

INFANRIX-IPV

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this vaccine, speak to your doctor or pharmacist.

1. Why is my infant or child being given INFANRIX-IPV?

INFANRIX-IPV contains the active ingredients diphtheria toxoid, tetanus toxoid, pertussis toxoid, filamentous haemagglutinin, pertactin, poliovirus Type 1, poliovirus Type 2 and poliovirus Type 3. INFANRIX-IPV is a vaccine used in infants to prevent four diseases, diphtheria, tetanus, pertussis (whooping cough) and poliomyelitis (polio).

For more information, see Section [1. Why is my infant or child being given INFANRIX-IPV?](#) in the full CMI.

2. What should I know before my infant or child is given INFANRIX-IPV?

Do not use if your infant or child has ever had an allergic reaction to INFANRIX-IPV or any of the ingredients listed at the end of the CMI.

Talk to your doctor if your infant or child has any other medical conditions or takes any other medicines.

For more information, see Section [2. What should I know before my infant or child is given INFANRIX-IPV?](#) in the full CMI.

3. What if my infant or child is taking other medicines?

Some medicines may interfere with INFANRIX-IPV and affect how it works.

A list of these medicines is in Section [3. What if my infant or child is taking other medicines?](#) in the full CMI.

4. How is INFANRIX-IPV given?

- INFANRIX-IPV will be injected into the thigh muscle in children over 12 months of age, and into the upper leg muscle/thigh muscle in infants under 12 months of age.
- INFANRIX-IPV is usually given as a total of three doses in the first year of life from the age of 2 months.

More instructions can be found in Section [4. How is INFANRIX-IPV given?](#) in the full CMI.

5. What should I know while my infant or child is being given INFANRIX-IPV?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist that your infant or child visits that they have been given INFANRIX-IPV.• Tell your doctor immediately if you notice any of the following: fever greater than 40°C, crying for 3 hours or more, collapse, or periods of unconsciousness or lack of awareness, seizures (convulsions) or fits.• Contact a doctor immediately, or go to the emergency department, if you notice any signs of an allergic reaction, including swelling of the face, lips, tongue or other parts of the body, difficulty breathing or hives.
Looking after your vaccine	<ul style="list-style-type: none">• Keep INFANRIX-IPV in the refrigerator stored between 2°C and 8°C. THE PACK SHOULD NEVER BE FROZEN. FREEZING DESTROYS THE VACCINE.• Keep the vaccine out of the reach of children.• Keep INFANRIX-IPV in the original pack until it is time for it to be given.• INFANRIX-IPV should be used immediately after opening.

For more information, see Section [5. What should I know while using INFANRIX-IPV?](#) in the full CMI.

6. Are there any side effects?

Most unwanted effects with INFANRIX-IPV are mild and usually clear up within a few days. These effects, as with other vaccines, generally occur around the injection site. They include: pain, redness, swelling, a hard lump around the injection site, fever between 38°C and 40°C, generally feeling unwell, runny nose or loss of appetite, unusual crying (for more than 1 hour), nausea, vomiting, diarrhoea, headache, sleepiness, tiredness, nervousness, restlessness, fussiness or difficulty sleeping, skin rash, bruising, or purple or red-brown spots visible through the skin (purpura).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

INFANRIX-IPV

Active ingredients: diphtheria toxoid, tetanus toxoid, pertussis toxoid, filamentous haemagglutinin, pertactin, poliovirus Type 1, poliovirus Type 2 and poliovirus Type 3.

Consumer Medicine Information (CMI)

This leaflet provides important information about using INFANRIX-IPV. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using INFANRIX-IPV.**

Keep this leaflet with this vaccine. You may need to read it again.

Where to find information in this leaflet:

- [1. Why is my infant or child being given INFANRIX-IPV?](#)
- [2. What should I know before my infant or child is given INFANRIX-IPV?](#)
- [3. What if my infant or child is taking other medicines?](#)
- [4. How is INFANRIX-IPV given?](#)
- [5. What should I know while my infant or child is being given INFANRIX-IPV?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why is my infant or child being given INFANRIX-IPV?

INFANRIX-IPV is a vaccine used to immunise against diphtheria, tetanus, pertussis (whooping cough) and poliomyelitis.

INFANRIX-IPV is not intended for use in adults.

Diphtheria, pertussis, tetanus and poliomyelitis are life-threatening diseases caused by bacterial and viral infections. The vaccine works by causing the body to produce its own protection (antibodies) against these diseases.

Diphtheria

Diphtheria is a bacterium that lives in the airways of humans and can also affect the skin. Generally, the airways become inflamed (swollen) causing severe breathing difficulties and sometimes suffocation. The bacteria release a toxin (poison) which can cause nerve damage, heart problems and death. The risk of serious complications and death is greater in the very young and elderly.

Tetanus (Lockjaw)

Tetanus bacteria enter the body through wounded skin. Wounds that are especially prone to infection are burn wounds, fractures, deep wounds or wounds contaminated with soil, dust, horse manure or wood splinters. The bacteria release toxins, which can cause muscle stiffness, painful spasms, fits and death. The spasm can be strong enough to cause bone fractures of the spine.

Pertussis (Whooping cough)

Pertussis is highly infectious. It affects the breathing tract causing severe spells of coughing that may interfere with normal breathing. The coughing is often accompanied by a “whooping” sound. The cough may last for 1-2 months or longer. Pertussis can also cause inner ear infections, long lasting bronchitis, pneumonia, fits, brain damage and death. The risk of severe complications and death is greatest in infants under 6 months of age.

Poliomyelitis (Polio)

There are various types of poliovirus (types I, II and III) that cause poliomyelitis. The virus infects the bowel, and from there can attack the nervous system causing meningitis or paralysis. Infection may be without symptoms or with only minor bowel upset. When infection spreads to the nervous system, it can cause paralysis. Incubation for poliomyelitis is commonly 7 to 14 days in severe cases and ranges from 3 to 35 days. Infection is spread by mouth and faeces.

Vaccination is the best way to protect against these diseases. INFANRIX-IPV cannot give your child diphtheria, tetanus, pertussis or polio infection. The vaccine will not protect against diseases caused by other types of bacteria, viruses or organisms.

2. What should I know before my infant or child is given INFANRIX-IPV?

Warnings

Do not use INFANRIX-IPV if your infant or child has had an allergic reaction to:

- INFANRIX-IPV, or any of the ingredients listed at the end of this leaflet.
- Any other diphtheria, tetanus, pertussis and poliomyelitis containing vaccine.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not use INFANRIX-IPV if your infant or child experienced a disease of the brain within 7 days after previous vaccination with a pertussis containing vaccine.

INFANRIX-IPV should not be given after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether your child should have INFANRIX-IPV, talk to your doctor or nurse.

Check with your doctor if your infant or child has any medical conditions, such as:

- a bleeding disorder or bruises easily. Sometimes INFANRIX-IPV may need to be given differently in people with bleeding problems.
- an immune deficiency condition (eg. are HIV positive).
- brain disease or Central Nervous System (CNS) disease such as epilepsy or a tendency to febrile convulsions (seizures /fits due to a high fever).
- your child has allergies to any other medicines or substances, such as dyes, foods or preservatives.
- your child has a severe infection with a high temperature. A minor infection such as a cold should not be a problem, but talk to your doctor or nurse about this before being vaccinated.
- breathing difficulties. 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).
- after having been given INFANRIX-IPV or another vaccine containing diphtheria, tetanus, pertussis, your child had problems such as:
 - a high temperature (over 40.0°C) within 2 days of vaccination
 - a collapse or shock-like state within 2 days of vaccination
 - crying lasting 3 hours or more within 2 days of vaccination
 - convulsions/fits with or without fever within 3 days of vaccination
- fainting with a previous injection. Fainting can occur following, or even before, any needle injection.
- allergies to any other medicines, foods, preservatives or dyes.

From the vaccination, your infant or child may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

3. What if my infant or child is taking other medicines?

Tell your doctor or pharmacist if your infant or child is taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Your doctor and pharmacist have more information on medicines to be careful with or avoid when your child is given INFANRIX-IPV.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect INFANRIX-IPV.

Having other vaccines

Tell your doctor or nurse if your child has received another vaccine recently.

Some vaccines may be affected by other vaccines. Your doctor, nurse or pharmacist will be able to tell you what to do if INFANRIX-IPV is to be given with another vaccine.

4. How is INFANRIX-IPV given?

The doctor or nurse will give INFANRIX-IPV as an injection.

If you have any concerns about how this vaccine is to be given, talk to your doctor, nurse or pharmacist.

How much is given

- The dose of INFANRIX-IPV is 0.5 mL.

How is it given

INFANRIX-IPV will be injected into the thigh muscle in children over 12 months of age, and into the upper leg muscle/thigh muscle in infants under 12 months of age. For infants and children with bleeding problems, the dose may need to be given under the skin (subcutaneously).

The vaccine should never be given intravenously.

When is it given

INFANRIX-IPV is given as a total of three doses in the first year of life from the age of 2 months. Each dose is given on a separate visit with at least 1 month break between doses. In order to maintain protection, a booster dose is recommended, which would be given at least 6 months after the third dose.

It is important to return at the recommended times for follow up doses.

If a dose is missed

If your child misses a scheduled dose, talk to your doctor or nurse and arrange another visit as soon as possible.

If you are not sure what to do, ask your doctor, nurse or pharmacist.

If too much INFANRIX-IPV is given

If you think that too much INFANRIX-IPV had been given, urgent medical attention may be required.

You should immediately:

- phone the Poisons Information Centre (**by calling 0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while my infant or child is being given INFANRIX-IPV?

Things you should do

Keep your child's visits with the doctor or clinic. It is important INFANRIX-IPV doses are given at the correct times. This will ensure the best effect of the vaccine in protecting your child against diphtheria, tetanus poliomyelitis and pertussis (whooping cough).

Looking after the vaccine

INFANRIX-IPV is usually stored at the doctor's clinic or surgery, or at the pharmacy.

If you need to store INFANRIX-IPV always:

- Keep INFANRIX-IPV in the refrigerator stored between +2°C and +8°C. THE PACK SHOULD NEVER BE FROZEN. FREEZING DESTROYS THE VACCINE.
- Keep the vaccine out of the reach of children.
- Keep INFANRIX-IPV in the original pack until it is time for it to be given.

Ask your pharmacist what to do with any left over INFANRIX-IPV that has expired or has not been used.

6. Are there any side effects?

Tell your doctor, nurse or pharmacist as soon as possible if your child does not feel well during or after having had a dose of INFANRIX-IPV.

INFANRIX-IPV helps protect children from diphtheria, tetanus, pertussis and poliomyelitis, but it may have unwanted side effects in some children. All medicines and vaccines can have side effects. Sometimes they are serious; most of the time they are not. Some side effects may need medical treatment. However, the chance of your child having a serious side effect is less than the chance of your child having a permanent injury from the infections.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Most unwanted effects with INFANRIX-IPV are mild and usually clear up within a few days. These effects, as with other vaccines, generally occur around the injection site.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • redness, swelling, a hard lump, soreness, bruising or itching around the injection site, skin rash • feeling generally unwell, fever (between 38°C and 40°C) • loss of appetite, or feeling sick (nausea), vomiting, constipation or diarrhoea • restlessness, unusual crying (for more than an hour) 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

More serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • swelling of limbs, face, eyes, inside of nose, mouth or throat • shortness of breath, breathing or swallowing difficulties • hives, itching (especially of the hands or feet), reddening of skin (especially around the ears), or severe skin reactions • unusual tiredness or weakness that is sudden and severe, muscular aches and pains • convulsions/fits, collapse or periods of unconsciousness • fever over 40°C • crying for 3 hours or more <p>As with all vaccines given by injection there is a very small risk of such reactions. Allergy to INFANRIX-IPV is rare. Any such severe reactions will usually occur within the first few hours of vaccination.</p>	<p>Call your doctor straight away, or go straight to the Accident and Emergency Department of your nearest hospital if you notice any of these serious side effects.</p>

Other side effects not listed above, can also occur during or soon after a dose of INFANRIX-IPV such as respiratory infections and middle ear infections.

Check with your doctor or nurse if you notice any other effects.

Do not be alarmed by this list of possible side effects. Your infant or child may not experience any of them.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects via <https://nzphvc.otago.ac.nz/reporting>.

By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

What INFANRIX-IPV contains

Active ingredients (main ingredients)	
	30 IU of diphtheria toxoid
	40 IU of tetanus toxoid
	25mcg of pertussis toxoid, 25mcg of filamentous haemagglutinin and 8mcg of 69Kd outer membrane protein (pertactin)
	40 D antigen units of inactivated poliovirus type 1, 8 D antigen units of inactivated poliovirus type 2 and 32 D

	antigen units of inactivated poliovirus type 3
Other ingredients (inactive ingredients)	aluminium salts, sodium chloride, Medium 199 (as stabiliser) and water for injections. Residues in this vaccine are: neomycin sulfate and polymyxin B sulfate.

Do not use this vaccine if your infant or child is allergic to any of these ingredients.

INFANRIX-IPV does not contain any infectious material.

What INFANRIX-IPV looks like

INFANRIX-IPV comes in a prefilled syringe (TT50-6570). It is a white, slightly milky liquid.

INFANRIX-IPV comes in packs of 1 or 10.

Who distributes INFANRIX-IPV

GlaxoSmithKline NZ Ltd
Private Bag 106600
Downtown
Auckland 1143
New Zealand

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

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