

INFANRIX

Consumer Medicine Information (CMI) summary

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

1. Why is your child being given INFANRIX?

INFANRIX is used to prevent three diseases: diphtheria, tetanus and pertussis (whooping cough). The vaccine is sometimes called DTPa vaccine. INFANRIX contains the active ingredients of non-infectious substances from diphtheria bacteria, tetanus bacteria and purified proteins of pertussis bacteria.

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

2. What should you know before your child is given INFANRIX?

Your child should not be given this vaccine if they have ever had an allergic reaction to INFANRIX or any of the ingredients listed at the end of the CMI.

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

For more information, see Section [2. What should you know before your child is given INFANRIX?](#) in the full CMI.

3. What if your child is taking other medicines?

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

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

4. How is INFANRIX given?

- INFANRIX will be injected into the upper leg muscle or the upper arm muscle. For children with bleeding problems, the dose may need to be given under the skin (subcutaneously). The vaccine should never be injected into a vein (intravenously).
- A primary course of INFANRIX is generally given as a total of three doses. Each dose is given on a separate visit. The first dose of INFANRIX is given at 2 months of age. The second and third doses are given every 2 months, at 4 and 6 months of age.
- A fourth dose of INFANRIX may also be given at 18 months of age and a fifth dose at 4 to 6 years of age to children who have previously been immunised with 3 or 4 doses of INFANRIX or another brand of diphtheria, tetanus and pertussis-containing vaccine. It is important to return at the recommended times for follow up doses.

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

5. What should you know while your child is being given INFANRIX?

Things you should do	<ul style="list-style-type: none">• Remind any doctor or pharmacist you visit that your child has received an INFANRIX vaccine recently• Keep your child's follow up visits with the doctor or clinic.• 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.
Looking after your vaccine	<ul style="list-style-type: none">• INFANRIX is usually stored at the doctor's clinic or surgery, or at the pharmacy.• If you need to store INFANRIX, store it in the refrigerator 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 in the original pack until it is time for it to be given. INFANRIX should be used immediately after opening.

For more information, see Section [5. What should you know while your child is being given INFANRIX?](#) in the full CMI.

6. Are there any side effects?

Most unwanted effects with INFANRIX are mild and usually clear up within a few days. These effects, as with other vaccines, generally occur around the injection site. Side effects that have been reported include pain, redness and swelling where the injection was given, feeling irritable, feeling tired, fever of 38°C or higher, loss of appetite, unusual crying, feeling restless, being sick (vomiting), diarrhoea, itchy skin and pain and swelling larger than 5 cm where the injection was given. For more information, including what to do if your child has any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

INFANRIX

Active ingredients: *diphtheria toxoid, tetanus toxoid, pertussis toxoid, pertussis filamentous haemagglutinin and pertactin*

Consumer Medicine Information (CMI)

This leaflet provides important information about INFANRIX. **You should also speak to your doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about your child being given INFANRIX.**

Where to find information in this leaflet:

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

1. Why is your child being given INFANRIX?

INFANRIX contains the active ingredients of non-infectious substances from diphtheria bacteria, tetanus bacteria and purified proteins of pertussis bacteria. The vaccine is sometimes called the DTPa vaccine.

INFANRIX is used to prevent three diseases, diphtheria, tetanus and pertussis (whooping cough). The vaccine cannot cause these diseases.

Diphtheria, tetanus and pertussis are all serious life-threatening diseases caused by bacterial infection.

The vaccine works by causing the body to produce its own protection (antibodies) against these diseases.

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 10% 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.

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

2. What should you know before your child is given INFANRIX?

Warnings

Your child should not be given INFANRIX if:

- they are allergic to any of the ingredients listed at the end of this leaflet
- they have had an allergic reaction to any other diphtheria, tetanus or pertussis containing vaccine (such as Triple Antigen (DTPa) vaccine)
- they have had INFANRIX before and became unwell. Tell your doctor, nurse or pharmacist before the next dose is given
- they have experienced a disease of the brain within 7 days after previous vaccination with a pertussis containing vaccine
- they have 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
- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering.

Check with your doctor or nurse if your child:

- has any other medical conditions such as:
 - a brain disease or a central nervous system (CNS) disease (e.g. epilepsy)
 - a bleeding problem or bruises easily
 - lowered immunity due to medical treatment or a medical condition
 - encephalopathy (a disease of the brain)
 - a family history of seizures/fits
- has experienced any problems after having INFANRIX or other diphtheria, tetanus, pertussis containing vaccines (such as Triple Antigen (DTPa) vaccine), especially:
 - a high temperature (over 40.5°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
- has allergies to any other medicines or substances, such as dyes, foods or preservatives
- has received another vaccine recently, or is having any prescription or OTC (over-the-counter) medicines. In particular, mention to your doctor if your child is being given medicines which suppress the immune system, such as high-dose steroids.

If you are not sure whether your child should be given INFANRIX, talk to your doctor or nurse. Do not give this vaccine to anyone else; your doctor has prescribed it specifically for your child.

If your child was born very prematurely, please discuss with your doctor or nurse. In infants born very prematurely (before or at 28 weeks of pregnancy) breathing difficulties may be more common in the first three days following vaccination.

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

During treatment, your 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 your child is taking other medicines?

Tell your doctor, nurse or pharmacist if your 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.

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

4. How is INFANRIX given?

The doctor or nurse will give INFANRIX as an injection.

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

How much is given

- The dose of INFANRIX is 0.5 mL.

When is it given

- A primary course of INFANRIX is generally given as a total of three doses. Each dose is given on a separate visit.
- The first dose of INFANRIX is given at 2 months of age. The second and third doses are given every 2 months, at 4 and 6 months of age.
- A fourth dose of INFANRIX may also be given at 18 months of age and a fifth dose at 4 to 6 years of age to

children who have previously been immunised with 3 or 4 doses of INFANRIX or another brand of diphtheria, tetanus and pertussis-containing vaccine.

How is it given

- INFANRIX is injected into the upper leg muscle or the upper arm muscle. For infants and children with bleeding problems, the dose may need to be given under the skin (subcutaneously).
- The vaccine should never be injected into a vein (intravenously).
- It is important to return at the recommended times for follow up doses.

If your child misses a dose of INFANRIX

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

If your child is given too much INFANRIX

If you think that your child has been given too much INFANRIX, your child may need urgent medical attention.

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 you know while your child is being given INFANRIX?

Things you should do

Keep your child's follow up visits with the doctor or clinic. It is important that follow-up doses of INFANRIX are given at the correct times. This will ensure the best effect of the vaccine in protecting your child against diphtheria, tetanus and pertussis infection.

Remind any doctor or pharmacist you visit that your child has recently received INFANRIX.

Looking after your vaccine

INFANRIX is usually stored at the doctor's clinic or surgery, or at the pharmacy. But if you need to store INFANRIX:

- keep it in the refrigerator between 2°C and 8°C
- THE PACK SHOULD NEVER BE FROZEN. FREEZING DESTROYS THE VACCINE
- keep INFANRIX in the original pack until it is time for it to be given.

Follow the instructions on the carton on how to take care of your vaccine properly.

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 child does experience 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, nurse or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>General disorders and administration site conditions:</p> <ul style="list-style-type: none"> • pain, redness and swelling larger than 5 cm where the injection was given • feeling tired • fever of 38°C or higher • feeling irritable • loss of appetite • hard lump where the injection was given • unusual crying <p>Skin and subcutaneous tissue disorders:</p> <ul style="list-style-type: none"> • itchy skin • rash • large swelling of the vaccinated limb • hives (urticaria) <p>Respiratory disorders:</p> <ul style="list-style-type: none"> • cough • bronchitis <p>Nervous system disorders:</p> <ul style="list-style-type: none"> • headache • feeling restless <p>Gastrointestinal disorders:</p> <ul style="list-style-type: none"> • being sick (vomiting) • diarrhoea 	<p>Speak to your doctor if your child has any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Immune system disorders and allergic reactions:</p> <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 • sudden drop in blood pressure and loss of consciousness • crying for 3 hours or more • collapse, or periods of unconsciousness or lack of awareness within 2 to 3 days of vaccination • seizures (convulsions) or fits • fever over 39°C <p>Respiratory disorders:</p> <ul style="list-style-type: none"> • upper respiratory tract infection • breathing difficulties, which may be more common in the first three days following vaccination if your child is born prematurely (before or at 28 weeks of pregnancy) <p>Lymphatic disorders:</p> <ul style="list-style-type: none"> • swollen glands in the neck, armpit or groin (lymphadenopathy) <p>Skin and subcutaneous tissue disorders:</p> <ul style="list-style-type: none"> • bleeding • bruising more easily than normal (thrombocytopenia) 	<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, nurse or pharmacist if you notice anything else that may be making your child feel unwell.

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

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

Reporting side effects

After you have received medical advice for any side effects your child has 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 any of your child's medicines.

7. Product details

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

What INFANRIX contains

Active ingredients (main ingredients)	<ul style="list-style-type: none">30 IU (25 Lf) of diphtheria toxoid40 IU (10 Lf) of tetanus toxoid25 micrograms of pertussis toxoid25 micrograms of pertussis filamentous haemagglutinin8 micrograms of pertactin
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">aluminium hydroxide hydratesodium chloride (salt)water for injections

Your child should not be given this vaccine if they are 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 looks like

INFANRIX is a white, slightly milky liquid available in prefilled syringes (AUST R 142370).

Who distributes INFANRIX

GlaxoSmithKline Australia Pty Ltd
Level 4, 436 Johnston Street,
Abbotsford, Victoria, 3067
Phone: 1800 033 109
www.gsk.com.au

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