

<GSK Logo>

## Package leaflet: information for the user

### IPV Infanrix, suspension for injection in a pre-filled syringe

Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed)

**Read all of this leaflet carefully before your child starts 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 your child only. Do not pass it on to others.
- If your child gets 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 Infanrix is and what it is used for
2. What you need to know before your child receives IPV Infanrix
3. How IPV Infanrix is given
4. Possible side effects
5. How to store IPV Infanrix
6. Contents of the pack and other information

## 1. What IPV Infanrix is and what it is used for

IPV Infanrix is a vaccine used as a booster dose to protect your child against 4 diseases:

- **Diphtheria** - a serious bacterial infection that mainly affects the airways and sometimes the skin. The airways become swollen causing serious breathing problems and sometimes suffocation. The bacteria also release a poison. This can cause nerve damage, heart problems and even death.
- **Tetanus** - tetanus bacteria enter the body through cuts, scratches or wounds in the skin. Wounds that are more likely to get tetanus infection are burns, fractures, deep wounds or wounds that have soil, dust, horse manure or wood splinters in them. The bacteria release a poison. This 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.
- **Whooping cough (pertussis)** - a highly infectious illness that affects the airways. It causes severe coughing that may lead to problems with breathing. The coughing often has a 'whooping' sound. The cough may last for one to two months or longer. Whooping cough can also cause ear infections, chest infections (bronchitis) which may last a long time, lung infections (pneumonia), fits, brain damage and even death.
- **Polio** - a viral infection. Polio is often only a mild illness. However, sometimes it can be very serious and cause permanent damage or even death. Polio can make the muscles unable to move (paralysis of the muscles). This includes the muscles that are needed for breathing and walking. The arms or legs affected by the disease may be painfully twisted (deformed).

IPV Infanrix is for children from 16 months to 13 years of age inclusive. It is not intended for people over 14 years of age.

#### How the IPV Infanrix works

- IPV Infanrix helps your child's body make its own protection (antibodies). This will protect your child against these diseases.

- The vaccine cannot cause the diseases that it protects your child from.

## **2. What you need to know before your child receives IPV Infanrix**

### **IPV Infanrix should not be given:**

- If your child is allergic to any of the ingredients of this medicine (listed in Section 6)
  - or neomycin, polymyxin (types of antibiotics)
  - or formaldehyde.

Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue

- If your child has had an allergic reaction to any vaccine against diphtheria, tetanus, whooping cough or polio
- If your child experienced problems of the nervous system (encephalopathy) within 7 days after previous vaccination with a vaccine against whooping cough
- If your child has a severe infection with a high temperature (over 38°C). A minor infection such as a cold should not be a problem, but talk to your doctor first.

IPV Infanrix should not be given if any of the above apply to your child. If you are not sure, talk to your doctor or pharmacist before your child is given IPV Infanrix.

### **Warnings and precautions**

Talk to your doctor or pharmacist before your child is given IPV Infanrix if:

- after previously having IPV Infanrix or another vaccine against whooping cough, 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
  - 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.
- your child has a bleeding problem or bruises easily
- your child has a tendency to fits due to a fever or if there is a history in the family of this
- your child has problems with their immune system (including HIV infection). Your child may still be given IPV Infanrix. However, the protection against the infections may not be as high.

Fainting can occur (mostly in adolescents) following, or even before, any needle injection. Therefore tell the doctor or nurse if your child fainted with a previous injection.

If any of the above apply to your child (or you are not sure), talk to your doctor or pharmacist before your child is given IPV Infanrix.

### **Other medicines and IPV Infanrix**

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines.

In particular, tell your doctor or pharmacist if your child is using any of the following:

- medicines or other treatments (such as radiotherapy) that affect their immune system. Your child may still be given IPV Infanrix. However, IPV Infanrix may not work as well. If possible the vaccine should be given after this treatment has finished

- other vaccines. IPV Infanrix can be given at the same time as other vaccines. A different place for the injection will be used for each vaccine.

### **Pregnancy and breast-feeding**

It is unlikely that IPV Infanrix would be given to people who are pregnant or breast-feeding. This is because it is only intended to be used in children from 16 months to 13 years of age inclusive.

The use of this vaccine is not recommended during pregnancy or breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

It is unlikely that IPV Infanrix would be given to people who drive or use tools or machines. This is because it is only intended to be used in children from 16 months to 13 years of age inclusive.

Your child may feel sleepy after having this vaccination. If this happens, your child should not drive, cycle or use any tools or machines.

### **IPV Infanrix contains neomycin, polymyxin (antibiotics) and formaldehyde**

Your child should not be given IPV Infanrix if they are allergic to any of these ingredients. Please tell your doctor if your child has had an allergic reaction to these ingredients.

## **3. How IPV Infanrix is given**

### **When the vaccine will be given**

- Your doctor or nurse will tell you when your child should have this vaccine. It depends on official recommendations.

### **How IPV Infanrix is given**

- Your child will receive a single injection of IPV Infanrix.
- IPV Infanrix is always injected into a muscle.
- This will usually be in the shoulder muscle. However, in young children it can be given in the thigh.
- The vaccine should never be given into a vein.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this vaccine:

### **Allergic reactions**

If your child has an allergic reaction, see your doctor straight away. The signs may include:

- skin rashes that may be itchy or blistering
- swelling of the eyes and face
- difficulty in breathing or swallowing,
- a sudden drop in blood pressure
- loss of consciousness.

These signs usually start very soon after the injection has been given. Take your child to see a doctor straight away if they happen after leaving the clinic. Allergic reactions are very rare (less than 1 in 10,000 doses of the vaccine).

**See your doctor straight away if your child has any of the following serious side effects:**

- collapse
- loss of consciousness
- lack of awareness
- fits.

See your doctor straight away if you notice any of the above. These side effects have happened with other vaccines against whooping cough. They usually occur within 2 to 3 days after vaccination.

**Other side effects include:**

**Very common** (these may occur with more than 1 in 10 doses of the vaccine)

- feeling sleepy
- headache
- loss of appetite
- high temperature of 38°C or higher
- pain, redness and swelling at the injection site
- unusual crying
- feeling irritable or restless

**Common** (these may occur with up to 1 in 10 doses of the vaccine)

- diarrhoea
- nausea, vomiting (feeling or being sick)
- high temperature of 39.5°C or higher
- generally feeling unwell
- hard lump at the injection site
- feeling weak.

**Uncommon** (these may occur with up to 1 in 100 doses of the vaccine)

- skin allergies or rash.

**Rare** (these may occur with up to 1 in 1,000 doses of the vaccine)

- swollen glands in the neck, armpit and groin (lymphadenopathy)
- coughing or chest infection (bronchitis)
- itching
- lumpy rash (hives).

**Very rare** (these may occur with up to 1 in 10,000 doses of the vaccine)

- bleeding or bruising more easily than normal (thrombocytopenia)
- temporarily stopping breathing (apnoea)
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioneurotic oedema)
- blisters at the injection site.

Booster doses of IPV Infanrix may increase the risk of reactions at the injection site. Some of these affect the entire arm or leg that has been injected. These reactions usually begin within 48 hours of the injection and go away after 4 days.

**Reporting of side effects**

If your child gets 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, Earlsfort Terrace, IRL - Dublin 2;  
Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store IPV Infanrix

- Keep this medicine out of the sight and reach of children.
- Store in a refrigerator (2°C to 8°C).
- Store in the original package in order to protect from light.
- Do not freeze. Freezing destroys the vaccine.
- Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What IPV Infanrix contains

- The active substances are:	
Diphtheria toxoid <sup>1</sup>	not less than 30 IU
Tetanus toxoid <sup>1</sup>	not less than 40 IU
<i>Bordetella pertussis</i> antigens	
Pertussis toxoid <sup>1</sup>	25 micrograms
Filamentous Haemagglutinin <sup>1</sup>	25 micrograms
Pertactin <sup>1</sup>	8 micrograms
Poliovirus (inactivated) <sup>2</sup>	
type 1 (Mahoney strain)	40 D-antigen unit
type 2 (MEF-1 strain)	8 D-antigen unit
type 3 (Saukett strain)	32 D-antigen unit
<sup>1</sup> adsorbed on aluminium hydroxide, hydrated	0.5 milligrams Al <sup>3+</sup>
<sup>2</sup> propagated in VERO cells	

Aluminium hydroxide is included in this vaccine as an adjuvant. 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, Medium 199 (containing principally amino acids, mineral salts, vitamins), water for injections.

### What IPV Infanrix looks like and contents of the pack

- IPV Infanrix is a suspension for injection in pre-filled syringe (0.5 ml).
- The suspension is white, and slightly milky.
- Packs either contain 1, 10 or 20 pre-filled syringes with or without needles.
- Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

#### Marketing Authorisation Holder

GlaxoSmithKline (Ireland) Ltd.

Reason for update: Art 61(3) P001 Corrections to list of Member States under the cover of the FMD update to the carton text  
Market: Ireland  
Approval date: TBC  
Text Date: 21/11/2017  
Text Issue and Draft No.: Text Issue 4 Draft 1

12 Riverwalk  
Citywest Business Campus  
Dublin 24

**Manufacturer**

GlaxoSmithKline S.A.  
89, rue de l'Institute - 1330 Rixensart  
Belgium

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Greece, France, Portugal, Cyprus: InfanrixTetra  
Czech Republic, Estonia, Latvia, Lithuania, Norway, Slovak Republic, Finland, Sweden: Infanrix Polio  
Poland, United Kingdom: Infanrix-IPV  
Hungary: Infanrix IPV  
Ireland: IPV Infanrix  
Italy: PolioInfanrix

**This leaflet was last revised in 11/2017**

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

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The following information is intended for medical or healthcare professionals only:

Upon storage, a white deposit and clear supernatant may be observed. This does not constitute a sign of deterioration.

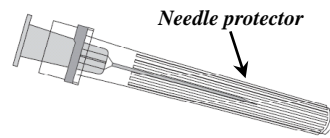
The syringe should be well shaken in order to obtain a homogeneous turbid white suspension.

The suspension should be inspected visually for any foreign particulate matter and/or abnormal physical appearance. In the event of either being observed, discard the vaccine.

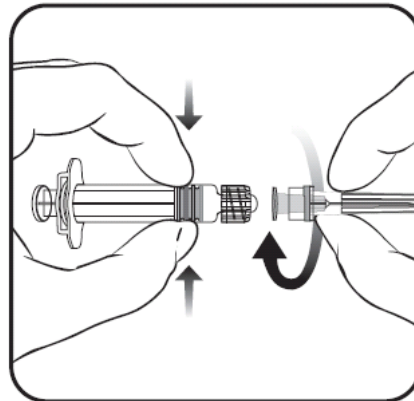
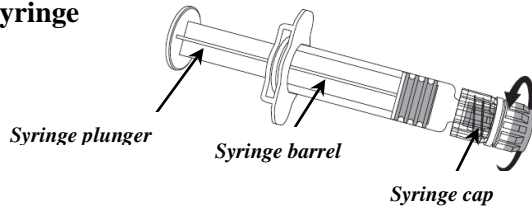
The pre-filled syringe can be supplied with either a ceramic coated treatment (CCT) of the luer tip or with a plastic rigid tip cap (PRTC) luer lock adaptor.

- ***Instructions for use of pre-filled syringe if supplied with a PRTC luer lock adaptor***

## Needle



## Syringe



1. Holding the syringe **barrel** in one hand (avoid holding the syringe plunger), unscrew the syringe cap by twisting it anticlockwise.
2. To attach the needle to the syringe, twist the needle clockwise into the syringe until you feel it lock (see picture).
3. Remove the needle protector, which on occasion can be a little stiff.
4. Administer the vaccine.

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

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