BOOSTRIX-IPV

Combined diphtheria-Tetanus-acellular pertussis (dTpa) and Inactivated Poliovirus Vaccine

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using BOOSTRIX-IPV.

This leaflet answers some common questions about BOOSTRIX-IPV. 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 risks of you receiving BOOSTRIX-IPV against the expected benefits they expect it will have.

If you have any concerns about receiving BOOSTRIX-IPV, ask your doctor, nurse or pharmacist.

Keep this leaflet with the vaccine. You may need to read it again.

What BOOSTRIX-IPV is used for

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 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 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 only 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 use of BOOSTRIX-IPV 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.

BOOSTRIX-IPV cannot give you or your child diphtheria, tetanus, pertussis or polio infection.

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

Ask your doctor if you have any questions about why this medicine has been prescribed for you.
Your doctor may have prescribed it for another reason.

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

There is not enough information to recommend the use of this medicine for children under the age of 4 years.

Before you are given BOOSTRIX-IPV

When you must not be given it

Do not have BOOSTRIX-IPV if:

- You or your child has had an allergic reaction to:
  - BOOSTRIX-IPV, or any ingredient contained in this vaccine. The ingredients in BOOSTRIX-IPV are listed at the end of this leaflet
  - to any other vaccine containing diphtheria, tetanus, pertussis or inactivated polio (such as Infanrix, Triple Antigen, Tripacel or Ipol vaccine)

  Some of the symptoms 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
- 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 vaccine previously.

Do not use this vaccine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.
If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before being given BOOSTRIX-IPV

Tell your doctor if you or your child have or have had any of the following medical problems:

- after having BOOSTRIX-IPV or another pertussis-containing vaccine (such as Infanrix or Triple Antigen) you or your child had any problems, especially:
  - a high temperature (≥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 (seizures/fits) with or without a fever within 3 days of vaccination
- you or your child has a severe infection with a high temperature. A minor infection such as a cold should not be problem, but talk to your doctor or nurse about this before vaccination
- a family history of Sudden Infant Death Syndrome (SIDS)
- a tendency to febrile convulsions (seizures/fits due to a fever or high body temperate)
- brain disease or central nervous system (CNS) disease (i.e.. epilepsy etc.)
- a bleeding problem or bruises easily
- allergy to the antibiotics neomycin sulfate and polymyxin sulfate
- lowered immunity due to medical treatment or a medical condition.
- you or your child fainted with a previous injection. Fainting can occur following, or even before any needle injection.

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

Tell your doctor if you or your child has allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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

It is not known if BOOSTRIX-IPV passes into breast milk.

If you have not told your doctor about any of the above, tell him/her before you receive BOOSTRIX-IPV.

Taking other medicines

Tell your doctor, nurse or pharmacist if you or your child are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and BOOSTRIX-IPV may interfere with each other.

The following medicines may affect how well BOOSTRIX-IPV works:

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

Your doctor, nurse or pharmacist have more information on medicines to be careful with or avoid when given this vaccine.

Having other vaccines

Tell your doctor or nurse 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.

How BOOSTRIX-IPV is 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 much is given

The dose of BOOSTRIX-IPV is 0.5 mL.

How it is given

BOOSTRIX-IPV will be injected in the upper arm muscle. Each dose of BOOSTRIX-IPV is for single use only. Any residual vaccine must be discarded.

The vaccine should never be given intravenously.

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 diptheria, pertussis and polio is also required, provided no previous dose of tetanus vaccine was given within five years previously.

Do not give your medicine to anyone else, even if they have the same condition as you.

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 are not sure what to do, ask your doctor, nurse or pharmacist.

While being given BOOSTRIX-IPV

Things you must do

Keep the 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.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you or your child do not feel well during or after having had a dose of BOOSTRIX-IPV.

BOOSTRIX-IPV helps protect most children and adults from diphtheria, tetanus, pertussis and poliovirus infection, but it may have unwanted side effects in a few people. 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.

The chance of you or your child having a serious side effect is very much less than the chance of having a permanent injury from the natural infections.

Most unwanted effects with BOOSTRIX-IPV are mild and usually clear up within a few days. These effects, as with other vaccines, generally occur around the injection site.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Side effects that occurred in children from 4 to 9 years of age

Very common (these may occur with more than 1 in 10 doses of the vaccine):

- sleepiness
- swelling, pain, redness at the injection site

Common (these may occur with up to 1 in 10 doses of the vaccine):

- loss of appetite
- irritability
- headache
- fever (more than 37.5°C)
- bleeding at the injection site.

Uncommon (these may occur with up to 1 in 100 doses of the vaccine):

- swollen glands in the neck, armpit or groin
- sleeping problems
- apathy
- dry throat
- diarrhoea, vomiting, nausea
- stomach pain or discomfort
- tiredness.

Side effects that occurred in adults, teenagers and children from the age of 10 years onwards

Very common (these may occur with more than 1 in 10 doses of the vaccine):

- headache
- swelling, pain, redness at the injection site
- tiredness.

Common (these may occur with up to 1 in 10 doses of the vaccine):

- fever (more than 37.5°C)
- bruising at the injection site
- nausea, vomiting, diarrhoea and/or abdominal pain.

Uncommon (these may occur with up to 1 in 100 doses of the vaccine):

- oral herpes
- swollen glands in the neck, armpit or groin
- decreased appetite
- tingling or numbness of the hands or feet
- sleepiness
- dizziness
- asthma

- itching
- joint pain, muscle pain
- fever (more than 39°C)
- chills
- pain.

The following side effects are not specific for any age group:

Rare (these may occur with up to 1 in 1,000 doses of the vaccine):

- swelling of the face, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- fits (with or without fever)
- hives
- hard lump at the injection site
- extensive swelling of the vaccinated limb
- unusual weakness.

Additionally, the following side effects have been reported during clinical studies or routine use of Boostrix (GlaxoSmithKline Biological's booster vaccine against diphtheria, tetanus and pertussis):

Side effects that occurred in children from 4 to 9 years of age

Common (these may occur with up to 1 in 10 doses of the vaccine):

- nausea, vomiting, diarrhoea and/or abdominal pain.

Uncommon (these may occur with up to 1 in 100 doses of the vaccine):

- upper respiratory tract infection
- disturbances in attention
- discharge with itching of the eyes and crusty eyelids
- skin rash
- pain
- hard lump at the injection site.

Side effects that occurred in adults, teenagers and children from the age of 10 years onwards

Very common (these may occur with more than 1 in 10 doses of the vaccine):

- generally feeling unwell

Common (these may occur with up to 1 in 10 doses of the vaccine):

- nausea
- hard lump and abscess at the injection site.

Uncommon (these may occur with up to 1 in 100 doses of the vaccine):

- upper respiratory tract infection
- sore throat and discomfort when swallowing
- fainting
- cough
- diarrhoea, vomiting
- excessive sweating
- skin rash
- joint or muscle stiffness
- flu-like symptoms, such as fever, sore throat, runny nose, cough and chills.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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.

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.

Other side effects not listed above, can also occur during or soon after a dose of BOOSTRIX-IPV.

Check with your doctor or nurse if you or your child has any other side effects.

How to store BOOSTRIX-IPV

Storage

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

- Keep BOOSTRIX-IPV 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
- BOOSTRIX-IPV should be used immediately after opening
- Keep BOOSTRIX-IPV in the original pack until it is time for it to be given.
- Protect from light.

Disposal

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

Product description

What it looks like

BOOSTRIX-IPV comes in a prefilled syringe. It is a white, slightly milky liquid.

Ingredients

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

The vaccine cannot cause these diseases.

Each 0.5 mL dose contains:

- 2 IU of diphtheria toxoid
- 20 IU of tetanus toxoid
- 8 micrograms of pertussis toxoid, 8 micrograms of filamentous haemagglutinin and 2.5 micrograms of pertactin
- 40 D-antigen units of poliovirus Type 1, 8 D-antigen units of poliovirus Type 2 and 32 D-

antigen units of poliovirus Type 3.

The inactive ingredients in the vaccine are: aluminium hydroxide hydrate and aluminium phosphate as adjuvants, sodium chloride (salt), Medium 199 (which contains phenylalanine), water for injections, and traces of polysorbate 80, neomycin sulfate and polymyxin B sulfate.

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.

Supplier

GlaxoSmithKline Australia Pty Ltd
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Abbotsford, Victoria 3067
Australia.

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BOOSTRIX-IPV 0.5mL injection syringe (AUST R 96137)

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