

BOOSTRIX

Combined diphtheria, tetanus, acellular pertussis (dTpa) vaccine

CONSUMER MEDICINE INFORMATION

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 with this vaccine. 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 4 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 (Lockjaw)

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.

The use of BOOSTRIX during pregnancy will help to protect your baby from whooping cough in the first few months of life before he/she receives the primary immunisation.

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 BOOSTRIX or any other ingredients 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 or swelling of the face or tongue
- you/your child had an allergic reaction to any other diphtheria, tetanus, pertussis vaccine
- 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, nurse or pharmacist about this before being vaccinated.
- you/your child has experienced any inflammation of the brain or problems with the nervous system within 7 days after previous vaccination with a vaccine against pertussis (whooping cough) disease
- you/your child experienced a temporary reduction in blood platelets (which increases risk of bleeding or bruising), or problems with the brain or nerves after previous vaccination with a vaccine against diphtheria and/or tetanus
- 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, nurse or pharmacist.

BEFORE BOOSTRIX IS GIVEN TELL YOUR DOCTOR, NURSE OR PHARMACIST IF:

- you/your child has a severe infection with a high temperature. In these cases, the vaccination will be postponed until recovery. A minor infection such as a cold should not be a problem but talk to your doctor first.
- after having been given BOOSTRIX or another vaccine containing diphtheria, tetanus, pertussis, your child had problems such as:
 - high temperature (40.0°C or more) 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 suffered 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.
- you/your child has a bleeding disorder or bruises easily. Sometimes BOOSTRIX may need to be given differently in people with bleeding problems
- you/your child has an immune deficiency condition (eg. are HIV positive)
- you/your child has a tendency to seizures/fits due to a fever, or if there is a family history of this
- 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
 - your doctor will discuss with you the possible risks and benefits of receiving BOOSTRIX during pregnancy.

Collapse or periods of unconsciousness or lack of awareness, seizures or fits have occurred in children given other vaccines containing one or more of the active constituents of BOOSTRIX. They usually occur within two to three days after vaccination.

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

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.

HOW BOOSTRIX IS GIVEN

The doctor, nurse or pharmacist 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 0.5 mL

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 IS 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, nurse or pharmacist 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, nurse or pharmacist 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 in order to protect from light.

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 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 0.5 mL dose contains:

- not less than 2 IU of diphtheria toxoid
- not less than 20 IU of tetanus toxoid
- 8 micrograms of pertussis toxoid, 8 micrograms of filamentous haemagglutinin and 2.5 micrograms pertactin.

Inactive ingredients in the vaccine are aluminium hydroxide, aluminium phosphate, formaldehyde, polysorbate 80, sodium chloride, glycine and water for injections.

BOOSTRIX does not contain any infectious material.

FURTHER INFORMATION

BOOSTRIX is only available if prescribed by a doctor, nurse or pharmacist.

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

DISTRIBUTOR

GlaxoSmithKline NZ Ltd

Private Bag 106600

Downtown Auckland

NEW ZEALAND

Ph: (09) 367 2900

Fax: (09) 367 2910

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