PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed according to a physician's prescription only

Boostrix

Suspension for injection

Each dose (0.5 ml) contains:
diphtheria toxoid – NLT 2 IU
tetanus toxoid – NLT 20 IU
pertussis toxoid (PT) – 8 mcg
filamentous haemagglutinin (FHA) – 8 mcg
pertactin (PRN, or 69kDa OMP) – 2.5 mcg

For the list of the inactive and allergenic ingredients in the medicine, see section 2 – "Important information about some of the ingredients in the medicine" and section 6 – "Additional information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Booster vaccination against diphtheria, tetanus and pertussis of individuals from the age of four years onwards.

The administration should be based on official recommendations.

Therapeutic group: bacterial vaccines, pertussis vaccines.

How does the vaccine work?

The vaccine works by causing the body to produce its own protection (antibodies) against these diseases (diphtheria, tetanus, and pertussis).

None of the ingredients of this vaccine can cause these diseases.

2. BEFORE USING THE MEDICINE

Do not use this medicine if:

- you or your child have previously had any allergic reaction to Boostrix or to any of the additional ingredients contained in this vaccine (listed in section 6), or to formaldehyde. Signs of an allergic reaction may include itchy skin rash, shortness of breath, and swelling of the face or tongue.

- you or your child have previously had an allergic reaction to any vaccine against diphtheria, tetanus or pertussis diseases.

- you or your child experienced problems of the nervous system (encephalopathy) within 7 days after previous vaccination with a vaccine against the pertussis disease.

- you or your child have a severe infection with high temperature (over 38°C). A minor infection should not be a problem, but talk to your physician first.

- you or your child experienced a temporary reduction in blood platelets (which increases the risk of bleeding or bruising) or problems with the brain or nerves after a previous vaccination with a vaccine against diphtheria and/or tetanus.

Special warnings regarding use of the medicine

Talk to your physician or pharmacist before you or your child are vaccinated with Boostrix if:

- after previously getting Boostrix or another vaccine against pertussis disease, you or your child had any problems, especially:
  - A high temperature (over 40°C) within 48 hours of vaccination.
  - A collapse or shock-like state within 48 hours of vaccination.

- persistent crying lasting 3 hours or more within 48 hours of vaccination.
- seizures/fits with or without a high temperature within 3 days of vaccination.

• your child is suffering from an undiagnosed or progressive disease of the brain or uncontrolled epilepsy. After control of the disease the vaccine should be administered.
• you or your child have a bleeding problem or bruise easily.
• you or your child have a tendency to seizures/fits due to fever, or if there is a family history of this.
• you or your child have long-standing immune system problems for any reason (including HIV [human immunodeficiency virus] infection). You or your child may still be given Boostrix, but the protection against infections after getting the vaccine may not be as good as in children or adults with good immunity to infections.

Fainting can occur (mostly in adolescents) following, or even before, any needle injection. Therefore tell the physician or nurse if you or your child fainted with a previous injection.
As with other vaccines, Boostrix may not completely protect all people who are vaccinated.

Drug interactions

If you or your child are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist.
Boostrix can be given at the same time as some other vaccines. A different injection site will be used for each type of vaccine.
Boostrix may not work as well if you or your child are taking medicines that reduce the effectiveness of your/their immune system in fighting infection.

Pregnancy and breast-feeding

Your physician will discuss with you the possible risks and benefits of receiving Boostrix during pregnancy.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your physician or pharmacist for advice before you are given this vaccine.
It is not known if Boostrix passes into breast milk. Your physician will discuss with you the possible risks and benefits of having Boostrix during breast-feeding.

Driving and using machines
It is unlikely that this medicine will affect your ability to drive or use machines.

Important information about some of the ingredients in the medicine
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. HOW SHOULD YOU USE THE MEDICINE?
Always use the preparation according to the physician's instructions. Check with the physician or pharmacist if you are uncertain about the preparation dosage and treatment regimen.
The dosage and treatment regimen will be determined by the physician only.

The recommended dosage that you or your child will receive is usually a single injection of Boostrix.
- Boostrix is given as an injection into the muscle.
- The vaccine should never be injected into a blood vessel.
- Your physician will verify if you or your child have previously received vaccines against diphtheria, tetanus and/or pertussis.
- Boostrix may be used in case of a suspected infection with tetanus, although additional provisions, i.e. elaborate wound dressing and/or application of tetanus antitoxin will be taken as well to reduce the risk of manifestation of the disease.
- Your physician will advise you about repeating the vaccination.

Do not exceed the recommended dose.
Shake before use.
Adhere to the treatment regimen recommended by your physician.
Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Boostrix may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

As with all injectable vaccines severe allergic reactions (anaphylactic and anaphylactoid reactions) may occur very rarely (in up to 1 in 10,000 vaccination doses). These can be recognized by:
• rash that may be itchy or blistering
• **swelling of the eyes and face**
• **difficulty in breathing or swallowing**
• A sudden drop in blood pressure and **loss of consciousness.**

These symptoms may occur when you are still at the clinic. However, **if you or your child get any of these symptoms you should contact a physician immediately.**

Side effects that occurred during clinical trials in children from the age of 4 to 8 years
Very common side effects
These may occur with **more than 1 in 10** doses of the vaccine:
• pain, redness, and swelling at the injection site
• irritability
• sleepiness
• tiredness

Common side effects

These may occur with up to 1 in 10 doses of the vaccine:

• loss of appetite

• headache

• fever of 37.5°C or higher (also includes fever higher than 39°C)

• large swelling of the vaccinated limb

• vomiting and diarrhoea

Uncommon side effects

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

• hard lump at the injection site

• pain

Side effects that occurred during clinical trials in adults, adolescents, and children from the age of 10 years onwards

Very common side effects

These may occur with more than 1 in 10 doses of the vaccine:

• pain, redness, and swelling at the injection site

• headache

• tiredness

• generally feeling unwell

Common side effects

These may occur with up to 1 in 10 doses of the vaccine:

• fever equal to or greater than 37.5°C

• dizziness

• nausea

• hard lump and abscess at the injection site.

Uncommon side effects

These may occur with up to 1 in 100 doses of the vaccine:

• fever greater than 39°C
• pain
• joint and muscle stiffness
• vomiting
• diarrhoea
• joint stiffness, joint pain, muscle ache
• itching
• excessive sweating (hyperhidrosis)
• skin rash
• swollen glands in the neck, armpit or groin (lymphadenopathy)
• sore throat and discomfort when swallowing (pharyngitis)
• upper respiratory tract infection
• cough
• fainting (syncope)
• flu-like symptoms, such as fever, sore throat, runny nose, cough, and chills.

The following side effects occurred during routine use of Boostrix and are not specific to any age group:

• swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema)
• collapse or periods of unconsciousness or lack of awareness
• seizures or fits (with or without fever)
• itchy bumps – urticaria (hives)
• unusual weakness (asthenia)

Following administration of vaccines against tetanus a temporary inflammation of the nerves, causing pain, weakness, and paralysis in the extremities, often progressing to the chest and face have been reported very rarely (in up to 1 in 10,000 vaccination doses) (Guillain-Barré syndrome).

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il/

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C–8°C). Do not freeze.
- Store in the original package in order to protect from light.
- Shake before use.
- Do not discard medicines in the wastewater or household waste. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredients, this medicine also contains:
  Sodium chloride, aluminium (as aluminium salts), water for injection.
  Also see section 2 in this leaflet - "Important information about some of the ingredients in the medicine".
- What the medicine looks like and the contents of the package:
  Boostrix is a white, slightly milky liquid.
  Boostrix is supplied in a pre-filled syringe (0.5 ml) or in a vial.
  Pack sizes:
  A pack containing 1 or 10 syringes. Packs may also contain needle(s).

A pack containing 1 or 10 vials.

Not all package sizes may be marketed.

- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel Street, Petach Tikva.
- Manufacturer: GlaxoSmithKline Biologicals S.A., Rixensart, Belgium.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 121-34-30059

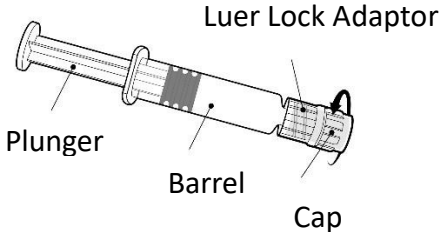
Revised in December 2023 according to MoH guidelines.

Boostrix PT V3B

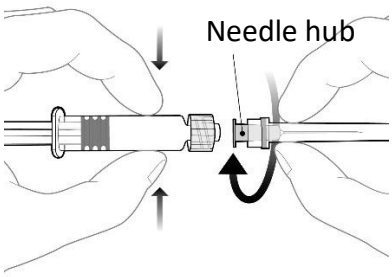
The following information is intended for healthcare professionals only:

Boostrix is for deep intramuscular injection preferably in the deltoid region. Prior to use, the vaccine should be at room temperature, and well shaken in order to obtain a homogeneous turbid white suspension. Prior to administration, the vaccine should be visually inspected for any foreign particulate matter and/or variation of physical aspect. In the event of either being observed, do not administer the vaccine.

Instructions for the pre-filled syringe



Hold the syringe by the barrel, not by the plunger.
Unscrew the syringe cap by twisting it anticlockwise.



To attach the needle, connect the hub to the Luer Lock Adaptor and rotate a quarter turn clockwise until you feel it lock.
Do not pull the syringe plunger out of the barrel. If it happens, do not administer the vaccine.

Disposal:

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.