

# BOOSTRIX

## Consumer Medicine Information (CMI) summary

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

### 1. Why is my child or I being given BOOSTRIX?

BOOSTRIX is used for booster vaccination in adults and children aged 4 years and older to prevent three diseases: diphtheria, tetanus and pertussis (whooping cough). BOOSTRIX is also used during pregnancy to help protect your baby from whooping cough in the first few months of life before he/she receives the primary immunisation.

BOOSTRIX 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 my child or I being given BOOSTRIX?](#) in the full CMI.

### 2. What should I know before my child or I are given BOOSTRIX?

Do not receive this vaccine if you or your child has ever had an allergic reaction to BOOSTRIX, or any of the ingredients listed at the end of the CMI. Tell your doctor, nurse or pharmacist if you or your child have a very high fever or any other infection.

**Talk to your doctor if you or your child has any other medical conditions, take any other medicines, or if you are pregnant or plan on becoming pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before my child or I are given BOOSTRIX?](#) in the full CMI.

### 3. What if my child or I are taking other medicines?

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

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

### 4. How is BOOSTRIX given?

- Your doctor, nurse or pharmacist will give BOOSTRIX as an injection into your/your child's upper arm muscle.
- If you have bleeding problems, the dose may need to be given under the skin (subcutaneously).
- The vaccine should never be given intravenously (into the vein).

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

### 5. What should I know while my child or I are being given BOOSTRIX?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell your doctor, nurse or pharmacist immediately if you or your child notice any of the following: fever greater than 40°C, crying for 3 hours or more, collapse, or periods of unconsciousness or lack of awareness, seizures (convulsions) or fits.</li><li>• Tell your doctor, nurse or pharmacist, or go to the emergency department if you notice any signs of an allergic reaction, including itchy skin rash, shortness of breath or swelling of the face or tongue or severe skin reactions.</li><li>• Keep a record of you/your child's vaccination history.</li></ul>
<b>Looking after your vaccine</b>	<ul style="list-style-type: none"><li>• BOOSTRIX is usually stored at the doctor's clinic or surgery, or at the pharmacy. If you need to store BOOSTRIX, store in the refrigerator between 2°C and 8°C and protect from light.</li><li>• THE PACK SHOULD NEVER BE FROZEN. FREEZING DESTROYS THE VACCINE.</li></ul>

For more information, see Section [5. What should I know while my child or I are being given BOOSTRIX?](#) in the full CMI.

### 6. Are there any side effects?

Side effects which have been reported following the administration of BOOSTRIX include loss of appetite, irritability, diarrhoea, vomiting, feeling sick (nausea), constipation, redness, swelling, a hard lump, soreness, bruising or itching around the injection site, fever (more than 37.5°C). Allergic reactions have also occurred following administration of BOOSTRIX. Allergy is rare and severe reactions will usually occur within the first few hours of vaccination. If this occurs, go to the Emergency Department of the nearest hospital immediately. As with all vaccines, there is a very small risk of serious allergic reaction. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# BOOSTRIX

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

## Consumer Medicine Information (CMI)

This leaflet provides important information about BOOSTRIX. **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 BOOSTRIX.**

**Where to find information in this leaflet:**

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

## 1. Why is my child or I being given BOOSTRIX?

BOOSTRIX is used for booster vaccination in adults and children aged 4 years and older against diphtheria, tetanus and acellular pertussis (whooping cough).

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

The vaccine works by causing the body to produce its own protection (antibodies) against the disease. The vaccine is sometimes called dTpa vaccine.

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

### 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 a highly infectious illness. 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 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.

## 2. What should I know before my child or I are given BOOSTRIX?

### Warnings

**You should not be given BOOSTRIX if:**

- you/your child have had an allergic reaction to BOOSTRIX or any other 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 or swelling of the face or tongue
- you/your child have had an allergic reaction to any other diphtheria, tetanus, pertussis vaccine
- you/your child 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, nurse or pharmacist about this before being vaccinated
- you/your child have 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 have 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.**

**Check with your doctor if you or 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 receiving BOOSTRIX or another vaccine containing diphtheria, tetanus, pertussis has problems such as:

- high temperature (40°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
- suffered brain disease or Central Nervous System (CNS) disease such as epilepsy or a tendency to experience febrile convulsions (seizures /fits due to a high fever)
- has a bleeding disorder or bruises easily. Sometimes BOOSTRIX may need to be given differently in people with bleeding problems
- has an immune deficiency condition (e.g. are HIV positive)
- has a tendency to experience seizures/fits due to a fever, or if there is a family history of this
- has never been given a vaccine for diphtheria, tetanus or pertussis or have not completed a full course of diphtheria and tetanus vaccinations.

During treatment, you 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?](#)

### **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant. Your doctor will discuss with you the possible risks and benefits of receiving BOOSTRIX during pregnancy.

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 series. Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if BOOSTRIX passes into breast milk.

## **3. What if my child or I are taking other medicines?**

Tell your doctor or pharmacist if you or your child are 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 medicines may interfere with BOOSTRIX and affect how it works.**

### **Having other vaccines**

Tell your doctor, nurse or pharmacist if you or your child have received another vaccine recently.

**Some vaccines may be affected by other vaccines.**

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you or your child are taking and if these affect BOOSTRIX.**

## **4. How is BOOSTRIX 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 it is given**

- BOOSTRIX is given as a 0.5 mL injection 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 (into the vein).**

### **When it is given**

- BOOSTRIX is given in accordance with official recommendations for booster vaccination, when a booster dose for tetanus, diphtheria or pertussis is required.
- BOOSTRIX can be administered to pregnant women during the second or the third trimester in accordance with official recommendations.
- BOOSTRIX can be used in the management of tetanus prone injuries in persons who have previously received a primary vaccination series of tetanus toxoid vaccine.

### **If a dose of BOOSTRIX is missed**

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

### **If you or your child is given too much BOOSTRIX**

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

#### **You should immediately:**

- phone the Poisons Information Centre (by calling **0800 POISON** or **0800 764 766**), 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 I know while my child or I are being given BOOSTRIX?**

### **Things you must do**

- Keep a record of you or your child's vaccination history.
- Ensure that BOOSTRIX is given at the correct schedule as this will help to ensure the best protection against diphtheria, tetanus and whooping cough.

### **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how BOOSTRIX affects you.**

BOOSTRIX is unlikely to produce an effect on the ability to drive and use machines.

## Looking after your vaccine

BOOSTRIX is usually stored at the doctor's clinic or surgery, or at the pharmacy.

If you need to store BOOSTRIX:

- store in a refrigerator between 2°C and 8°C
- THE PACK SHOULD NEVER BE FROZEN. FREEZING DESTROYS THE VACCINE
- store in the original pack until it is time to be given
- protect from light.

Follow the instructions in 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 receive 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 you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Children from 4 to 9 years of age:</b></p> <p><b>General disorders and administration site conditions</b></p> <ul style="list-style-type: none"> <li>• injection site reactions including pain, redness and swelling</li> <li>• fatigue</li> <li>• fever <math>\geq 37.5^{\circ}\text{C}</math> (including fever <math>&gt; 39^{\circ}\text{C}</math>)</li> </ul> <p><b>Nervous system disorders</b></p> <ul style="list-style-type: none"> <li>• fatigue</li> <li>• irritability</li> <li>• drowsiness</li> <li>• disturbances in attention</li> </ul> <p><b>Eye disorders</b></p>	<p><b>Speak to your doctor if you or your child have any of these less serious side effects that are troublesome or ongoing after vaccination.</b></p>

<ul style="list-style-type: none"> <li>• conjunctivitis</li> </ul> <p><b>Skin disorders</b></p> <ul style="list-style-type: none"> <li>• rash</li> </ul> <p><b>Adults, adolescents and children from the age of 10 years onwards</b></p> <p><b>General disorders and administration site conditions</b></p> <ul style="list-style-type: none"> <li>• injection site reactions including pain, redness and swelling</li> <li>• fatigue</li> <li>• fever <math>\geq 37.5^{\circ}\text{C}</math> (including fever <math>&gt; 39^{\circ}\text{C}</math>)</li> </ul> <p><b>Respiratory disorders</b></p> <ul style="list-style-type: none"> <li>• sore throat</li> <li>• cough</li> </ul> <p><b>Nervous system disorders</b></p> <ul style="list-style-type: none"> <li>• headache</li> <li>• dizziness</li> <li>• fainting</li> </ul> <p><b>Gastrointestinal disorders</b></p> <ul style="list-style-type: none"> <li>• nausea</li> <li>• diarrhoea</li> <li>• vomiting</li> </ul> <p><b>Skin disorders</b></p> <ul style="list-style-type: none"> <li>• excessive sweating</li> <li>• rash</li> </ul> <p><b>Musculoskeletal and connective tissue disorders</b></p> <ul style="list-style-type: none"> <li>• joint stiffness/pain</li> <li>• muscle stiffness/pain</li> </ul>	
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### Serious side effects

Serious side effects	What to do
<p><b>All age groups:</b></p> <p><b>Immune system disorders and allergic reactions:</b></p> <p>As with all vaccines given by injection, there is a very small risk of serious allergic reaction. Signs of an allergic reaction include:</p> <ul style="list-style-type: none"> <li>• swelling of limbs, face, eyes, inside of nose, mouth or throat</li> <li>• shortness of breath, or breathing or swallowing difficulties</li> <li>• hives, itching (especially of the hands or feet), reddening of skin (especially around the ears), or severe skin reactions</li> </ul>	<p><b>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 in you or your child.</b></p>

<ul style="list-style-type: none"> <li>unusual tiredness or weakness that is sudden and severe, muscular aches and pains.</li> <li>convulsions/fits, collapse or periods of unconsciousness</li> <li>fever over 40°C.</li> </ul> <p>Allergy to BOOSTRIX is rare. Any such severe reactions will usually occur within the first few hours of vaccination.</p> <p><b>Respiratory disorders:</b></p> <ul style="list-style-type: none"> <li>upper respiratory tract infections</li> <li>influenza like illness</li> </ul> <p><b>Ear disorders:</b></p> <ul style="list-style-type: none"> <li>middle ear infections</li> </ul> <p><b>Children from 4 to 9 years of age:</b></p> <p><b>Metabolism and nutrition disorders</b></p> <ul style="list-style-type: none"> <li>anorexia</li> </ul> <p><b>Blood and lymphatic system disorders</b></p> <ul style="list-style-type: none"> <li>enlarged lymph nodes</li> </ul>	
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**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

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

### Reporting side effects

After you have received medical advice for any side effects that you or your child experience, you can report side effects via

<https://pophealth.my.site.com/carmreportnz/s/>.

By reporting side effects, you can help provide more information on the safety of this vaccine.

## 7. Product details

This vaccine is only available with a doctor or nurse's prescription, or when given by a registered pharmacist qualified as a vaccinator.

### What BOOSTRIX contains

<b>Active ingredients (main ingredients)</b>	<ul style="list-style-type: none"> <li>≥2 IU (2.5 Lf U) of diphtheria toxoid</li> <li>≥20 IU (5 Lf U) of tetanus toxoid</li> <li>8 micrograms of pertussis toxoid, 8 micrograms of pertussis filamentous haemagglutinin and 2.5 micrograms of pertactin</li> </ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>aluminium hydroxide</li> <li>aluminium phosphate</li> <li>sodium chloride</li> </ul>

	<ul style="list-style-type: none"> <li>water for injections</li> </ul>
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**You should not be given this vaccine if you are allergic to any of these ingredients.**

**BOOSTRIX does not contain any infectious material.**

### What BOOSTRIX looks like

BOOSTRIX is a white, slightly milky liquid and comes as a prefilled syringe in packs of 1 or 10 (TT50-6346).

### Who distributes BOOSTRIX

GlaxoSmithKline NZ Ltd  
Private Bag 106600  
Downtown  
Auckland 1143  
New Zealand

Phone: (09) 367 2900

Facsimile: (09) 367 2910

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