

BOOSTRIX[®]-IPV

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

CONSUMER MEDICINE INFORMATION LEAFLET

WHAT IS IN THIS LEAFLET

This leaflet answers some of the common questions about BOOSTRIX-IPV 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-IPV against the expected benefits.

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

Keep this leaflet with this 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 diseases 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 wheel chair. The limbs affected by the disease may be painfully deformed.

Vaccination is the best way to protect against these diseases. BOOSTRIX-IPV vaccine 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.

A primary course of tetanus, diphtheria, pertussis and polio vaccine is usually given during early childhood with doses given at 2, 4, 6 and one further dose at 4 years of age.

BEFORE VACCINATION

BOOSTRIX-IPV SHOULD NOT BE GIVEN 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. 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-IPV before and became unwell, tell your doctor, nurse or pharmacist before the next dose is given.
- 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 has had an allergic reaction to any other diphtheria, tetanus, pertussis or inactivated polio containing vaccine (such as INFANRIX[®], Triple Antigen[™], Tripacel[™] or IPOL[™] 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 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.
- you or your child suffer from neurological disorders, including infantile spasms, uncontrolled epilepsy or progressive encephalopathy (a brain disease).
- 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-IPV vaccine, talk to your doctor or nurse. Do not give this vaccine to anyone else; your doctor has prescribed it specifically for you/your child.

BEFORE BOOSTRIX-IPV IS GIVEN TELL YOUR DOCTOR OR NURSE IF:

- you or your child has any medical problems such as:
 - ◆ brain disease or central nervous system (CNS) disease (ie. epilepsy etc.)

- ◆ a bleeding problem or bruises easily
 - ◆ 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)
 - ◆ a family history of Sudden Infant Death Syndrome (SIDS)
 - ◆ allergy to the antibiotics: neomycin sulfate and polymyxin sulfate.
- you or your child has not previously received the full course of diphtheria and tetanus vaccination. BOOSTRIX-IPV will not work in this situation.
 - 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 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 BOOSTRIX-IPV during pregnancy (in particular during the 3rd trimester)
 - you are breast feeding. It is not known if BOOSTRIX-IPV passes into breast milk
 - you or your child has allergies to any other medicines or substances, such as dyes, foods or preservatives
 - you or your child fainted with a previous injection. Fainting can occur following, or even before, any needle injection.

TAKING OTHER MEDICINES

Tell your doctor or nurse if you/your child is having any prescription or OTC (over-the-counter) medicines. In particular, mention if you/your child is being given medicines which suppress the immune system, such as high-dose steroids.

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

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.

USE IN CHILDREN

BEFORE BOOSTRIX-IPV IS GIVEN TELL YOUR DOCTOR OR NURSE 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.

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 0.5mL.

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 diphtheria, pertussis and polio 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-IPV vaccine.

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.

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

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.

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

- ◆ 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, tiredness
- ◆ dry throat
- ◆ vomiting, diarrhoea,
- ◆ nausea, stomach pain or discomfort

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

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
- ◆ fever (more than 39.0°C)
- ◆ sleepiness
- ◆ dizziness
- ◆ asthma
- ◆ itching

- ◆ joint pain, muscle pain
- ◆ chills
- ◆ pain

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

- ◆ 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

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 effects.**

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

STORAGE

BOOSTRIX-IPV vaccine 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.

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 0.5mL dose contains:

- 2 IU of diphtheria toxoid
- 20 IU of tetanus toxoid
- 8 mcg of pertussis toxoid, 8 mcg of filamentous haemagglutinin and 2.5 mcg 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, aluminium phosphate, sodium chloride (salt), polysorbate 80, neomycin (traces), polymyxin (traces), formaldehyde (traces) and water.

BOOSTRIX-IPV does not contain any infectious material.

FURTHER INFORMATION

BOOSTRIX-IPV is only available if prescribed by a doctor.

BOOSTRIX-IPV comes in a prefilled syringe in packs of 1 or 10.

DISTRIBUTOR

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