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Package leaflet: Information for the user

Boostrix, Suspension for injection in pre-filled syringe

Diphtheria, tetanus, and pertussis (acellular, component) vaccine (adsorbed, reduced antigen(s) content)

Read all of this leaflet carefully before you or your child start receiving this vaccine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for you or your child only. Do not pass it on to others.
- If you or your child get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Boostrix is and what it is used for

Boostrix is a vaccine used as a booster dose in children from 4 years onwards, teenagers and adults to prevent three diseases: diphtheria, tetanus (lockjaw) and pertussis (whooping cough). The vaccine works by causing the body to produce its own protection (antibodies) against these diseases.

- **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 even death.
- **Tetanus** (Lockjaw): Tetanus bacteria enter the body through cuts, scratches or wounds in the skin. Wounds that are especially prone to infection are burns, fractures, deep wounds or wounds contaminated with soil, dust, horse manure/dung or wood splinters. The bacteria release a toxin (poison), which can cause muscle stiffness, painful muscle spasms, fits and even death. The muscle spasms can be strong enough to cause bone fractures of the spine.
- **Pertussis** (Whooping cough): Pertussis is a highly infectious illness. The disease affects the airways causing severe spells of coughing that may interfere with normal breathing. The coughing is often accompanied by a “whooping” sound, hence the common name “whooping cough”. The cough may last for 1-2 months or longer. Pertussis can also cause ear infections, bronchitis which may last a long time, pneumonia, fits, brain damage and even death.

None of the ingredients in the vaccine can cause diphtheria, tetanus or whooping cough.

The use of Boostrix 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. What you need to know before you or your child receive Boostrix

Boostrix should not be given:

- if you or your child have previously had any allergic reaction to Boostrix, or any of the other ingredients contained in this vaccine (listed in section 6). 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 have previously had an allergic reaction to any vaccine against diphtheria, tetanus or whooping cough diseases.
- if you or your child experienced problems of the nervous system (encephalopathy) within 7 days after previous vaccination with a vaccine against pertussis (whooping cough) disease.
- if 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 doctor first.
- if you or your child experienced a temporary reduction in blood platelets (which increases risk of bleeding or bruising) or problems with the brain or nerves after previous vaccination with a vaccine against diphtheria and/or tetanus.

Warnings and precautions

Talk to your doctor or pharmacist before you or your child are given Boostrix:

- if after previously having Boostrix or another vaccine against pertussis (whooping cough) 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
- if 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.
- if you or your child have a bleeding problem or bruise easily
- if you or your child have a tendency to seizures/fits due to a fever, or if there is a family history of this
- if you or your child have long standing immune system problems due to any reason (including HIV infection). You or your child may still be given Boostrix 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 doctor or nurse if you or your child fainted with a previous injection.

As with all vaccines Boostrix may not completely protect all people who are vaccinated.

Other medicines and Boostrix

Tell your doctor or pharmacist if you or your child are taking, have recently taken, or might take any other medicines or have recently received any other vaccine.

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 to fight infection.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you are given this vaccine.

It is not known if Boostrix passes into breast milk. Your doctor will discuss with you the possible risks and benefits of having Boostrix during breastfeeding.

Driving and using machines

Boostrix is unlikely to produce an effect on the ability to drive and use machines.

Boostrix contains sodium

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

3. How Boostrix is given

- Boostrix will be given as an injection into the muscle.
- The vaccine should never be given into blood vessels.
- You or your child will receive a single injection of Boostrix.
- Your doctor 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-anti-Toxin will be taken as well to reduce the risk of manifestation of the disease.
- Your doctor will give you advice on repeat vaccination.

4. Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets 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.**

Such reactions may occur before leaving the doctor's surgery. However, **if you or your child get any of these symptoms you should contact a doctor immediately.**

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

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

- Loss of appetite
- Headache
- Fever equal to or greater than 37.5°C (including fever greater than 39°C)
- Large swelling of the vaccinated limb
- Vomiting and diarrhoea

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
- Hard lump where the injection was given
- Pain

Side effects that occurred during clinical trials 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):

- Pain, redness and swelling at the injection site
- Headache
- Tiredness
- Generally feeling unwell

Common (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 (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 for 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)
- Hives (urticaria)
- Unusual weakness (asthenia)

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).

Reporting of side effects
If you or your child get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Boostrix

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date which is stated on the carton and the pre-filled syringe label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).
Do not freeze. Freezing destroys the vaccine.
Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you or your child no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Boostrix contains

- The active substances are:

Diphtheria toxoid[1]	not less than 2 International Units (IU) (2.5 Lf)
Tetanus toxoid[1]	not less than 20 International Units (IU) (5 Lf)
Bordetella pertussis antigens	
Pertussis toxoid[1]	8 micrograms
Filamentous Haemagglutinin[1]	8 micrograms
Pertactin[1]	2.5 micrograms

[1] adsorbed on aluminium hydroxide, hydrated ($Al(OH)_3$)	0.3 milligrams Al^{3+}
and aluminium phosphate ($AlPO_4$)	0.2 milligrams Al^{3+}

Aluminium hydroxide and aluminium phosphate are included in this vaccine as adjuvants. Adjuvants are substances included in certain vaccines to accelerate, improve and/or prolong the protective effects of the vaccine.

- The other ingredients are: sodium chloride and water for injections.

What Boostrix looks like and contents of the pack

Suspension for injection in pre-filled syringe.

Boostrix is a white, slightly milky liquid presented in a pre-filled syringe (0.5 ml).

Boostrix is available in packs of 1 or 10 with or without needles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
GlaxoSmithKline (Ireland) Ltd.
12 Riverwalk
Citywest Business Campus

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Dublin 24
Ireland

Manufacturer:
GlaxoSmithKline Biologicals s.a.
Rue de l'Institut 89
B-1330 Rixensart
Belgium

This leaflet was last revised in September 2021

The following information is intended for healthcare professionals only:

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.

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