

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 from 6 weeks of age and over 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 upper leg muscle in infants under 12 months of age. In children over 12 months of age the injection may be given in the upper arm muscle instead.
- INFANRIX-IPV is usually given as a total of three doses at 2 months of age, 4 months of age and 6 months of age. There is not enough information to recommend the use of this medicine for children under the age of 6 weeks.

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 39.5°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 39.5°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.**

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 contains non-infectious substances from tetanus, diphtheria bacteria, purified proteins of pertussis bacteria and inactivated poliovirus.

INFANRIX-IPV is vaccine used in infants from 6 weeks of age and over to prevent four diseases, diphtheria, tetanus, pertussis (whooping cough) and poliomyelitis (polio). The vaccine works by causing the body to produce its own protection (antibodies) against these diseases.

Diphtheria, tetanus, and pertussis are all serious life-threatening diseases caused by bacterial infection. Poliomyelitis is an infectious disease caused by viral infection.

Diphtheria

Diphtheria mainly affects the airways and sometimes the skin. Generally, the airways become inflamed (swollen) causing severe breathing difficulties and sometimes suffocation. The bacteria also 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 burns, fractures, deep wounds or wounds contaminated with soil, dust, horse manure or wood splinters. The bacteria release a toxin (poison), which can cause muscle stiffness, painful muscle spasms, fits and death. The spasms can be strong enough to cause bone fractures of the spine. The death rate is 30-40% of cases.

Pertussis (Whooping cough)

Pertussis is a highly infectious illness. The disease 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. The death rate is 0.5% for infants under 6 months of age.

Poliomyelitis (Polio)

Polio is a viral infection that can have variable effects. Often it causes only a mild illness but in some people it causes permanent injury or death.

In its severest form, polio infection causes paralysis of the muscles, including those needed for breathing and walking. Polio infection can leave a person unable to breathe without the help of an iron lung machine, unable to walk without leg braces, or confined to a wheelchair. The limbs affected by the disease may be painfully deformed.

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 vaccine containing diphtheria, tetanus, pertussis or inactivated polio (such as Infanrix, Triple Antigen, Tripacel or Ipol vaccine)
- Always check the ingredients before this vaccine is given.

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 it has expired or is damaged, return it to your pharmacist for disposal.

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 of the following:

- After having INFANRIX-IPV or another pertussis-containing vaccine (such as Infanrix or Triple Antigen) your child had any problems, including:
 - a high temperature (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 (seizures/fits) with or without a fever within 3 days of vaccination
- a brain disease or central nervous system (CNS) disease (i.e. epilepsy etc.)
- a tendency to febrile convulsions (seizures/fits due to a fever or high body temperature)
- a family history of Sudden Infant Death Syndrome (SIDS)
- 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 vaccination
- a bleeding problem or bruises easily
- allergy to the antibiotics neomycin sulfate and polymyxin sulfate
- lowered immunity due to medical treatment or a medical condition
- 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)
- 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 upper leg muscle in infants under 12 months of age. In children over 12 months of age the injection may be given in the upper arm muscle instead.
- Each dose of INFANRIX-IPV is for single use only.
- Any residual vaccine must be discarded.
- The vaccine should never be given intravenously.

When is it given

INFANRIX-IPV is usually given as a total of three doses as follows:

- First dose: 2 months of age
- Second dose: 4 months of age
- Third dose: 6 months of age

If you have any concerns about how this vaccine is to be given, talk to your doctor, nurse or pharmacist. Each dose is given on a separate visit.

INFANRIX-IPV should not be given at birth.

It is also recommended that children up to 6 years of age receive a single booster (follow up) dose of INFANRIX-IPV.

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

You should discuss with your doctor what is needed for your child.

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 13 11 26**), 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 follow up visits with the doctor or clinic. It is important that the follow-up doses of INFANRIX-IPV are given at the correct times. This will ensure the best effect of the vaccine in protecting your child against diphtheria, tetanus, pertussis and poliovirus infection.

Remind any doctor, dentist or pharmacist that your child is using INFANRIX-IPV.

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 INFANRIX-IPV in the original pack until it is time for it to be given.
- INFANRIX-IPV should be used immediately after opening.

Keep it where young children cannot reach it.

Getting rid of any unwanted vaccine

If you no longer need to use this vaccine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this vaccine after the expiry date.

6. Are there any side effects?

All vaccines can have side effects. If your infant or child experiences any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• pain, redness, swelling, a hard lump around the injection site• fever between 38°C and 39.5°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). <p>Other events reported after INFANRIX-IPV vaccination, but not necessarily related to the vaccine include:</p> <ul style="list-style-type: none">• coughing, respiratory infections, bronchitis or viral infection of the middle ear that may cause earache and temporary hearing loss• toothache, sore throat.	<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">• fever greater than 39.5°C• crying for 3 hours or more• collapse, or periods of unconsciousness or lack of awareness• seizures (convulsions) or fits. <p>Signs of allergic reaction</p> <ul style="list-style-type: none">• sudden sign of allergy such as rash, itching or hives on the skin, swelling of limbs, face, eyes, lips, mouth, throat or other part of the body• shortness of breath, breathing or swallowing difficulties• unusual tiredness or weakness that is sudden and severe. <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 Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects experienced, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this vaccine.

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

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7. Product details

This vaccine is only available with a doctor's prescription.

What INFANRIX-IPV contains

Active ingredients (main ingredients)	30 IU (25 Lf U) of diphtheria toxoid 40 IU (10 Lf U) of tetanus toxoid 25 micrograms of pertussis toxoid, 25 micrograms of filamentous haemagglutinin and 8 micrograms of pertactin 40 D-antigen units of poliovirus Type 1, 8 D-antigen units of poliovirus Type 2 and 32 D-antigen units of poliovirus Type 3.
Other ingredients (inactive ingredients)	aluminium hydroxide hydrate, medium 199, sodium chloride (salt) and water for injection. The 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.

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.

What INFANRIX-IPV looks like

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

AUST R 159563

Who distributes INFANRIX-IPV

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