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

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

Boostrix Polio

Suspension for injection in pre-filled syringe

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

inactivated poliovirus type 1 – 40 DU

inactivated poliovirus type 2 – 8 DU

inactivated poliovirus type 3 – 32 DU

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?

- For booster vaccination against diphtheria, tetanus and pertussis and poliomyelitis of individuals from the age of three years onwards.
- For passive protection against pertussis in early infancy following maternal immunisation during pregnancy.

The administration of Boostrix Polio should be based on official

recommendations.

Therapeutic group: Bacterial and viral vaccines combined.

How this vaccine works?

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

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

The use of Boostrix Polio 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.

2. BEFORE USING THE MEDICINE

Do not use Boostrix Polio if:

- you or your child have previously had any allergic reaction to Boostrix Polio or to any of the additional ingredients contained in this vaccine (listed in section 6), or neomycin, polymyxin (antibiotics) 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, pertussis, or poliomyelitis diseases.

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

- 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 previous vaccination with a vaccine against diphtheria and/or tetanus.

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

Special warnings regarding use of the medicine

Tell the physician or pharmacist before you or your child are vaccinated with Boostrix Polio, if:

- after previous vaccination with Boostrix Polio or another vaccine against pertussis, you or your child had any problem, 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 a fever, or if there is a family history of this.
- you or your child have long-standing immune system problems due to any reason (including HIV [human immunodeficiency virus] infection). You or your child may still be given Boostrix Polio but the protection against infections after having 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 Polio 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 Polio can be given at the same time as some other vaccines. A different injection site will be used for each type of vaccine.

Boostrix Polio may not work as well if you or your child are taking medicines that reduce the effectiveness of your/their immune system to fight infection.

Pregnancy and breast-feeding

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 being vaccinated with this medicine.

It is not known if Boostrix Polio passes into breast milk. Your physician will discuss with you the possible risks and benefits of receiving Boostrix Polio during breast-feeding.

Driving and using machines

it is unlikely that Boostrix Polio will affect your ability to drive or use machines.

Important information about some of the ingredients in the medicine

Boostrix Polio contains neomycin and polymyxin

Boostrix Polio contains neomycin and polymyxin (antibiotics). Tell your physician if you or your child have had an allergic reaction to either of these ingredients.

Boostrix Polio contains para-aminobenzoic acid, phenylalanine, sodium and potassium

Boostrix Polio contains para-aminobenzoic acid. It may cause allergic reactions (possibly delayed), and exceptionally, bronchospasm.

This medicine contains 0.0298 microgram phenylalanine in each dose.

Phenylalanine may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

This medicine contains less than 1 mmol potassium (39 mg) per dose, that is to say essentially ‘potassium-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 for you or your child is usually a single injection of Boostrix Polio.

- Boostrix Polio will be given as an injection into the muscle.
- The vaccine should never be given into blood vessels.
- Your physician will verify if you or your child have previously received vaccines against diphtheria, tetanus, pertussis and/or polio.
- Boostrix Polio may be used in case of a suspected infection with tetanus, although additional provisions, i.e. elaborate wound dressing and/or application of tetanus-anti-toxin will be taken as well to reduce the risk of manifestation of the disease.
- Your physician will give you advice on repeat 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 Polio 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 (with up to 1 in 10,000 doses of the vaccine). These can be recognised by:
• rashes 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 while 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
• sleepiness

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 (including fever greater than 39°C)
• bleeding, itching, and a hard lump at the injection site

• large swelling of the vaccinated limb
• loss of appetite
• irritability
• headache

Uncommon side effects
These may occur with up to 1 in 100 doses of the vaccine:
• diarrhoea, nausea, vomiting
• stomach pain
• swollen glands in the neck, armpit, or groin (lymphadenopathy)
• sleeping problems
• apathy
• dry throat
• tiredness

Co-administration with measles-mumps-rubella (MMR) or measles-mumps-rubella-varicella (MMRV) vaccines in children aged 3 to 6 years:
In studies where Boostrix Polio was given at the same time as a MMR or MMRV vaccine, skin rash and upper respiratory tract infection (including runny nose and sore throat) were commonly reported.
Fever, irritability, fatigue, loss of appetite, and gastrointestinal disorders (including diarrhoea and vomiting) were reported more frequently (very common) than in studies where Boostrix Polio was given alone.

Side effects that occurred during clinical trials in adults, teenagers, 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
• tiredness
• headache

Common side effects

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

- fever equal to or higher than 37.5°C
- bruising, itching, hard lump, warmth numbness at the injection site
- stomach pain, nausea, vomiting

Uncommon side effects

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

- fever higher than 39°C
- large swelling of the vaccinated limb
- chills
- pain
- dizziness
- joint pain, muscle ache
- itching
- oral herpes
- swollen glands in the neck, armpit, or groin (lymphadenopathy)
- decreased appetite
- tingling and numbness of the hands or feet (paraesthesia)
- sleepiness
- asthma

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

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

Additionally, the following side effects have been reported during clinical trials with Boostrix (GSK booster vaccine against diphtheria, tetanus, and

pertussis):

Side effects that occurred in children from the age of 4 to 8 years

Uncommon side effects

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

• disturbances in attention

• discharge with itching of the eyes and crusty eyelids (conjunctivitis)

• pain

Side effects that occurred in adults, teenagers, 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:

• generally feeling unwell

Common side effects

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

• hard lump or abscess at the injection site

Uncommon side effects

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

• upper respiratory tract infection

• sore throat and discomfort when swallowing (pharyngitis)

• fainting (syncope)

• cough

• diarrhoea

• excessive sweating (hyperhidrosis)

• skin rash

• joint stiffness, joint and muscle stiffness

• flu-like symptoms such as fever, sore throat, runny nose, cough, and chills

Following administration of vaccines against tetanus a temporary inflammation of the nerves, causing pain, weakness and paralysis in the

extremities and often progressing to the chest and face have been reported very rarely (with up to 1 in 10,000 doses of the vaccine) (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 bin. 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, the medicine also contains:
  Medium 199 (containing amino acids (including phenylalanine), mineral salts (including sodium and potassium), vitamins (including para-aminobenzoic acid) and other substances), aluminium (as aluminium salts), sodium chloride, 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 Polio is a white, slightly milky liquid. Upon storage, a white deposit and clear supernatant can be seen. The liquid is supplied in a pre-filled syringe (0.5 ml).
  Pack sizes: The pack contains 1 or 10 doses.
  Packs may contain needle(s).
  Not all pack sizes may be marketed.

- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: GlaxoSmithKline Biologicals S.A., Rixensart, Belgium.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 136-97-31449

Revised in March 2024.

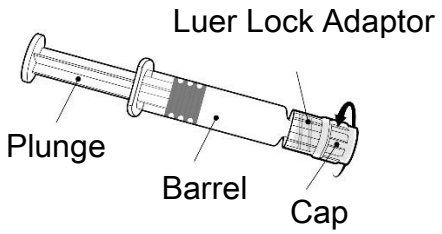
Boostrix Polio PT V4A

The following information is intended for healthcare professionals only:

Boostrix Polio is for deep intramuscular injection preferably in the deltoid region.

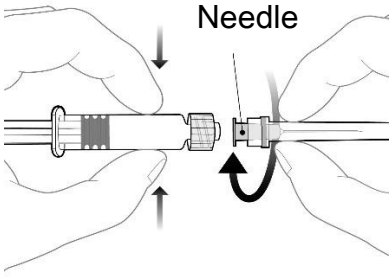
Prior to use, the vaccine should be at room temperature, and well shaken in order to obtain a homogeneous turbid white suspension. Prior to administration, the vaccine should be visually inspected for any foreign particulate matter and/or variation of physical aspect. In the event of either being observed, 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.