AUSTRALIAN PRODUCT INFORMATION

INFANRIX IPV (combined diphtheria, tetanus, acellular pertussis (DTPa) and inactivated poliovirus vaccine) suspension for injection

1 NAME OF THE MEDICINE

Combined diphtheria, tetanus, acellular pertussis (DTPa) and inactivated poliovirus vaccine.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose (0.5 mL) contains:

Diphtheria toxoid[1]	not less than 30 International units (25 Lf)
Tetanus toxoid[1]	not less than 40 International units (10 Lf)
Bordetella pertussis antigens	
Pertussis toxoid (PT)[1]	25 micrograms
Filamentous Haemagglutinin (FHA)[1]	25 micrograms
Pertactin (PRN)[1]	8 micrograms
Poliovirus (inactivated) (IPV)	
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 hydrate ($Al(OH)_3$)	0.5 milligrams Al^{3+}

[2]propagated in VERO cells

The diphtheria and tetanus toxoids are obtained by formaldehyde treatment of purified Corynebacterium diphtheriae and Clostridium tetani toxins. The acellular pertussis vaccine components are obtained by extraction and purification from phase I Bordetella pertussis cultures, followed by irreversible detoxification of the pertussis toxin by glutaraldehyde and formaldehyde treatment, and formaldehyde treatment of FHA and pertactin. The three polioviruses are cultivated on a continuous VERO cell line, purified and inactivated with formaldehyde.

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.

INFANRIX IPV vaccine meets the World Health Organisation requirements for manufacture of biological substances, of diphtheria, tetanus, pertussis and combined vaccines, and of inactivated poliomyelitis vaccines.

List of excipients with known effect

INFANRIX IPV also contains residual amounts of neomycin sulfate and polymyxin B sulfate, which are carried over from the manufacturing process.

For the full list of excipients, see Section 6.1 LIST OF EXCIPIENTS.

This medicine contains less than 1 mmol (39 mg) per dose of potassium and less than 1 mmol (23 mg) per dose of sodium, i.e., essentially 'potassium-free' and 'sodium-free'.

3 PHARMACEUTICAL FORM

INFANRIX IPV vaccine is a sterile suspension for injection.

INFANRIX IPV is presented as a turbid white suspension. Upon storage, a white deposit and clear supernatant can be observed.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

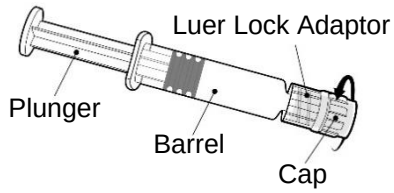
INFANRIX IPV is indicated for use in a three dose primary schedule for immunisation of infants from 6 weeks of age and over, against diphtheria, tetanus, pertussis and poliomyelitis.

INFANRIX IPV is also indicated as a single booster dose for children, up to and including 6 years of age, who have previously been immunised against DTP and polio.

4.2 DOSE AND METHOD OF ADMINISTRATION

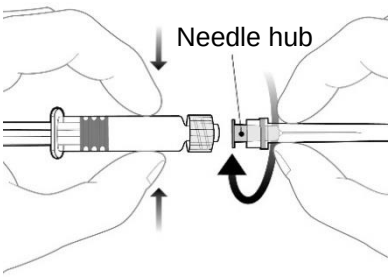
All parenteral drug and vaccine products should be inspected visually for any particulate matter or discolouration prior to administration. Before use of INFANRIX IPV, the vaccine should be well shaken to obtain a homogenous turbid suspension. Discard the vaccine if it appears otherwise. The vaccine should be administered immediately after opening.

<u>Instructions for the pre-filled syringe</u>



Hold the syringe by the barrel, not by 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.

Dosage

Each dose consists of a 0.5 mL ready to use sterile suspension.

Administration

INFANRIX IPV is administered by deep intramuscular injection.

For infants, the preferred site of injection is the anterolateral aspect of the thigh because of the small size of their deltoid muscle. In older children, the booster vaccination should be administered in the deltoid region of the arm.

The recommended dose (0.5 mL) of vaccine must be administered. Each dose of INFANRIX IPV is for single use only. Any residual vaccine must be discarded.

INFANRIX IPV VACCINE SHOULD NEVER BE ADMINISTERED INTRAVENOUSLY.

Immunisation Schedule

Primary

The primary vaccination course consists of three doses of INFANRIX IPV. INFANRIX IPV is recommended for administration at 2, 4 and 6 months of age. An interval of at least 1 month should be maintained between subsequent doses.

Booster

A single booster dose of INFANRIX IPV can be given up to and including 6 years of age.

4.3 CONTRAINDICATIONS

INFANRIX IPV should not be administered to subjects with known hypersensitivity to the active substances or to any of the excipients or residues (see Section 2 QUALITATIVE AND QUANTITATIVE COMPOSITION and Section 6.1 LIST OF EXCIPIENTS).

INFANRIX IPV should not be administered to subjects having shown signs of hypersensitivity after previous administration of diphtheria, tetanus, pertussis, or inactivated polio vaccines.

INFANRIX IPV is contraindicated if the child has experienced an encephalopathy of unknown aetiology occurring within 7 days following previous vaccination with a pertussis

containing vaccine. In these circumstances pertussis vaccination should be discontinued and the vaccination should be continued with diphtheria-tetanus and polio vaccines.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

INFANRIX IPV should under no circumstances be administered intravenously.

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

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.

If any of the following events are known to have occurred in temporal relation to receipt of whole cell or acellular pertussis-containing vaccine, the decision to give further doses of vaccine containing the pertussis component should be carefully considered. There may be circumstances, such as a high incidence of pertussis, when the potential benefits of vaccination outweigh the possible risks, particularly since these events are not associated with permanent sequelae.

- Temperature of $\geq$ 40.0°C within 48 hours, not due to another identifiable cause.
- Collapse or shock-like state (hypotonic-hyporesponsive episode) within 48 hours of vaccination.
- Persistent, inconsolable crying lasting $\geq$ 3 hours, occurring within 48 hours of vaccination.
- Convulsions with or without fever, occurring within 3 days of vaccination.

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.

A history of febrile convulsions, a family history of convulsions, a family history of Sudden Infant Death Syndrome (SIDS) or a family history of an adverse event following DTPa and/or IPV vaccination do not constitute contra-indications.

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

INFANRIX 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. Firm pressure should be applied to the injection site (without rubbing) for at least two minutes.

INFANRIX IPV contains traces of neomycin sulfate and polymyxin sulfate. The vaccine should be used with caution in patients with known hypersensitivity to one of these antibiotics.

Human Immunodeficiency Virus (HIV) infection is not considered a contra-indication to INFANRIX IPV vaccination. However in patients with immunodeficiency or in patients receiving immunosuppressive therapy, the expected immunologic response may not be achieved. No data currently exist on use of INFANRIX IPV in these patients.

The potential risk of apnoea and the need for respiratory monitoring for 48-72h should be considered when administering the primary immunisation series to very premature infants (born ≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.

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.

Use in the elderly

No data available

Paediatric use

See Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Effects on laboratory tests

No data available

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

It is routine practice in paediatric vaccination to co-administer different vaccines during the same session. Injectable vaccines should always be given at different injection sites.

INFANRIX IPV can be administered concomitantly with hepatitis B vaccine, and/or Haemophilus influenzae type b vaccine, the injections being administered at different injection sites. Routine simultaneous administration of Hib vaccine and hepatitis B vaccine may be performed for children who are at the recommended age to receive these vaccines.

Concomitant administration of INFANRIX IPV and the PRP-OMP type Hib vaccine, measles, mumps and rubella combined vaccine, and varicella vaccine has not been assessed in clinical studies. The Australian Immunisation Handbook accepts that these vaccines may be given at the same time if separate injection sites are used.

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

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available

Use in pregnancy

Adequate human data on use during pregnancy and adequate animal reproduction studies are not available.

Use in lactation

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

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Clinical Trial Experience

Adverse reactions associated with INFANRIX IPV vaccination have been evaluated in 13 clinical trials, with more than 2,400 doses administered. Adverse event data were actively collected using diary cards and by questioning the parents at clinic visits.

Events are listed within body systems and categorised by frequency according to the following definitions:

Frequencies per dose are defined as follows:

Very common: ≥ 1/10

Common: ≥ 1/100 and < 1/10

Uncommon: ≥ 1/1,000 and < 1/100

Rare: ≥ 1/10,000 and < 1/1,000

Very rare: < 1/10,000

Primary vaccination with INFANRIX IPV

Incidence (%) of general solicited symptoms reported within 48 hours following primary immunisation of infants with INFANRIX® IPV at a 3, 4.5, 6 month schedule

Solicited Symptoms	**% incidence** (N = 726)
Local Reactions:	
Pain at the injection site	16.3
Redness (>20 mm)	4.4
Swelling (>20 mm)	3.4
General Symptoms:	
Fever:	
Any[#]	6.1
Grade 3[@]	0.1

Loss of appetite	10.7
Restlessness	22.7
Unusual crying	18.2
Vomiting	6.5
Diarrhoea	11.6

N = Total number of doses administered over a 3 dose primary vaccination course
 # = A temperature of ≥ 37.5°C (axillary or oral) or ≥ 38°C (rectal)
@ = A temperature of > 39°C (axillary or oral) or > 39.5°C (rectal)

The following events were also reported in temporal association with vaccination in clinical trials evaluating the 3 dose primary vaccination schedules. It should be noted that causality has not necessarily been established for these events.

Events are listed within body systems and categorised by frequency according to the following definitions:

Frequencies per dose are defined as follows:

Very common: ≥ 1/10

Common: ≥ 1/100 and < 1/10

Uncommon: ≥ 1/1,000 and < 1/100

Rare: ≥ 1/10,000 and < 1/1,000

Very rare: < 1/10,000

Body as a whole:

Uncommon: bacterial infection, fungal injection, viral infection, herpes zoster (chicken pox), moniliasis

Cardiovascular:

Uncommon: haematoma

Central Nervous System:

Very Common: somnolence

Dermatological:

Uncommon: rash[3], dermatitis, dermatitis contact, eczema, rash erythematous, urticaria

Gastrointestinal:

Common: tooth ache, vomiting

Uncommon: dyspepsia, hiccup, abdominal pain, gastroenteritis, gastro-oesophageal reflux, constipation, flatulence

General disorders and administration site conditions:

Very common: redness, local swelling at injection site (≤ 50 mm), fever (> 38˚C)

Common: injection site mass (> 50 mm)[1], asthenia, injection site reactions including induration

Uncommon: diffuse swelling of the injected limb, sometimes involving the adjacent joint[1], fever (≥ 39.5˚C)

Nervous System:

Uncommon: insomnia

Psychiatric:

Very common: irritability

Respiratory:

Common: rhinitis, pharyngitis, upper respiratory tract infection

Uncommon: asthma, coughing[3], pneumonia, respiratory disorder, bronchitis[3]

Special senses:

Common: otitis media;

Uncommon: conjunctivitis

Urogenital:

Uncommon: pyelonephritis

Booster vaccination with INFANRIX IPV at 4-6 years of age

Incidence (%) of solicited symptoms reported within 48 hours from a study of booster immunisation with INFANRIX IPV at 4-6 years of age

	following primary immunisation (study A)	following primary and first booster immunisation (study B)
Solicited Symptoms	**% incidence** (*N = 210)	**% incidence** (*N = 73)
Local Reactions:		
Pain at the injection site:		
Any	71.4	82.2
Grade 3	2.9	5.5
Redness:		
Any	61.0	65.8
>50 mm	25.7	9.6
Swelling:		
Any	53.3	52.1
>50 mm	13.3	5.5

General Symptoms:		
Fever:		
Any[#]	21.0	9.6
Grade 3[@]	0.5	0.0
Irritability	16.7	13.7
Vomiting	not solicited	1.4
Diarrhoea	not solicited	2.7
Loss of appetite	19.0	12.3
Restlessness	not solicited	6.8
Sleeping more than usual/drowsiness	24.8	17.8

Note: Study A: Primary immunisation with DTPa-containing vaccines at 3, 5, 11 months of age; Study B: Primary and first booster immunisation with DTPw-IPV or DTPw-IPV/Hib vaccine
The occurrence and severity of symptoms was assessed using diary cards listing the events tabulated. "Not solicited" indicates that the event was not listed on the diary card for evaluation.
**N =Number of subjects*
 # = A temperature of ≥ 37.5°C (axillary or oral) or ≥ 38°C (rectal)
@ = A temperature of > 39°C (axillary or oral) or > 39.5°C (rectal)

The following events were also reported in temporal association with vaccination in clinical trials evaluating booster vaccination schedules. It should be noted that causality has not necessarily been established for these events.

Events are listed within body systems and categorised by frequency according to the following definitions:

Frequencies per dose are defined as follows:

Very common: ≥ 1/10

Common: ≥ 1/100 and < 1/10

Uncommon: ≥ 1/1,000 and < 1/100

Rare: ≥ 1/1,000 and < 1/10,000

Very rare: < 1/10,000

<u>Injection site:</u>

Very common: local swelling at the injection site (≤ 50 mm)

Common: local swelling at the injection site (>50 mm)[1], injection site reactions including induration.

Uncommon: diffuse swelling of the injected limb, sometimes involving the adjacent joint[1]

<u>Body as a whole:</u>

Common: asthenia, malaise;

Uncommon: viral infection

<u>Blood and lymphatic system disorders</u>:

Rare: Lymphadenopathy

Dermatological:

Common: pruritis

Uncommon: dermatitis allergic

Rare: urticaria,

Gastrointestinal:

Common: nausea, vomiting, diarrhoea

Uncommon: abdominal pain

Musculoskeletal:

Uncommon: myalgia

Nervous system disorders:

Very common: Headache (age range 6-13 years old), somnolence

Psychiatric disorders:

Very common: restlessness, crying abnormally

Respiratory:

Common: coughing[3], rhinitis, pharyngitis;

Uncommon: bronchitis[3]

Special senses:

Common: otitis media

Post-marketing Experience

During post marketing surveillance, other reactions have been reported in temporal association with INFANRIX IPV or with other DTPa-containing vaccines. None of the reactions were reported with a frequency higher than 0.01%.

Note that exact incidence rates cannot be calculated under post-marketing experience.

Administration site conditions:

Very rare: injection site mass, swelling of the entire injected limb[1], injection site vesicles.

Body as a whole:

Very rare: Allergic reactions (including rash and pruritus), including anaphylactic[3] and anaphylactoid reactions (including urticaria),

Blood and lymphatic system disorders:

Thrombocytopenia[2]

Dermatological:

Very rare: angioneurotic oedema.[3]

Neurological disorders:

Very rare: convulsions (with or without fever) within 2 to 3 days of vaccination, collapse or shock-like state (hypotonic-hyporesponsiveness episode).

Respiratory disorders:

Apnoea[3] (see Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE for apnoea in very premature infants (≤ 28weeks of gestation))

[1]Children primed with acellular pertussis vaccines are more likely to experience swelling reactions after booster administration in comparison with children primed with whole cell vaccines. Local swelling at the injection site (> 50 mm) and diffuse swelling may be more frequent (very common and common, respectively) when the booster dose is administered between 4 and 6 years. These reactions resolve over an average of 4 days.

[2]Reported with D and T vaccines

[3]Reported with GSK's DTPa containing vaccines

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Cases of overdose have been reported during post-marketing surveillance. Adverse events, when reported, are not specific but similar to adverse events reported with normal vaccine administration.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

INFANRIX IPV is providing immunity against diphtheria, tetanus, pertussis and poliovirus by inducing the production of antibodies and the ability to mount an immunological memory.

Clinical trials

More than 1,800 doses of *INFANRIX IPV* have been administered in clinical studies evaluating use in primary vaccination schedules. In addition, 721 doses have been administered as a single booster dose in infants and children ranging from 15 months to 13 years.

Immune response to the DT components:

One month after a 3 dose primary vaccination course with *INFANRIX IPV*, more than 99% of vaccinated infants had antibody titres of ≥ 0.1 IU/mL to both tetanus and diphtheria.

Following administration of a booster dose of *INFANRIX IPV*, more than 99.5% of children had antibody titres of ≥ 0.1 IU/mL for both antigens.

Antibody titres ≥ 0.1 IU/mL are deemed to correlate with seroprotection against diphtheria and tetanus.

Immune response to the Pa component:

One month after the 3-dose primary vaccination course with *INFANRIX IPV*, 100% of infants were seropositive (antibodies ≥ 5 EL.U/mL) for the three pertussis components (PT, FHA, pertactin). Overall response rates, for each of the three individual pertussis antigens were ≥ 94%. A vaccine response was defined as induction of antibodies to the individual pertussis antigens, taking into account the age and the pre-vaccination serological status of the subject.

In booster studies, a vaccine response was seen in ≥ 96.6% of vaccinees against the pertussis antigens; lower response rates were seen in studies where the pre-vaccination levels of antibodies were high. A vaccine response was defined as a post-vaccination titre ≥ 2x the pre-vaccination titre for subjects initially seropositive, and a titre ≥ the assay cut-off (5 EL.U/ml) for subjects initially seronegative. All subjects were seropositive one month after this dose.

Protective efficacy of the Pa component:

As the immune response to pertussis antigens following *INFANRIX IPV* administration is equivalent to that of *INFANRIX*, it can be assumed that the protective efficacy of the two vaccines will also be equivalent.

The clinical protection of the DTPa component, against WHO-defined typical pertussis (≥ 21 days of paroxysmal cough) was demonstrated in:

- a prospective blinded household contact study was 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 calculated to be 88.7%.
- a US National Institute of Health (NIH) sponsored efficacy study was performed in Italy (2, 4, 6 months schedule). This study determined the vaccine efficacy to be 84%. In a follow-up of the same cohort, the efficacy was confirmed for up to 4 years of age.

Immune response to the IPV component:

One month after the 3 dose primary vaccination course with *INFANRIX IPV*, the overall seropositivity for each of the three polio serotypes (type 1, 2 and 3) was ≥ 99.5%. Antibody titres ≥ 8 are deemed to correlate with seroprotection against poliomyelitis.

Following administration of a booster dose of *INFANRIX IPV*, 100% of children were seropositive for the three polio serotypes.

In all booster trials, vaccination with *INFANRIX IPV* induced a marked increase in antibody levels with respect to pre-booster values.

Geometric Mean Antibody Titres (GMTs) following primary immunisation with INFANRIX® IPV vaccine in children at 7 months of age

Antigen	Primary immunisation GMT [95% confidence interval]
Diphtheria Toxoid (N=203)	1.83 [1.69 – 1.98]
Tetanus Toxoid (N=193)	3.72 [3.47 – 3.99]
Pertussis Toxoid (N=198)	87.2 [81.7 – 93.0]
Pertussis FHA (N=188)	91.1 [80.6 – 102.9]
Pertactin (N=188)	166.6 [151.6 – 183.1]
Poliovirus Type 1 (N=174)	374.5 [326.8 – 429.1]
Poliovirus Type 2 (N=175)	406.1 [352.9 – 467.2]
Poliovirus Type 3 (N=175)	1115.0 [978.4 – 1270.6]

Note: Primary immunisation with DTPa-IPV vaccine at 3, 4.5, 6 months
IU = International Units; EL.U = ELISA Units; N = Number of subjects
Assay cut-offs for each antigen are as follows: D & T: ≥ 0.1IU/mL; PT, FHA & PRN: 5 EL.U/mL; POLIO types 1,2,3: ≥ 8.
The cut-off values for diphtheria, tetanus and polio correlate with seroprotection. Currently there are no known serological correlates for protection for the pertussis antigens.

Geometric Mean Antibody Titres (GMTs) from a study of booster immunisation with INFANRIX IPV at 4-6 years of age, following primary immunisation

Antigen	**Booster immunisation** **GMT** **(95% confidence interval)** **Pre-booster** **Post-booster**

Diphtheria Toxoid (N=201 [pre] and 208 [post])	0.08 (0.07-0.09)	6.24 (5.39 – 7.23)
Tetanus Toxoid (N=200 [pre] and 208 [post])	0.15 (0.12-0.17)	9.96 (8.79-11.28)
Pertussis Toxoid (N= 200 [pre] and 208 [post])	3.6 (3.2-4.0)	63.2 (56.1-71.2)
Pertussis FHA (N=201 [pre] and 208 [post])	30.0 (24.9-36.2)	735.2 (653.4-827.4)
Pertactin (N=201 [pre] and 208 [post])	27.2 (23.0-32.3)	995.6 (863.5-1147.9)
Poliovirus Type 1 (N=193 [pre] and 193 [post])	65.3 (49.9-85.4)	2096.0 (1817.6-2417.0)
Poliovirus Type 2 (N=194 [pre] and 197 [post])	41.4 (32.0-53.5)	1702.4 (1482.1-1955.4)
Poliovirus Type 3 N=192 [pre] and 189 [post])	23.5 (19.3-28.7)	2542.6 (2122.0-3046.5)

Note: Primary immunisation with DTPa-containing vaccines at 3, 5 and 11 months of age
N = Number of subjects; IU = International Units; EL.U = ELISA Units
Assay cut-offs for each antigen are as follows: D & T: ≥ 0.1IU/mL; PT, FHA & PRN: 5 EL.U/mL; POLIO types 1,2,3: ≥ 8.
The cut-off values for diphtheria, tetanus and polio correlate with seroprotection. Currently there are no known serological correlates for protection for the pertussis antigens.

Geometric Mean Antibody Titres (GMTs) from a study of booster immunisation with INFANRIX® IPV at 5-6 years of age, following primary and first booster immunisation

Antigen	**Booster immunisation GMT (95% confidence interval)**	
	Pre-booster	**Post-booster**
Diphtheria Toxoid (N=72 [pre] and 73 [post])	0.12 (0.09 – 0.15)	6.19 (4.83 – 7.93)
Tetanus Toxoid (N=72 [pre] and 73 [post])	0.25 (0.20 – 0.32)	13.58 (11.30 – 16.31)
Pertussis Toxoid (N=72 [pre] and 66 [post])	3.6 (3.0 – 4.3)	84.7 (62.5 – 114.9)
Pertussis FHA (N=70 [pre] and 72 [post])	31.8 (22.1 – 45.9)	1051.1 (898.3 – 1299.8)
Pertactin (N=72 [pre] and 73 [post])	16.8 (12.7 – 22.3)	820.1 (656.8 – 1024.0)
Poliovirus Type 1 (N=72)	15.6 (11.7 – 20.8)	1533.2 (1156.6 – 2032.2)

Poliovirus Type 2 (N=72 [pre] and 71 [post])	21.8 (16.3 – 29.0)	1053.4 (819.7 – 1353.6)
Poliovirus Type 3 (N=71)	44.4 (31.9 – 61.7)	1740.7 (1315.7 – 2303.0)

Note: Primary and first booster immunisation with DTPw-IPV or DTPw-IPV/Hib vaccine
N = Number of subjects; IU = International Units; EL.U = ELISA Units
Assay cut-offs for each antigen are as follows: D & T: ≥0.1IU/mL; PT, FHA & PRN: 5 EL.U/mL; POLIO types 1,2,3: ≥8.
The cut-off values for diphtheria, tetanus and polio correlate with seroprotection. Currently there are no known serological correlates for protection for the pertussis antigens.

5.2 PHARMACOKINETIC PROPERTIES

Not relevant to vaccines.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

The final vaccine also contains the excipients aluminium hydroxide hydrate, medium 199, sodium chloride and water for injections. The vaccine also contains the following residues: neomycin sulfate and polymyxin B sulfate.

6.2 INCOMPATIBILITIES

See Section 4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

INFANRIX IPV should be stored between +2°C and +8°C. DO NOT FREEZE. Discard if vaccine has been frozen. Protect from light.

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

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 with a rubber tip cap.

The tip cap and rubber plunger stopper of the pre-filled syringe are not made with natural rubber latex.

INFANRIX IPV is supplied in packs of 1 or packs of 10.

Not all pack sizes may be distributed in Australia.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

Not relevant to vaccines

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 4 – Prescription Only Medicine

8 SPONSOR

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street,

Abbotsford, Victoria, 3067

9 DATE OF FIRST APPROVAL

21 April 2009

10 DATE OF REVISION

17 July 2023

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
4.2	Introduction of pictograms for the pre-filled syringe
6.5	Update to description of syringe and cap, including a statement that tip cap and rubber plunger stopper are not made of natural rubber latex

Version 9.0