

INFANRIX™

Combined diphtheria, tetanus, acellular pertussis (DTPa) vaccine

Consumer Medicine Information Leaflet

What Is In This Leaflet?

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 INFANRIX talk to your doctor, nurse or pharmacist.

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

What Is INFANRIX Used For

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

INFANRIX is not intended for use in adults.

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

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

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.

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

Before Receiving INFANRIX

INFANRIX Must Not Be Given If:

- your child has had an allergic reaction to INFANRIX, or any ingredient contained in this vaccine. The ingredients are listed at the end of this leaflet. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.
- your child has had an allergic reaction to any other diphtheria, tetanus, pertussis vaccine
- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering

If you are not sure whether INFANRIX should be given, talk to your doctor or nurse.

Tell your doctor if:

- your child has any medical conditions, such as:
 - a bleeding disorder. Sometimes INFANRIX 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
- after having been given INFANRIX or another vaccine containing diphtheria, tetanus, pertussis, your child had problems such as:
 - 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/fits with or without fever within 3 days of vaccination
- your child is receiving any other medication or vaccines

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.

Giving INFANRIX

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 0.5mL

HOW IS IT GIVEN

INFANRIX will be injected into the upper arm 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 IT WILL BE GIVEN

INFANRIX is given as a total of four or five doses. Each dose is given on a separate visit.

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

INFANRIX can be used for the fourth and/or fifth doses of DTP (diphtheria, tetanus and pertussis) vaccine, in children previously given 3 doses of another brand of vaccine (whole cell or acellular).

If A Dose Is Missed

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

While Getting INFANRIX

THINGS YOU MUST DO

Keep your child's visits with the doctor or clinic. It is important INFANRIX doses are given at the correct times. This will ensure your child has the best protection against diphtheria, tetanus and pertussis (whooping cough).

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.

INFANRIX helps protect most children from diphtheria, tetanus and pertussis infection, 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 are mild and usually clear up within a few days. These effects, as with other vaccines, generally occur around the injection site.

MILD EFFECTS

Tell your doctor if you notice any of the following that are troublesome or ongoing after vaccination:

- 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)

SERIOUS EFFECTS

As with all vaccines given by injection there is a very small risk of serious allergic reaction. Contact your doctor immediately or go to the Accident and Emergency 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, muscular aches and pains
- convulsions/fits, collapse or periods of unconsciousness
- fever over 40°C
- crying for 3 hours or more

Those are signs of an allergic reaction. Allergy to INFANRIX is rare. Any such severe reactions will usually occur within the first few hours of vaccination.

Other side effects not listed above, can also occur during or soon after a dose of INFANRIX 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 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 or 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 0.5mL dose contains:

- 25Lf of diphtheria toxoid
- 10Lf of tetanus toxoid
- 25mcg of pertussis toxoid, 25mcg of filamentous haemagglutinin and 8mcg of 69Kd outer membrane protein (pertactin).

Inactive ingredients in the vaccine are: aluminium hydroxide, 2-phenoxyethanol, sodium chloride, and water.

INFANRIX does not contain any infectious material.

Further Information

INFANRIX is only available if prescribed by a doctor.

The vaccine comes in the following:

INFANRIX comes as a prefilled syringe in packs of 1

Distributor

Distributed In New Zealand by:
GlaxoSmithKline NZ Ltd
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