

PRODUCT MONOGRAPH

INFANRIX[®]-IPV

Diphtheria, tetanus, acellular pertussis and
inactivated poliomyelitis vaccine

Sterile suspension for injection

Active immunizing agent

GlaxoSmithKline Inc.
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INFANRIX®-IPV

Diphtheria, tetanus, acellular pertussis and
inactivated poliomyelitis vaccine

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
Intramuscular injection	Sterile suspension for injection/ not less than 25 limit of flocculation (Lf) [30 International Units (IU)] of diphtheria toxoid; 10 Lf (40 IU) of adsorbed tetanus toxoid; 25 µg of pertussis toxoid; 25 µg of filamentous haemagglutinin; 8 µg of pertactin adsorbed onto aluminum hydroxide (0.5 mg Al ³⁺); 40 D-antigen units (DU) type 1 poliovirus; 8 DU type 2 poliovirus; and 32 DU type 3 poliovirus per 0.5 mL dose.	Sodium chloride, aluminum salts, Medium 199 (as stabilizer including amino acids, mineral salts and vitamins), water for injections and trace amounts of neomycin and polymixin.

DESCRIPTION

INFANRIX®-IPV (diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine) contains diphtheria toxoid, tetanus toxoid, three purified pertussis antigens [pertussis toxoid (PT), filamentous haemagglutinin (FHA) and pertactin (69 kiloDalton (kDa) outer membrane protein)] adsorbed onto aluminium salts and purified inactivated poliovirus types 1, 2 and 3.

INFANRIX®-IPV meets the World Health Organization requirements for manufacture of biological substances.

INDICATIONS AND CLINICAL USE

INFANRIX[®]-IPV (diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine) is indicated:

- as a booster dose in children up to and including 6 years of age, who have previously been immunized with three or four doses of either diphtheria, tetanus and acellular pertussis (DTPa) vaccine or diphtheria, tetanus and whole-cell pertussis (DTPw) vaccine.

CONTRAINDICATIONS

INFANRIX[®]-IPV (diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine) should not be administered:

- to subjects with known hypersensitivity to any component of the vaccine (see DOSAGE FORMS, COMPOSITION AND PACKAGING).
- to subjects having shown signs of hypersensitivity after previous administration of diphtheria, tetanus, pertussis or poliomyelitis vaccines. Because of the uncertainty as to which component of the vaccine might be responsible, no further vaccination with any of these components should be given. Alternatively, because of the importance of tetanus vaccination, such individuals may be referred to an allergist for evaluation.
- if the child has experienced an encephalopathy of unknown etiology, 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.

The following do not constitute contraindications:

- a history of febrile convulsions.
- a family history of convulsive disorders.
- a family history of SIDS.
- a family history of an adverse event following INFANRIX[®]-IPV injection.
- Human Immunodeficiency Virus (HIV) infection.

Elective immunization of individuals over 6 months should be deferred during an outbreak of poliomyelitis.

WARNINGS AND PRECAUTIONS

General

INFANRIX[®] - IPV (diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine) should under no circumstances be administered intravenously.

As for all diphtheria, tetanus and pertussis vaccines, each injection should be given deep intramuscularly and each injection of the immunization series should be made into a different site.

Diphtheria toxoid may cause severe but transient local and febrile reactions in children and adults, the frequency increasing with age, the doses of toxoid and the number of doses given.

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.

As with other vaccines, the administration of INFANRIX[®] - IPV should be postponed in subjects suffering from moderate or severe illness with or without fever. The presence of minor illnesses with or without a low-grade fever are not a contraindication.

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, INFANRIX[®]-IPV may not protect 100% of individuals receiving the vaccine.

If any of the following events occur in temporal relation to receipt of DTPa or DTPw vaccine, the decision to give subsequent 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 outweigh possible risks, particularly since these events are not associated with permanent sequelae.

The following events were previously considered contraindications for DTPw and can now be considered general precautions:

- Temperature of $\geq 40.0^{\circ}\text{C}$ (rectal) 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.

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.

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.

Hematologic

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.

Immune

In patients receiving immunosuppressive therapy or patients with immunodeficiency an adequate immunologic response may not be achieved.

Sensitivity

INFANRIX[®]-IPV contains traces of neomycin and polymixin. The vaccine should be used with caution in patients with known hypersensitivity to one of these antibiotics.

Special Populations

Pregnant Women: Infanrix[®]-IPV is indicated for vaccination in children up to 6 years of age. Adequate human data on use during pregnancy and adequate animal reproduction studies are not available.

Nursing Women: Infanrix[®]-IPV is indicated for vaccination in children up to 6 years of age. Adequate human data on use during lactation and adequate animal reproduction studies are not available.

Pediatrics: DTPa vaccine should not be administered to persons 7 years of age or older because of the dangers of reactions to the diphtheria toxoid and pertussis antigens.

The potential risk of apnea and the need for respiratory monitoring for 48-72h should be considered when administering the primary immunization 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.

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.

In a controlled clinical trial in children between 15 and 20 months of age given a booster injection of INFANRIX[®]-IPV (diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine) given separately or mixed with Hib conjugate vaccine or of DTPw-IPV + Hib containing the traditional pertussis component, the incidence of local or systemic side effects reported within 48 hours considered to be vaccine-related is outlined in Table 1.

Table 1 Incidence of Local or Systemic Side Effects Reported within 48 hours considered to be Vaccine Related

Symptoms	INFANRIX [®] -IPV-Hib (both vaccines mixed)	INFANRIX [®] -IPV+ Hib (two vaccines injected separately)	DTPw- IPV + Hib
Local reactions:	%	%	%
pain (severe)	3.3	2.7	10.6
redness (>20mm)	16.4	18.9	31.9
swelling (>20mm)	4.9	5.4	19.1
Systemic reactions:	%	%	%
fever $\geq 38^{\circ}\text{C}$	18.0	8.1	44.7
unusual crying	6.6	0	19.1
loss of appetite	3.3	0	12.8
agitation	6.6	2.7	14.9

The safety profile presented below is based on data from more than 2200 subjects.

Very common: $\geq 10\%$

Appetite lost, restlessness, crying abnormal, irritability, headache¹, somnolence, injection site reactions such as pain, redness, local swelling at the injection site (≤ 50 mm), fever $\geq 38.0^{\circ}\text{C}$

Common: ≥ 1% and < 10%

Nausea¹, vomiting, diarrhea, local swelling at the injection site (>50 mm)⁴, asthenia, malaise¹, injection site reactions including induration

Uncommon: ≥ 0.1% and < 1%

Dermatitis allergic, diffuse swelling of the injected limb, sometimes involving the adjacent joint⁴, fever⁵ (>39.5°C)

Rare: ≥ 0.01% and < 0.1%

Lymphadenopathy¹, bronchitis², cough², urticaria, rash^{2,3}

Post-Market Adverse Drug Reactions

Blood and lymphatic system disorders

Thrombocytopenia⁶

Immune system disorders

Allergic reactions, including anaphylactic² and anaphylactoid reactions

Nervous system disorders

Collapse or shock-like state (hypotonic-hyporesponsiveness episode), convulsions (with or without fever) within 2 to 3 days of vaccination

Respiratory thoracic and mediastinal disorders

Apnea² [see section “Warnings and Precautions” for apnea in very premature infants (≤28 weeks of gestation)]

Skin and subcutaneous tissue disorders

Pruritus, angioneurotic oedema²

General disorders and administration site conditions

Swelling of the entire injected limb⁴, injection site vesicles

¹Reported only with booster vaccination

²Reported with GSK’s DTPa containing vaccines

³Uncommonly reported with booster vaccination

⁴Children 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.

⁵Commonly reported with booster vaccination

⁶Reported with D and T vaccines

DRUG INTERACTIONS

Drug-Drug Interactions

INFANRIX[®]-IPV (diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine) can be administered simultaneously with other pediatric vaccines provided that a different syringe and needle are used at separate sites.

Drug-Food Interactions

Interactions with food have not been established.

Drug-Herb Interactions

Interactions with herbal products have not been established.

Drug-Laboratory Interactions

Interactions with laboratory tests have not been established.

DOSAGE AND ADMINISTRATION

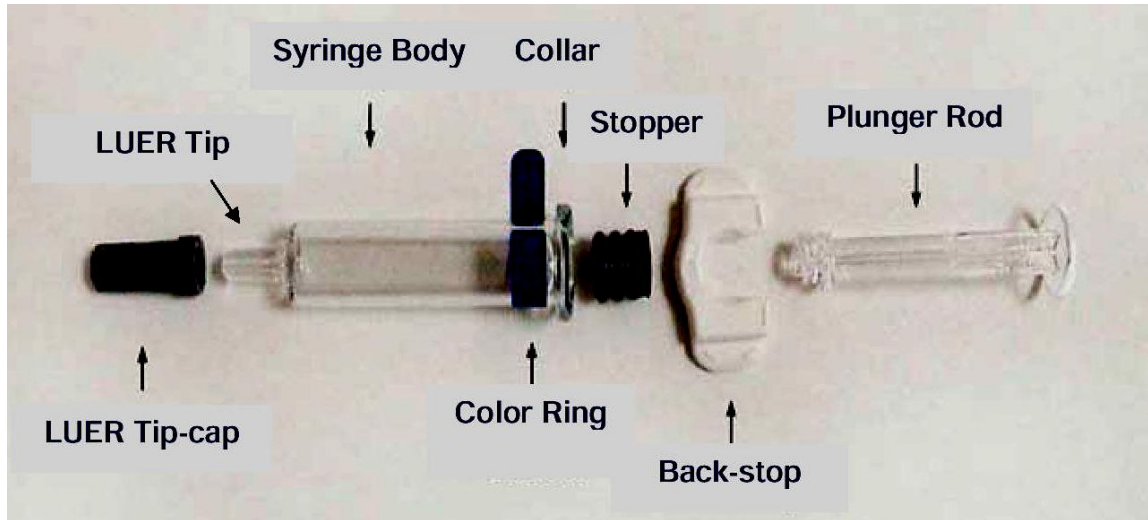
Recommended Dose

The Canadian Immunization Guide recommends a booster dose of diphtheria, tetanus, pertussis, poliomyelitis at 15 to 18 months of age, and a second booster dose of diphtheria, tetanus, pertussis and poliomyelitis at 4 to 6 years of age.

INFANRIX[®]-IPV (diphtheria, tetanus, pertussis and inactivated poliomyelitis vaccine) can be used alone for the first booster dose at 15 to 18 months of age and may also be mixed in the same syringe with HIBERIX[®] (*Haemophilus influenzae* type b) or other monovalent *Haemophilus influenzae* type b vaccines (conjugated to a tetanus protein carrier) for the second booster dose at 4 to 6 years of age. If for any reason primary immunization is delayed, the same booster interval may be used up to the seventh birthday.

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.



INFANRIX[®]-IPV should be inspected visually for any foreign particulate matter and/or variation of physical aspect prior to administration. In the event of either being observed, discard the vaccines.

INFANRIX[®]-IPV can be mixed in the same syringe with monovalent *Haemophilus influenzae* type b vaccine conjugated to a tetanus protein carrier initially used in primary immunization. INFANRIX[®]-IPV should not be mixed with any other vaccines in the same syringe, unless specified by the manufacturer.

The reconstituted vaccine is for **deep intramuscular** injection. Each injection of the primary immunization series should be made into a different site.

It is good clinical practice that in patients with thrombocytopenia or bleeding disorders the vaccine should be administered subcutaneously.

The vastus lateralis (mid-thigh laterally) is the preferred site of injection in infants. The deltoid muscle should be used as the injection site in children when the muscle has developed sufficiently to accommodate the vaccine. The site of injection should be prepared with a suitable antiseptic. Do not inject subcutaneously except in case of thrombocytopenia or bleeding disorder. **Never inject intravenously.**

OVERDOSAGE

For management of a suspected drug overdose, contact your regional Poison Control Centre.

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.

ACTION AND CLINICAL PHARMACOLOGY

INFANRIX[®]-IPV (diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine) contains pertussis toxoid (PT), filamentous haemagglutinin (FHA) and pertactin, antigens which are considered to play an important role in protection against pertussis disease.

Immune Response to DTPa-IPV Administered as a Booster Dose

Pertussis Antigens (PT - FHA - 69 kDa):

Before booster vaccination of children 15 to 24 months of age, the percentage of PT seronegative subjects ranged from 75 to 87% for three groups of vaccinees and between 17 and 33% for the FHA and 69 kDa fractions (group 1: DTPa-IPV+Hib as a single injection; group 2: DTPa-IPV+Hib separate injections; and group 3: DTPw-IPV+Hib single injection). After booster dose injection, the percentage of responsive subjects in the 3 groups for FHA and 69 kDa ranged from 92.9 to 100%. For the PT antigenic component, the percentage was slightly lower among DTPw-IPV vaccinees (87%) compared with 97 to 98% for recipients of DTPa-IPV. In subjects initially seronegative, the seroconversion rate (titre ≥ 5 EL.U/mL) was 100% for FHA and 69 kDa in groups 1 and 2 (DTPa-IPV) and group 3 (DTPw-IPV), compared with 97.9%, 100% and 85% for PT in groups 1, 2 and 3 respectively.

Diphtheria and Tetanus Toxoid Antigens:

Prior to booster injection of the vaccine, over 50% of subjects did not have diphtheria antibody titres ≥ 0.1 IU/mL; 3.5 to 6.5% did not have antibodies against tetanus. After the booster dose, all subjects had protective antibody levels of ≥ 0.1 IU/mL.

Polioviruses 1, 2 and 3:

Prior to booster injection of the vaccine, 6 to 12% of subjects were seronegative for all 3 types of polioviruses. After the booster dose, protection ranged from 90.6% to 96.4% in group 1, from 93.9% to 100% in group 2 and from 88.4% to 92.7% in group 3.

STORAGE AND STABILITY

INFANRIX[®]-IPV (diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine) vaccine must be stored at +2 to +8°C. Do not use beyond the expiry date printed on the label.

Do not freeze; discard if vaccine has been frozen.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Dosage Forms

INFANRIX[®]-IPV (diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine) is available as a white opalescent suspension. During storage white sediment with a clear supernatant may be observed.

Composition

Each 0.5 mL dose of the vaccine contains: not less than 25 limit of flocculation (Lf) [30 International Units (IU)] of diphtheria toxoid; 10 Lf (40 IU) of adsorbed tetanus toxoid; 25 µg PT, 25 µg FHA; 8 µg pertactin adsorbed onto aluminum hydroxide (0.5 mg Al³⁺); inactivated poliovirus: type 1 [40 D-antigen units (DU)], type 2 (8 DU) and type 3 (32 DU). May contain trace amounts of neomycin and polymixin.

INFANRIX[®]-IPV meets the World Health Organization requirements for manufacture of biological substances.

Packaging

INFANRIX[®]-IPV is available as single prefilled syringes (in packages of 10) which are made of neutral glass type I, which conforms to European Pharmacopoeia Requirements.

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: diphtheria, tetanus, acellular pertussis and
inactivated poliomyelitis vaccine

Product Characteristics

INFANRIX[®]-IPV (diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine) contains diphtheria toxoid, tetanus toxoid, three purified pertussis antigens [pertussis toxoid (PT), filamentous haemagglutinin (FHA) and pertactin (69 kiloDalton outer membrane protein)] adsorbed onto aluminum salts and purified inactivated poliovirus types 1, 2 and 3.

CLINICAL TRIALS

Refer to PART I: ACTION AND CLINICAL PHARMACOLOGY.

DETAILED PHARMACOLOGY

Not applicable.

MICROBIOLOGY

Not applicable.

TOXICOLOGY

Not applicable.

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PART III: CONSUMER INFORMATION

INFANRIX®-IPV

Diphtheria, tetanus, acellular pertussis and inactivated poliovirus vaccine

This leaflet is part III of a three-part "Product Monograph" published for INFANRIX®-IPV (Diphtheria, tetanus, acellular pertussis and inactivated poliovirus vaccine), approved for sale in Canada, and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about INFANRIX®-IPV. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

INFANRIX®-IPV is a vaccine used in children for protection against diphtheria, tetanus (lockjaw), pertussis (whooping cough) and poliomyelitis (polio) diseases.

Vaccination is the best way to protect against these diseases.

What it does:

INFANRIX®-IPV works by helping the body makes its own protection (antibodies) which protect your child against these diseases.

When it should not be used:

INFANRIX®-IPV should not be used:

- in children with known allergy to any component of the vaccine (see "What the important nonmedicinal ingredients are" section) or children having shown signs of an allergic reaction after a previous dose of this vaccine or any injection containing diphtheria, tetanus (lockjaw), pertussis (whooping cough) and poliomyelitis (polio). Signs of an allergic reaction may include skin rash, shortness of breath and swelling of the face or tongue.
- if your child has an infection or a high temperature (over 38°C). A minor infection such as a cold should not be a problem, talk to your doctor.
- vaccination should not be received if your child's defences against infections (immunity mechanisms) are impaired.
- in persons 7 years of age or older.
- in infants who experienced problems of the nervous system within 7 days following previous vaccination with pertussis (whooping cough) vaccine.

What the medicinal ingredient is:

INFANRIX®-IPV contains the following medicinal ingredients: diphtheria and tetanus toxoids, three purified pertussis antigens [pertussis toxoid, filamentous haemagglutinin and pertactin (69 kiloDalton outer membrane protein)] and inactivated polio virus types 1, 2 and 3.

None of the components in the vaccine are infectious. You cannot get the diseases from the INFANRIX®-IPV vaccine.

What the important nonmedicinal ingredients are:

INFANRIX®-IPV contains the following nonmedicinal ingredients: sodium chloride, aluminum salts, Medium 199 (as stabilizer including amino acids, mineral salts and vitamins), water for injections and may contain trace amounts of neomycin and polymyxin.

What dosage forms it comes in:

INFANRIX®-IPV is supplied as a cloudy suspension for injection in a pre-filled glass syringe.

WARNINGS AND PRECAUTIONS

Before you use INFANRIX®-IPV talk to your doctor or pharmacist if:

- your child had any problems (such as high fever, collapse or shock-like state or persistent crying lasting 3 hours or more) with 48 hours or fits (with or without a fever) within 3 days of vaccination with INFANRIX®-IPV or another vaccine against pertussis (whooping cough).
- you have a family history of convulsions.
- your child is suffering from neurological disorders, including infantile spasms, uncontrolled epilepsy or progressive encephalopathy (disease of brain).
- your child has a bleeding problem or bruises easily. INFANRIX®-IPV should be given with caution since bleeding may occur following vaccination.
- your child has an infection with a high temperature (over 38°C).
- your child has any known allergies.
- your child is taking any other medicine or has recently received any other vaccine.
- your child has any serious health problem.
- your child has breathing difficulties, please contact your doctor. This may be more common in the first three days following vaccination if your child is born prematurely (before or at 28 weeks of pregnancy).
- your child has had an allergic reaction to neomycin or polymyxin (antibiotics).

Fainting can occur following, or even before, any needle injection; therefore, tell the doctor or nurse if your child fainted with a previous injection.

INTERACTIONS WITH THIS MEDICATION

INFANRIX[®]-IPV can be given at the same time as other pediatric vaccines provided that a different syringe and needle are used at different sites, such as *Haemophilus influenzae* type b vaccine or hepatitis B vaccine.

PROPER USE OF THIS MEDICATION

Usual dose:

Your child should receive 1 booster dose at 15 to 18 months of age and a 2nd booster dose at 4 to 6 years of age. Each injection will be given intramuscularly (into a muscle).

Missed Dose:

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

Make sure your child finishes the complete vaccination course. If not, your child may not be fully protected against infection.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all vaccines, INFANRIX[®]-IPV may occasionally cause unwanted effects.

As with other vaccines in any age group, allergic reactions may occur very rarely (in less than 1 in 10,000 doses of the vaccine). This can be recognised by symptoms such as itchy rash of the hands and feet, swelling of the eyes and face, difficulty in breathing or swallowing and a sudden drop in blood pressure and loss of consciousness. Such reactions will usually occur before leaving the doctor's office. However, you should seek immediate treatment in any event.

See your doctor straight away if your child has any of the following serious side effects:

- collapse
- times when they lose consciousness or have a lack of awareness
- fits – this may be when they have a fever

These side effects have happened very rarely with other vaccines against whooping cough. They usually happen within 2 to 3 days after vaccination.

Other side effects:

Very common side effects (in more than 1 in 10 doses of the vaccine) after having INFANRIX[®]-IPV are headache, loss of appetite, irritability, unusual crying, restlessness, pain, redness and swelling at injection site, fever more than 38°C and sleepiness.

Common side effects (in more than 1 in 100 doses of the vaccine) after having INFANRIX[®]-IPV are nausea, vomiting, diarrhea, fatigue, generally feeling unwell, swelling larger than 5 cm at injection site and a hard lump at injection site.

Uncommon side effects (in more than 1 in 1,000 doses of the vaccine) after having INFANRIX[®]-IPV are skin allergies, fever more than 39.5°C and swelling occurring over a large area of the injected limb.

Rare side effects (in more than 1 in 10,000 doses of the vaccine) after having INFANRIX[®]-IPV are swollen glands in the neck, armpit or groin, bronchitis, cough, hives and rash.

Very rare side effects (in less than 1 in 10,000 doses of the vaccine) after having INFANRIX[®]-IPV are bleeding or bruising more easily than normal, temporarily stopping breathing, in babies born very prematurely (at or before 28 weeks of gestation) longer gaps than normal between breaths may occur for 2-3 days after vaccination, itching, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, swelling of the entire injected limb and blisters at the injection site.

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

If your child develops 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 your child will have no side effects from vaccination

This is not a complete list of side effects. For any unexpected effects while taking INFANRIX[®]-IPV, contact your doctor or pharmacist.

HOW TO STORE IT

Store INFANRIX®-IPV in a refrigerator between 2° and 8°C.
Do not freeze. Discard if the vaccine has been frozen.

Do not use after expiration date shown on the label. The date for last use corresponds to the last day of the month mentioned.

Store in the original package in order to protect from light.

Store all vaccines out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

To monitor vaccine safety, the Public Health Agency of Canada collects case reports on adverse events following immunization.

For health care professionals:

If a patient experiences an adverse event following immunization, please complete the appropriate Adverse Events following Immunization (AEFI) Form and send it to your local Health Unit in [your province/territory](#).

For the General Public:

Should you experience an adverse event following immunization, please ask your doctor, nurse, or pharmacist to complete the Adverse Events following Immunization (AEFI) Form.

If you have any questions or have difficulties contacting your local health unit, please contact Vaccine Safety Section at 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

At the following website:

<http://www.phac-aspc.gc.ca/im/vs-sv/index-eng.php>

By regular mail:

**The Public Health Agency of Canada
 Vaccine Safety Section
 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 INFANRIX®-IPV 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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