

BOOSTRIX™

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 BOOSTRIX 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 BOOSTRIX against the expected benefits.

If you have any concerns about BOOSTRIX talk to your doctor, nurse or pharmacist.

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

What Is BOOSTRIX Used For

BOOSTRIX is a vaccine used for booster vaccination against diphtheria, tetanus and pertussis (whooping cough). The vaccine is sometimes called dTpa vaccine.

BOOSTRIX is intended for use in children aged 10 years and older and 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. BOOSTRIX vaccine cannot give you or your child diphtheria, tetanus or pertussis infection. The vaccine will not protect against diseases caused by other types of bacteria or organisms.

Before Receiving BOOSTRIX

BOOSTRIX Must Not Be Given If:

- you/your child has had an allergic reaction to INFANRIX®, any ingredient contained in this vaccine or any other diphtheria, tetanus or pertussis vaccine. The ingredients are listed at the end of this leaflet. Signs of an allergic reaction may include itchy skin rash, shortness of breath or swelling of the face or tongue.
- you/your child has had blood clotting problems or problems with the nervous system following an earlier immunisation against diphtheria and/or tetanus.

- you/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.
- you/your child has experienced an inflammation/disease in the brain, which occurred 7 days following previous vaccination with a pertussis vaccine. Another type of vaccine should be used for a booster in this case.
- you/your child suffer from neurological disorders, including infantile spasms, uncontrolled epilepsy or progressive encephalopathy (a brain disease).
- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering

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

Tell your doctor if:

- you/your child has any medical conditions, such as:
- a bleeding disorder. Sometimes BOOSTRIX 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)
- you/your child has allergies to any other medicines or substances, such as dyes, foods or preservatives.
- after having been given INFANRIX or another vaccine containing diphtheria, tetanus, pertussis, your child had problems such as:
- 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
- you/your child is receiving any other medication or vaccines
- you/your child has never been given a vaccine for diphtheria, tetanus or pertussis or have not completed a full course of diphtheria and tetanus vaccinations
- You are pregnant, trying to become pregnant or are breastfeeding

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 BOOSTRIX is to be given with another vaccine or medicine.

Giving BOOSTRIX

How BOOSTRIX Is Given

The doctor or nurse will give BOOSTRIX 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 BOOSTRIX is 0.5mL

HOW IS IT GIVEN

BOOSTRIX will be injected into a muscle, normally the upper arm muscle. In patients with bleeding problems, the dose may need to be given under the skin (subcutaneously).

The vaccine should never be given intravenously (IV).

WHEN IT WILL BE GIVEN

BOOSTRIX is given in accordance with local medical practice for booster vaccination, when a booster dose for tetanus, diphtheria or pertussis is required.

To provide effective protection against diphtheria and tetanus, a booster vaccine should be given every 10 years.

If A Dose Is Missed

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

While Getting BOOSTRIX

THINGS YOU MUST DO

Keep your and your child's visits with the doctor or clinic. It is important that the BOOSTRIX dose are given on the correct schedule. 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 you/your child does not feel well during or after having had a dose of BOOSTRIX.

BOOSTRIX helps protect most children and adults from diphtheria, tetanus and pertussis infection, but it may have unwanted side effects in some patients. 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 you/your child having a serious side effect is less than the chance of you/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 BOOSTRIX 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, or a rash on your skin
- feeling generally unwell, fever (between 38°C and 40°C), aches and pains
- loss of appetite, or feeling sick (nausea), vomiting, constipation or diarrhoea
- restlessness, irritability, loss of appetite

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, or 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

Those are signs of an allergic reaction. Allergy to BOOSTRIX 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 BOOSTRIX, including as respiratory infections and middle ear infections. **Check with your doctor or nurse if you notice any other effects.**

Be aware, but do not be alarmed by this list of possible side effects. You/your child may not experience any of them.

STORAGE

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

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

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

Product Description

WHAT IT LOOKS LIKE

BOOSTRIX comes in glass vials or prefilled syringes. It is a white, slightly milky liquid.

INGREDIENTS

The active ingredients of BOOSTRIX are non-infectious substances from tetanus and diphtheria bacteria, and purified proteins of pertussis bacteria. The vaccine cannot cause these diseases.

Each 0.5mL dose contains:

- 2.5Lf U of diphtheria toxoid
- 5Lf U of tetanus toxoid
- 8mcg of pertussis toxoid, 8mcg of filamentous haemagglutinin and 2.5mcg of 69Kd outer membrane protein (pertactin).

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

BOOSTRIX does not contain any infectious material.

Further Information

BOOSTRIX is only available if prescribed by a doctor.

The vaccine comes in the following:

BOOSTRIX comes as a prefilled syringe in packs of 1 or 10.

BOOSTRIX is also available in vials, single dose in packs of 1 or 10

Distributor

Distributed In New Zealand by:

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