within two weeks before delivery, VE in the infant may be lower than the figures in the table.

Persistence of immunity to diphtheria, tetanus, pertussis and polio

Five years following vaccination with BOOSTRIX-IPV, the following seroprotection / seropositivity rates were observed in 344 children from the age of 4 onwards:

Antigen	Seroprotection/seropositivity	Children from the age of 4 years onwards (% vaccinees)
Diphtheria	≥ 0.1 IU/ml	89.4%
	≥ 0.016 IU/ml*	98.2%
Tetanus	≥ 0.1 IU/ml	98.5%
Pertussis Pertussis toxoid Filamentous haemagglutinin Pertactin	≥ 5 EL.U/ml	 40.9% 99.7% 97.1%
Poliovirus type 1 Poliovirus type 2 Poliovirus type 3	≥ 8 ED50	98.8% 99.7% 97.1%

*Percentage of subjects with antibody concentrations associated with protection against disease (≥ 0.1 IU/ml by ELISA assay or ≥ 0.016 IU/ml by an in-vitro Vero-cell neutralisation assay).

The following seroprotection / seropositivity rates for diphtheria, tetanus and pertussis were observed 3 to 3.5 years, 5 to 6 years and 10 years following vaccination with BOOSTRIX (dTpa component of BOOSTRIX-IPV*)* in children, adolescents and adults:

Antigen	Seroprotection/ seropositivity	Adults and adolescents from the age of 10 years onwards (% vaccinees)					
		3-3.5 years persistence		5 years persistence		10 years persistence	
		Adult	Adole-scent	Adult	Adole-scent	Adult	Adole-scent
Diphtheria	≥ 0.1 IU/ml*	71.2%	91.6%	84.1%	86.8%	64.6%	82.4%
	≥ 0.016 IU/ml*	97.4%	100%	94.4%	99.2%	89.9%	98.6%
Tetanus	≥ 0.1 IU/ml	94.8%	100%	96.2%	100%	95.0%	97.3%
Pertussis Pertussis toxoid Filamentous haemagglutinin Pertactin	≥ 5 EL.U/ml	90.6% 100% 94.8%	81.6% 100% 99.2%	89.5% 100% 95.0%	76.8% 100% 98.1%	85.6% 99.4% 95.0%	61.3% 100% 96.0%

* Percentage of subjects with antibody concentrations associated with protection against disease (≥ 0.1 IU/ml by ELISA assay or ≥ 0.016 IU/ml by an in-vitro Vero-cell neutralisation assay).

BOOSTRIX-IPV administered in subjects ≥40 years of age with an incomplete, unknown or no history of a primary series of diphtheria and tetanus toxoid vaccination history induced an antibody response against pertussis and protected against tetanus and diphtheria in the majority of cases.

Two subsequent doses maximised the vaccine response against diphtheria and tetanus when administered at one and six months.

Immune response after a repeat dose of BOOSTRIX-IPV

The immunogenicity of BOOSTRIX-IPV, administered 5 years after a previous booster dose of BOOSTRIX-IPV at 4 to 8 years of age, has been evaluated. One month post vaccination, ≥ 99 % of subjects were seropositive against pertussis and seroprotected against diphtheria, tetanus and all three polio types.

The immunogenicity of BOOSTRIX, administered 10 years after a previous booster dose with BOOSTRIX or reduced-antigen content diphtheria, tetanus and acellular pertussis vaccines has been evaluated in adults. One month after the decennial BOOSTRIX dose, ≥99 % of subjects were seroprotected against diphtheria and tetanus and all were seropositive for antibodies against pertussis antigens PT, FHA and PRN.

5.2 Pharmacokinetic properties

Evaluation of pharmacokinetic properties is not required for vaccines.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of safety and toxicity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Medium 199 (as stabilizer containing amino acids, mineral salts, vitamins and other substances)

Sodium chloride

Water for injections.

For adjuvants, see section 2.

6.2 Incompatibilities

BOOSTRIX-IPV should not be mixed with other vaccines in the same syringe.

6.3 Shelf life

The shelf life of the vaccine is 3 years.

The expiry date of the vaccine is indicated on the label and packaging.

6.4 Special precautions for storage

BOOSTRIX-IPV should be stored at +2°C to +8°C.The vaccine should not be frozen. Discard if it has been frozen.

Protect from light.

6.5 Nature and contents of container

0.5 mL of suspension in a pre-filled syringe (type I glass) with a plunger stopper (butyl rubber) and a rubber tip cap. The tip cap and rubber plunger stopper are not made with natural rubber latex.

Pack size: 1, 10

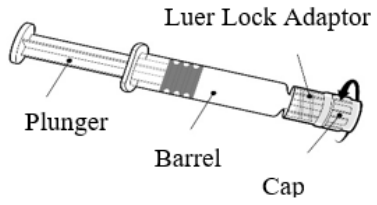
Not all pack sizes may be distributed in New Zealand.

6.6 Special precautions for disposal and other handling

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, do not administer the vaccine.

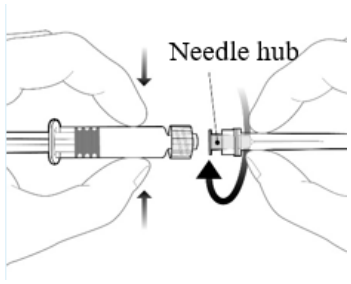
Upon removal from refrigerator, the vaccine is stable for 8 hours at + 21°C.

Instructions for the pre-filled syringe



Hold the syringe by the barrel and not the plunger.

Unscrew the syringe cap by twisting it anticlockwise.



To attach the needle, connect the hub to the Luer Lock Adaptor and rotate a quarter turn clockwise until you feel it lock.

Do not pull the syringe plunger out of the barrel. If it happens, do not administer the vaccine.

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MEDICINE SCHEDULE

Prescription Medicine

8. SPONSOR

GlaxoSmithKline NZ Limited
Private Bag 106600
Downtown
Auckland
NEW ZEALAND

Phone: (09) 367 2900
Facsimile: (09) 367 2910

9. DATE OF FIRST APPROVAL

Date of publication in the New Zealand Gazette of consent to distribute the medicine:
18 August 2005

10. DATE OF REVISION OF THE TEXT

16 March 2023

Summary table of changes:

Section changed	Summary of new information
6.5	Updated information regarding the pre-filled syringe container
6.6	Added instructions for using the pre-filled syringe

Version 13.0