

INFANRIX[®]

Diphtheria-tetanus-acellular pertussis (DTPa) vaccine

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before your child is given INFANRIX.

This leaflet answers some of the common questions about INFANRIX vaccine.

It does not contain all the available information.

It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines and vaccines have risks and benefits. Your doctor has weighed the possible risks of your child having INFANRIX against the expected benefits.

If you have any concerns about your child receiving INFANRIX talk to your doctor, nurse or pharmacist.

Keep this leaflet with this vaccine.

You may need to read it again.

What INFANRIX is used for

INFANRIX is a vaccine used to prevent three diseases, diphtheria, tetanus, and pertussis (whooping cough). The vaccine is sometimes called DTPa vaccine.

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 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.

Vaccination is the best way to protect against these three diseases.

INFANRIX vaccine cannot give your child diphtheria, tetanus, or pertussis infection. The vaccine will not protect against diseases caused by other types of bacteria or organisms.

Before vaccination

INFANRIX should not be given if your child has had an allergy to:

- INFANRIX or any ingredient contained in this vaccine
- an allergic reaction to any other diphtheria, tetanus, pertussis containing vaccine (such as Triple Antigen (DTPa) 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

INFANRIX should not be given if:

- your child had INFANRIX before and became unwell, tell your doctor, nurse or pharmacist before the dose is given
- your child experienced a disease of the brain within 7 days after previous vaccination with a pertussis containing vaccine
- 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 vaccination

- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering

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

Before INFANRIX is given tell your doctor or nurse if:

- your child has any medical problems such as:
 - brain disease or central nervous system (CNS) disease (that is, epilepsy etc)
 - a bleeding problem or bruises easily
 - lowered immunity due to medical treatment or a medical condition
 - a tendency to febrile convulsions (seizures/fits due to a fever or high body temperatures)
 - a family history of seizures/fits
- after having INFANRIX or diphtheria, tetanus, pertussis vaccination (such as Triple Antigen (DTPa) vaccine) your child had any problems, 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
- your child has allergies to any other medicines or substances, such as dyes, foods or preservatives

- your child has received another vaccine recently, or is having any prescription or OTC (over-the-counter) medicines. In particular mention if your child is being given medicines which suppress the immune system, such as high-dose steroids.

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.

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.

If your infant was born very prematurely, please discuss with your doctor.

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

How INFANRIX is 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, nurse or pharmacist.

How much is given

The dose of INFANRIX is 0.5 mL.

How it is given

INFANRIX will be 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).

When it is 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 (such as DTPa).

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.

While using INFANRIX

Things you must do

Keep your child's follow up visits with the doctor or clinic. It is important the 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.

Side effects

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

INFANRIX helps protect most children from diphtheria, tetanus, and pertussis infection, but it may have

unwanted side effects in a few 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. The chance of your child having a serious side effect is very much less than the chance of your child having a permanent injury from the natural infections.

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

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.

Tell your doctor if your child has any of the following that are troublesome or ongoing:

Very common (may occur in more than 1 in 10 doses of the vaccine)

- feeling irritable
- feeling tired
- pain, redness and swelling where the injection was given
- fever of 38°C or higher

Common (may occur in up to 1 in 10 doses of the vaccine)

- loss of appetite
- unusual crying
- feeling restless
- being sick (vomiting)
- diarrhoea
- itchy skin
- pain
- swelling larger than 5 cm where the injection was given

Uncommon (may occur in up to 1 in 100 doses of the vaccine)

- headache
- cough
- upper respiratory tract infection
- rash
- hard lump where the injection

was given

- fever higher than 39°C
- feeling sleepy
- large swelling of the vaccinated limb
- bronchitis

Rare (may occur with up to 1 in 1,000 doses of the vaccine):

- hives (urticaria)

Very rare (may occur with up to 1 in 10,000 doses of the vaccine)

- swollen glands in the neck, armpit or groin (lymphadenopathy)

Other side effects that may occur include bleeding or bruising more easily than normal (thrombocytopenia)

Contact your doctor immediately or take your child to the casualty department of your nearest hospital if any of the following happens:

- 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

These are signs of an allergic reaction. As with all vaccines given by injection there is a very small risk of such reactions. Allergy to INFANRIX is rare. Any such severe reactions will usually occur within the first few hours of vaccination.

- 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 40°C
- 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)

Other side effects not listed above, can also occur during or soon after a dose of INFANRIX.

Check with your doctor or nurse if your child has any other effects.

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

Storage

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

- Keep INFANRIX 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 in the original pack until it is time for it to be given.

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

Product Description

What it looks like

INFANRIX comes in glass vials and prefilled syringes. It is a white, slightly milky liquid.

Ingredients

The active ingredients of INFANRIX are non-infectious substances from tetanus, diphtheria bacteria and purified proteins of pertussis bacteria.

The vaccine cannot cause these diseases.

Each 0.5 mL dose contains:

- 30 IU (25Lf) of diphtheria toxoid
- 40 IU (10Lf) of tetanus toxoid
- 25 mcg of pertussis toxoid, 25 mcg of filamentous haemagglutinin and 8mcg of pertactin.

The inactive ingredients in the vaccine are: aluminium hydroxide, sodium chloride (salt) and water.

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.

Supplier

Your INFANRIX is supplied by
GlaxoSmithKline Australia Pty Ltd
Level 4, 436 Johnston Street
Abbotsford Victoria 3067
Australia.

Manufacturer

GlaxoSmithKline Biologicals s.a.
rue de l'Institut 89,
1330 Rixensart, Belgium.

Further information

INFANRIX is only available if prescribed by a doctor.

The information provided applies only to: INFANRIX®.

INFANRIX is a trade mark of the GSK group of companies.

INFANRIX 0.5 mL injection vial:
AUST R 142369*

INFANRIX 0.5 mL injection
syringe: AUST R 142370

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*The vial presentation is not currently marketed in Australia

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