Package leaflet: Information for the user

IPV-Boostrix, Suspension for injection in pre-filled syringe
Diphtheria, tetanus, pertussis (acellular component) and poliomyelitis (inactivated) 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 IPV-Boostrix is and what it is used for

IPV-Boostrix is a vaccine used as a booster dose in children from 3 years onwards, teenagers and adults to prevent four diseases: diphtheria, tetanus (lockjaw), pertussis (whooping cough) and poliomyelitis (polio). 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.
- **Poliomyelitis** (Polio): Poliomyelitis, sometimes called simply "polio" is a viral infection that can have variable effects. Often it causes only a mild illness but in some people it causes permanent damage or even death. In its severest form, polio infection causes paralysis of the muscles (muscles cannot move), including those muscles needed for breathing and walking. The limbs affected by the disease may be painfully deformed.

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

The use of IPV-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 IPV-Boostrix

IPV-Boostrix should not be given:

- if you or your child have previously had any allergic reaction to IPV-Boostrix, or any of the other ingredients of this vaccine (listed in section 6) or neomycin, polymyxin (antibiotics) or formaldehyde. 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, pertussis (whooping cough) or poliomyelitis 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 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.
- 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.

Warnings and precautions

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

- if after previously having IPV-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 IPV-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, IPV-Boostrix may not completely protect all people who are vaccinated.

Other medicines and IPV-Boostrix

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

IPV-Boostrix can be given at the same time as some other vaccines. A different injection site will be used for each type of vaccine.

IPV-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 IPV-Boostrix passes into breast milk. Your doctor will discuss with you the possible risks and benefits of having IPV-Boostrix during breastfeeding.

Driving and using machines

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

IPV-Boostrix contains neomycin and polymyxin

This vaccine contains neomycin and polymyxin (antibiotics). Please tell your doctor if you or your child have had an allergic reaction to these ingredients.

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

IPV-Boostrix 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 potassium, less than 1 mmol (39 mg) per dose, i.e. essentially 'potassium-free'.

3. How IPV-Boostrix is given

- IPV-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 IPV-Boostrix.
- Your doctor will verify if you or your child have previously received vaccines against diphtheria, tetanus, pertussis and/or polio.
- IPV-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
- Sleepiness

Common (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 hard lump at the injection site
- Large swelling of the vaccinated limb
- Loss of appetite
- Irritability
- Headache

Uncommon (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 3-6 years

In studies where IPV-Boostrix 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 IPV-Boostrix was given alone.

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
- Tiredness
- Headache

Common (these may occur with up to 1 in 10 doses of the vaccine):
- Fever equal to or greater than 37.5°C
- Bruising, itching, hard lump, warmth and/or numbness at the injection site
- Stomach pain, nausea, vomiting

Uncommon (these may occur with up to 1 in 100 doses of the vaccine):
- Fever greater 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 or numbness of the hands or feet (paraesthesia)
- Sleepiness
- Asthma

The following side effects occurred during routine use of IPV-Boostrix and are not specific for 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)
- Hives (urticaria)
- Unusual weakness (asthenia)

Additionally, the following side effects have been reported during clinical trials with Boostrix (GlaxoSmithKline Biologicals' booster vaccine against diphtheria, tetanus and pertussis):

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

Uncommon (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 (these may occur with more than 1 in 10 doses of the vaccine):
- Generally feeling unwell

Common (these may occur with up to 1 in 10 doses of the vaccine):
- Hard lump or 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 (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).

Reporting of side effects
If you or your child get any side effects, talk to your doctor or pharmacist. This includes any 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 IPV-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 protect the environment.

6. Contents of the pack and other information

What IPV-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
Inactivated poliovirus	
type 1 (Mahoney strain)[2]	40 D-antigen unit
type 2 (MEF-1 strain)[2]	8 D-antigen unit
type 3 (Saukett strain)[2]	32 D-antigen unit

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

[2]propagated in VERO cells

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: Medium 199 (containing amino acids (including phenylalanine), mineral salts (including sodium and potassium), vitamins (including para-aminobenzoic acid) and other substances), sodium chloride and water for injections.

What IPV-Boostrix looks like and contents of the pack

Suspension for injection in pre-filled syringe.

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

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

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

GlaxoSmithKline (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland

Manufacturer
GlaxoSmithKline Biologicals S.A., Rue de l'Institut 89, 1330 Rixensart, Belgium

This medicine is authorised in the Member States of the European Economic Area under the following names:

Boostrix Polio: België/Belgique/Belgien, България, Česká republika, Danmark, Deutschland, Ελλάδα, España, Ísland, Latvija, Lietuva, Luxembourg/Luxemburg, Magyarország, Nederland, Norge, Österreich, Polska, Portugal, Slovenija, Slovenská republika, Suomi/Finland, Sverige
Boostrix Tetra: France
IPV-Boostrix: Ireland, Malta
Polio Boostrix: Italia
Boostrix-IPV: România

This leaflet was last revised in September 2022

Other sources of information

Detailed information on this medicine is available on the web site of: the Health Products Regulatory Authority (HPRA)

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.