

BOOSTRIX-IPV

Consumer Medicine Information (CMI) summary

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

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

BOOSTRIX-IPV is a vaccine used as a booster to prevent four diseases, diphtheria, tetanus, pertussis (whooping cough) and poliomyelitis (polio) in adults and children aged 4 years and older who have been previously vaccinated against these diseases. BOOSTRIX-IPV contains the active ingredients of non-infectious substances from diphtheria bacteria, tetanus bacteria, purified proteins of pertussis bacteria and inactivated poliovirus.

For more information, see Section [1. Why are my child or I being given BOOSTRIX-IPV?](#) in the full CMI.

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

Do not receive this vaccine if you or your child have ever had an allergic reaction to BOOSTRIX-IPV or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you or your child have any other medical conditions, take any other medicines, or if you are pregnant or 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-IPV?](#) in the full CMI.

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

Some medicines may interfere with BOOSTRIX-IPV 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-IPV given?

BOOSTRIX-IPV will be injected in 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-IPV given?](#) in the full CMI.

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

Things you should do	<ul style="list-style-type: none">Keep your follow up visits with the doctor or clinic.Tell your doctor or nurse immediately if you notice any of the following: sudden sign of allergy such as rash, itching or hives on the skin, swelling of limbs, face, eyes, lips, mouth, throat or other part of the body, shortness of breath, breathing or swallowing difficulties, unusual tiredness or weakness that is sudden and severe.
Looking after your vaccine	<ul style="list-style-type: none">BOOSTRIX-IPV is usually stored at the doctor's clinic or surgery, or at the pharmacy. If you need to store BOOSTRIX-IPV, store in the refrigerator between 2°C and 8°C.THE PACK SHOULD NEVER BE FROZEN. FREEZING DESTROYS THE VACCINE.

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

6. Are there any side effects?

Side effects which have been reported include swelling, pain, bruising, redness at the injection site, loss of appetite, irritability, headache, fever (more than 37.5°C), bleeding at the injection site, tiredness, nausea, vomiting, diarrhoea and/or abdominal pain, generally feeling unwell, upper respiratory tract infection and 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-IPV

Active ingredients: diphtheria toxoid, tetanus toxoid, pertussis toxoid, pertussis filamentous haemagglutinin and pertactin and inactivated poliovirus.

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

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

BOOSTRIX-IPV contains the active ingredients of non-infectious substances from diphtheria bacteria, tetanus bacteria, purified proteins of pertussis bacteria and inactivated poliovirus.

The vaccine cannot cause these diseases.

BOOSTRIX-IPV is a vaccine used as a booster to prevent four diseases: diphtheria, tetanus, pertussis (whooping cough) and poliomyelitis (polio) in adults and children aged 4 years and older who have been previously vaccinated against 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. Poliomyelitis is an infectious disease caused by viral 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 can 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 the 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 middle 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.

Poliomyelitis (Polio)

Polio is a viral infection that can have variable effects. Often it causes a mild illness but in some people, it causes permanent injury or death. In its severest form, polio infection causes paralysis of the muscles, including those needed for breathing and walking. Polio infection can leave a person unable to breathe without the help of an iron lung machine, unable to walk without leg braces, or confined to a wheelchair. The limbs affected by the disease may be painfully deformed.

Vaccination is the best way to protect against these diseases.

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

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

Warnings

You or your child should not be given BOOSTRIX-IPV if:

- there is a history of an allergic reaction to BOOSTRIX-IPV, or any of the ingredients listed at the end of this leaflet. Signs of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue, or other parts of the body, rash, itching or hives on the skin. Always check the ingredients to make sure you can receive this vaccine
- there is a history of an allergic reaction to any other vaccine containing diphtheria, tetanus, pertussis or inactivated polio (such as Infanrix, Vaxelis, Adacel or Quadracel).
- 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 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 not received a complete course of diphtheria or tetanus vaccination previously.

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

- have any other medical conditions or problems 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)
- after receiving BOOSTRIX-IPV or another pertussis-containing vaccine, you or your child experienced any problems such as:
 - 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
- 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 or nurse about this before vaccination
- have a family history of Sudden Infant Death Syndrome (SIDS)
- have a bleeding problem or bruises easily
- have an allergy to the antibiotics neomycin sulfate and/or polymyxin sulfate
- have fainted with a previous injection. Fainting can occur following, or even before any needle injection.

Use in children

Tell your doctor if your child is less than 4 years of age. The vaccine is only intended for use in children aged 4 years and above and in adults. The vaccine may not be as effective in infants younger than 4 years of age, because of the low diphtheria, tetanus and pertussis antigen content.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

The use of BOOSTRIX-IPV during pregnancy will help to protect your baby from whooping cough in the first few

months of life before your child receives the primary immunisation series.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor can discuss with you the risks and benefits of receiving BOOSTRIX-IPV during pregnancy.

It is not known whether BOOSTRIX-IPV 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-IPV and affect how it works:

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

Receiving other vaccines

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

Some vaccines may be affected by other vaccines. Your doctor, nurse or pharmacist will be able to tell you what to do if BOOSTRIX-IPV is to be given with another vaccine.

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-IPV.

4. How is BOOSTRIX-IPV given?

The doctor or nurse will give BOOSTRIX-IPV 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-IPV 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-IPV is generally given whenever a booster dose of diphtheria, tetanus and polio vaccine is required and where a booster for pertussis is desired.
- BOOSTRIX-IPV may also be given in the case of a tetanus-prone injury where a booster for diphtheria, pertussis and polio is also required, provided no previous dose of tetanus vaccine was given within five years previously.

If a dose is missed

If you or your child misses a scheduled dose, talk to your doctor or nurse and arrange another visit as soon as possible.

If you or your child are given too much BOOSTRIX-IPV

If you think that you or your child have been given too much BOOSTRIX-IPV, 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-IPV?

Things you must do

Keep your follow up visits with the doctor or clinic. It is important the follow-up doses of BOOSTRIX-IPV are given at the correct times. This will ensure the best effect of the vaccine in protecting you or your child against diphtheria, tetanus, pertussis and poliovirus infection.

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

Looking after your vaccine

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

If you need to store BOOSTRIX-IPV:

- store in the refrigerator between 2°C and 8°C
- THE PACK SHOULD NEVER BE FROZEN. FREEZING DESTROYS THE VACCINE
- BOOSTRIX-IPV should be used immediately after opening
- store in the original pack until it is time for it to be given
- protect from light.

Follow the instructions on the carton on how to take care of this 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.

This vaccine should not be given 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 or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Children from 4 to 9 years of age: General disorders and administration site conditions: <ul style="list-style-type: none">• swelling, pain, redness at the injection site• hard lump at the injection site• fever (more than 37.5°C)• bleeding at the injection site• sleeping problems• apathy• tiredness Nervous system disorders: <ul style="list-style-type: none">• headache• irritability Lymphatic disorders: <ul style="list-style-type: none">• swollen glands in the neck, armpit or groin Gastrointestinal disorders: <ul style="list-style-type: none">• loss of appetite• nausea, vomiting, diarrhoea• stomach pain or discomfort Respiratory disorders: <ul style="list-style-type: none">• dry throat. Adults, teenagers and children from the age of 10 years onwards: General disorders and administration site conditions: <ul style="list-style-type: none">• swelling, pain, redness at the injection site• hard lump at the injection site• fever (more than 37.5°C)• bruising at the injection site• tiredness• chills• pain Lymphatic disorders: <ul style="list-style-type: none">• swollen glands in the neck, armpit or groin Infections and infestations: <ul style="list-style-type: none">• oral herpes Nervous system disorders:	Speak to your doctor if you or your child have any of these less serious side effects and they worry you.

<ul style="list-style-type: none"> headache tingling or numbness of the hands or feet dizziness <p>Gastrointestinal disorders:</p> <ul style="list-style-type: none"> decreased appetite nausea, vomiting, diarrhoea and/or abdominal pain <p>Respiratory disorders:</p> <ul style="list-style-type: none"> asthma <p>Skin and subcutaneous tissue disorders:</p> <ul style="list-style-type: none"> itching <p>Musculoskeletal and connective tissue disorders:</p> <ul style="list-style-type: none"> joint pain, muscle pain. 	
<p>Additionally, the following side effects have been reported during clinical studies or routine use of BOOSTRIX (GSK's booster vaccine against diphtheria, tetanus and pertussis):</p> <p>Children from 4 to 9 years of age:</p> <p>General disorders and administration site conditions:</p> <ul style="list-style-type: none"> disturbances in attention pain hard lump at the injection site <p>Gastrointestinal disorders:</p> <ul style="list-style-type: none"> nausea, vomiting, diarrhoea and/or abdominal pain <p>Respiratory disorders:</p> <ul style="list-style-type: none"> upper respiratory tract infection eye disorders discharge with itching of the eyes and crusty eyelids <p>Skin and subcutaneous tissue disorders:</p> <ul style="list-style-type: none"> skin rash. <p>Adults, teenagers and children from the age of 10 years onwards:</p> <p>General disorders and administration site conditions:</p> <ul style="list-style-type: none"> generally feeling unwell hard lump and abscess at the injection site fainting flu-like symptoms, such as fever, sore throat, runny nose, cough and chills <p>Nervous system disorders:</p>	

<ul style="list-style-type: none"> excessive sweating <p>Gastrointestinal disorders:</p> <ul style="list-style-type: none"> nausea, vomiting, diarrhoea respiratory disorders: upper respiratory tract infection skin and subcutaneous tissue disorders: skin rash <p>Musculoskeletal and connective tissue disorders:</p> <ul style="list-style-type: none"> joint or muscle stiffness. 	
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Serious side effects

Serious side effects	What to do
<p>All age groups:</p> <p>General disorders and administration site conditions:</p> <ul style="list-style-type: none"> extensive swelling of the vaccinated limb <p>Nervous system disorders:</p> <ul style="list-style-type: none"> fits (with or without fever) <p>Immune system disorders and allergic reactions:</p> <ul style="list-style-type: none"> swelling of the face, mouth, tongue or throat which may cause difficulty in swallowing or breathing sudden sign of allergy such as rash, itching or hives on the skin, swelling of limbs, face, eyes, lips, mouth, throat or other part of the body shortness of breath, breathing or swallowing difficulties unusual tiredness or weakness that is sudden and severe. <p>These are signs of an allergic reaction. As with all vaccines given by injection there is a very small risk of such reactions. Allergy to BOOSTRIX-IPV is rare. Any such severe reactions will usually occur within the first few hours of vaccination.</p>	<p>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.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you or your child 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 you or your child experience, you can report side effects to the Therapeutic Goods Administration online at 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 or giving any of your child’s medicines.

7. Product details

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

What BOOSTRIX-IPV contains

Active ingredient (main ingredient)	2 IU of diphtheria toxoid 20 IU of tetanus toxoid 8 micrograms of pertussis toxoid 8 micrograms of filamentous haemagglutinin 2.5 micrograms of pertactin 40 D-antigen units of poliovirus Type 1 8 D-antigen units of poliovirus Type 2 32 D-antigen units of poliovirus Type 3
Other ingredients (inactive ingredients)	aluminium hydroxide hydrate aluminium phosphate sodium chloride (salt) Medium 199 (which contains phenylalanine) water for injections The residues in the vaccine are: <ul style="list-style-type: none">• polysorbate 80• neomycin sulfate• polymyxin B sulfate

You or your child 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-IPV looks like

BOOSTRIX-IPV is a white, slightly milky liquid in prefilled syringes (AUST R 96137).

Who distributes BOOSTRIX-IPV

GlaxoSmithKline Australia Pty Ltd
Level 4, 436 Johnston Street,

Abbotsford, Victoria, 3067

Phone: 1800 033 109

www.gsk.com.au

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This leaflet was prepared on 20 August 2025.

Version 8.0