

# 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, nurse or pharmacist.

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

BOOSTRIX is a vaccine used as a booster to prevent three diseases: diphtheria, tetanus and pertussis (whooping cough) in adults and children aged 4 years and older who have been previously vaccinated against these diseases. 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 are 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.

**Talk to your doctor if you or your child has any other medical conditions, take any other medicines, or if you are pregnant, plan to become 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?

BOOSTRIX will be injected into the upper arm muscle. 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>• Remind any doctor, dentist or pharmacist that your child or you visit that they or you have been given BOOSTRIX.</li><li>• Tell your doctor immediately if you notice any of the following: fever greater than 39.5°C, crying for 3 hours or more, collapse, or periods of unconsciousness or lack of awareness, seizures (convulsions) or fits.</li><li>• Contact a doctor immediately, or go to the emergency department, if you notice any signs of an allergic reaction, including swelling of the face, lips, tongue or other parts of the body, difficulty breathing or hives.</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.</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 include irritability, sleepiness, swelling, pain, redness where the injection was given, tiredness, loss of appetite, headache, vomiting, diarrhoea, fever (more than 37.5°C), generally feeling unwell, dizziness, hard lump and abscess at the injection site. As with all vaccines given by injection 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 or 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 are my child or I being given BOOSTRIX?

BOOSTRIX is a vaccine used as a booster to prevent three diseases: diphtheria, tetanus and pertussis (whooping cough) in adults and children aged 4 years and older who have been previously vaccinated against these diseases.

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, and purified proteins of pertussis bacteria.

The vaccine cannot cause these diseases.

The vaccine works by causing the body to produce its own protection (antibodies) against these diseases.

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

#### 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 10% 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 diseases.

The vaccine will not protect against diseases caused by other types of bacteria or organisms.

A primary course of tetanus, diphtheria and pertussis vaccine is usually given during early childhood.

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

#### Warnings

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

- you or your child has had an allergic reaction to BOOSTRIX, or any of the ingredients 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. Always check the ingredients to make sure you can receive this vaccine
- you or your child has had BOOSTRIX before and became unwell. Tell your doctor, nurse or pharmacist before the next dose is given
- you or your child has had an allergic reaction to any other diphtheria, tetanus or pertussis containing vaccine (such as Infanrix, Tripacel or Triple Antigen vaccine)
- you or your child experienced a disease of the brain within 7 days after previous vaccination with a pertussis containing vaccine
- you or your child had a low blood platelet count or bled or bruised more easily following earlier immunisation against diphtheria and/or tetanus even if only for a short time
- you or your child suffered from problems associated with your nervous system following earlier immunisation against diphtheria and/or tetanus even if only for a short time
- you or 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

- your child is under 11 years of age and has not received a complete course of diphtheria or tetanus vaccine previously
- your child is less than 4 years of age. The vaccine is only intended for use in children 4 years and older, adolescents and adults. The vaccine may not be as effective in infants younger than 4 years of age, because it is a low strength vaccine meant for older children and adults.

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

**Check with your doctor if you or your child:**

- has any other medical conditions such as:
  - neurological disorders, including infantile spasms, uncontrolled epilepsy or progressive encephalopathy (a disease of the brain)
  - lowered immunity due to medical treatment or a medical condition
  - a tendency to febrile convulsions (seizures/fits due to a fever or high body temperature)
- has a bleeding problem or bruises easily
- had any problems after receiving BOOSTRIX previously
- has not previously received the full course of diphtheria and tetanus vaccination
- experienced any problems after having a pertussis-containing vaccine (such as Infanrix, Tripacel or Triple Antigen), especially:
  - a high temperature (over 40°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.
- has fainted with a previous injection. Fainting can occur following, or even before, any needle injection.

During treatment, you or your child 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, nurse or pharmacist 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, nurse 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:**

- medicines which suppress the immune system, such as high-dose steroids.

### **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 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 it is given**

- BOOSTRIX is given as a 0.5 mL injection into the upper arm muscle.

**The vaccine should never be given intravenously (into the vein).**

### **When it is given**

- BOOSTRIX is generally given whenever a booster dose of diphtheria and tetanus vaccine is required and where a booster for pertussis is desired.
- BOOSTRIX may be given to pregnant women during the second or the third trimester of pregnancy in accordance with official recommendations.
- BOOSTRIX may also be given in the case of a tetanus-prone injury where a booster for diphtheria and pertussis is also required, provided no previous dose of tetanus vaccine was given within five years previously.

### **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 13 11 26), 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 should do

- Keep a record of you or your child's vaccination history.

Remind any doctor, dentist or pharmacist you visit that you/your child has been given BOOSTRIX.

### 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 affect 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 the refrigerator between 2°C and 8°C
- THE PACK SHOULD NEVER BE FROZEN. FREEZING DESTROYS THE VACCINE
- keep BOOSTRIX in the original pack until it is time for it 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 use 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.

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

### Less serious side effects

Less serious side effects	What to do
<b>All age groups:</b> General disorders and administration site conditions: <ul style="list-style-type: none"> <li>• swelling, pain, redness where the injection was given</li> </ul>	<b>Speak to your doctor if you or your child have any of these less serious</b>

- tiredness
- fever (more than 37.5°C)
- headache

Skin and subcutaneous tissue disorders:

- skin rash

Respiratory disorders:

- upper respiratory tract infection

Gastrointestinal disorders:

- vomiting
- diarrhoea

### Children from 4 to 9 years of age:

General disorders and administration site conditions:

- sleepiness
- disturbances in attention
- hard lump where the injection was given

Nervous system disorders:

- irritability

Gastrointestinal disorders:

- loss of appetite

Eye disorders:

- discharge with itching of the eyes and crusty eyelids (conjunctivitis)

### Adults, teenagers and children from the age of 10 years onwards:

General disorders and administration site conditions:

- hard lump and abscess at the injection site
- fainting
- flu-like symptoms (such as fever, sore throat, runny nose, cough and chills)
- generally feeling unwell

Nervous system disorders:

- dizziness
- excessive sweating

Gastrointestinal disorders:

- nausea

Lymphatic disorders:

- swollen glands in the neck, armpit or groin

Skin and subcutaneous tissue disorders:

- itching

**side effects and they worry you.**

Musculoskeletal and connective tissue disorders: <ul style="list-style-type: none"> <li>joint stiffness</li> <li>joint pain</li> <li>muscle ache</li> </ul> Respiratory disorders: <ul style="list-style-type: none"> <li>sore throat and discomfort when swallowing</li> <li>cough</li> </ul>	
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### Serious side effects

Serious side effects	What to do
<b>All age groups:</b> Immune system disorders and allergic reactions: <ul style="list-style-type: none"> <li>swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing</li> <li>hives</li> <li>large swelling of the injected limb</li> <li>unusual weakness</li> </ul> Nervous system disorders: <ul style="list-style-type: none"> <li>seizures (with or without fever)</li> </ul> <b>Adults, teenagers and children from the age of 10 years onwards:</b> General disorders and administration site conditions: <ul style="list-style-type: none"> <li>fever (more than 39°C)</li> </ul>	<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>

**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 to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This vaccine is only available with a doctor's prescription.

### 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> </ul>
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	<ul style="list-style-type: none"> <li>≥20 IU (5 Lf U) of tetanus toxoid</li> <li>8 micrograms of pertussis toxoid, 8 micrograms of 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 hydrate</li> <li>aluminium phosphate</li> <li>sodium chloride</li> <li>water for injections</li> </ul>

**You should not be given this vaccine if you are allergic to any of these ingredients.**

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.

### What BOOSTRIX looks like

BOOSTRIX is a white, slightly milky liquid in prefilled syringes (AUST R 158363).

### Who distributes BOOSTRIX

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street,

Abbotsford, Victoria, 3067

Phone: 1800 033 109

[www.gsk.com.au](http://www.gsk.com.au)

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