BOOSTRIX®

Combined Diptheria-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 having BOOSTRIX against the expected benefits.

If you have any concerns about receiving BOOSTRIX talk to your doctor, nurse or pharmacist

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

What BOOSTRIX is used for

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. 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. BOOSTRIX vaccine cannot give your child diphtheria, tetanus or pertussis infection. 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.

Before Boostrix is given

Boostrix should not be given if:

- You or your child has had an allergic reaction to BOOSTRIX, or any ingredient contained in this vaccine. The ingredients in BOOSTRIX are 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.
- If you or your child 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.
- You or your child 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.
- The expiry date printed on the pack has passed.
- The packaging is torn or shows signs of tampering.

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

Tell your doctor if

- You or your child has any medical 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)
- you or your child have a bleeding problem or bruise(s) easily
- you or your child had any problems after receiving BOOSTRIX previously
- you or your child has not previously received the full course of diphtheria and tetanus vaccination. BOOSTRIX will not work in this situation.
- you or your child experienced any problems after having a pertussis-containing vaccine (such as Infanrix, Tripacel or Triple Antigen), especially:
  - a high temperature (over 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 received another vaccine recently, or is having any prescription or OTC (over-the-counter) medicines. In particular mention if your child is being given medicines which suppress the immune system, such as high-dose steroids
- you are, or think you may be pregnant or if you intend to become pregnant. Your doctor will discuss with you the possible risks and benefits of receiving BOOSTIX during pregnancy (in particular during the 3rd trimester)
- you are breast feeding. It is not known if BOOSTRIX passes into breast milk
- you or your child fainted with a previous injection. Fainting can occur following, or even before, any needle injection.

Taking other medicines

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 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 much is given

The dose of BOOSTRIX is 0.5mL.

How it is given

BOOSTRIX will be injected 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 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.

Side effects

Tell your doctor or nurse as soon as possible if you or your child does not feel or look well during or after having had a dose of BOOSTRIX vaccine.

BOOSTRIX helps protect most people from diphtheria, tetanus and pertussis infection, but it may have unwanted side effects. 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 your child having a permanent injury from the natural 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. Side effects are more likely to occur with booster dosing.

As with all injectable vaccines, severe allergic reactions (e.g. anaphylactic reactions) may very rarely occur (with up to 1 in 10,000 doses of the vaccine). These can be recognized by:

- itchy rash of the hands and feet
- swelling of the eyes and face
- difficulty in breathing or swallowing
- sudden drop in blood pressure and loss of consciousness.

These reactions will usually occur before leaving the doctor's surgery. However, if you or your child gets any of these symptoms you should contact a doctor urgently.

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):

- irritability
- sleepiness
- swelling, pain, redness where the injection was given
- tiredness

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

- loss of appetite
- headache
- vomiting and diarrhoea
- fever (more than 37.5°C)

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 (conjunctivitis)
- skin rash
- pain
- hard lump where the injection was given

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 where the injection was given
- tiredness
- generally feeling unwell

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

- dizziness
- nausea
- fever (more than 37.5°C)
- 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
- swollen glands in the neck, armpit or groin
- fainting
- cough
- diarrhoea
- vomiting
- excessive sweating
- itching
- skin rash
- joint stiffness
- joint pain
- muscle ache
- fever (more than 39°C)
- flu-like symptoms, such as fever, sore throat, runny nose, cough and 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, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- seizures (with or without fever)
- hives
- large swelling of the injected limb
- unusual weakness

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

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

Do not be alarmed by this list of possible side effects. You or your child may not experience any of them.

Storage

BOOSTRIX vaccine 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.

Ask your pharmacist what to do with any left over BOOSTRIX vaccine that has expired or has not been used.

Product description

What it looks like

BOOSTRIX comes in glass vials and prefilled syringes. It is a white, slightly milky liquid.

Ingredients

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

The vaccine cannot cause these diseases.

Each 0.5mL dose contains:

- ≥ 2 IU (2.5 Lf U) of diphtheria toxoid
- ≥ 20 IU (5 Lf U) of tetanus toxoid
- 8 mcg of pertussis toxoid, 8 mcg of filamentous haemagglutinin and 2.5 mcg of pertactin

The inactive ingredients in the vaccine are: aluminium hydroxide, aluminium phosphate, formaldehyde, polysorbate 80, sodium chloride (salt), glycine and water.

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.

Further Information

BOOSTRIX is only available if prescribed by a doctor.

BOOSTRIX comes in a glass vial (AUST R 158362) or as a prefilled syringe (AUST R 158363)

Manufacturer/Distributor/ Supplier

GlaxoSmithKline Biologicals s.a.
rue de l'Institut 89,
1330 Rixensart, Belgium.

DISTRIBUTED IN AUSTRALIA BY:

GlaxoSmithKline Australia Pty Ltd
Level 4, 436 Johnston Street
Abbotsford, Victoria, 3067
Australia.

Date of Preparation:
17 January 2017

Version 5.0

Boostrix is a registered trade mark of the GSK group of companies.