

Infanrix® IPV vaccine

Patient Information Leaflet

Read all of this leaflet carefully before your child receives this vaccine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This vaccine has been prescribed for your child and should not be passed on to others.

In this leaflet:

1. What Infanrix-IPV is and what it is used for
2. Before your child receives Infanrix-IPV
3. How Infanrix-IPV is given
4. Possible side effects
5. Storing Infanrix-IPV
6. Further information
7. Specific information for the Healthcare Professional

The name of the vaccine is **Infanrix-IPV Suspension for injection in prefilled syringe**

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

Infanrix-IPV is a combined vaccine. The active substances in Infanrix-IPV are purified proteins from the three types of bacteria that cause diphtheria, tetanus (lockjaw) and pertussis (whooping cough) and inactivated poliomyelitis (polio) viruses. (For more about the diseases caused by these bacteria and viruses, refer to section 6 of this leaflet).

Each 0.5 ml dose contains:-

Diphtheria toxoid	not less than 30 IU
Tetanus toxoid	not less than 40 IU
Pertussis antigens:-	
Pertussis toxoid	25 micrograms
Filamentous haemagglutinin	25 micrograms
Pertactin	8 micrograms
Inactivated poliovirus produced in Vero cells:-	
type 1	40 D-antigen units
type 2	8 D-antigen units
type 3	32 D-antigen units

The other ingredients in Infanrix-IPV are: sodium chloride (NaCl), phenoxyethanol, aluminium hydroxide, medium 199 (contains amino acids, salts and vitamins) and water for injections. Infanrix-IPV may contain trace amounts of neomycin and polymyxin B, which are antibiotics, as well as formaldehyde, which is used to inactivate the polioviruses.

Marketing authorisation holder is:

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

Infanrix-IPV is presented as a slightly milky liquid in a prefilled syringe. Each syringe contains 0.5 ml of vaccine, which is one dose.

Infanrix-IPV is available in packs containing one prefilled syringe (one dose).

Infanrix-IPV is a booster vaccine that can be given to children aged between 16 months and 13 years who have previously received a full course of vaccinations against diphtheria, tetanus (lockjaw), pertussis (whooping cough) and poliomyelitis (polio). The vaccine works by causing the body to boost its own protection (antibodies) against these diseases.

The timing of your child's booster vaccination will be according to UK recommendations. Your doctor or nurse will tell you when your child should attend for this vaccination.

Vaccination is the best way to protect against these diseases. Remember, however, that no vaccine can provide complete, life-long protection in all people vaccinated.

This vaccine cannot cause any of the diseases against which it is intended to protect. That is, none of the active ingredients in the vaccine is infectious.

2. Before your child receives Infanrix-IPV

Infanrix-IPV must not be given to your child if the answer to any of the following questions is "YES". If you are not sure of anything, ask your doctor or nurse before Infanrix-IPV is given to your child.

- Has your child previously had any allergic reaction to any vaccine against diphtheria, tetanus or pertussis (whooping cough) or polio, or to any other ingredient contained in this vaccine? The other ingredients in Infanrix-IPV are listed at the beginning of the leaflet. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.
- Has your child ever had an allergic reaction to neomycin, polymyxin B or formaldehyde, which may be present in the vaccine in trace amounts left over from manufacture?
- Has your child experienced problems with the brain or nerves within 7 days after previous vaccination with a vaccine against pertussis (whooping cough)?
- Has your child experienced problems with the brain or nerves after previous vaccination with a vaccine against any of diphtheria, tetanus, pertussis (whooping cough) or polio?
- Does your child have a severe infection with a high temperature at present? If so, vaccination may have to be postponed. A minor infection such as a cold should not be a problem, but talk to your doctor or nurse first.

Also, remember that Infanrix-IPV is not recommended for children less than 16 months of age or older than 13 years of age.

If the answer to any of the following questions is "YES", Infanrix-IPV may or may not be suitable for your child. Your doctor or nurse will advise you.

- After previously having a vaccine containing a pertussis (whooping cough) component, did your child have any of the following?:-
 - ◆ 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
- Does your child have a bleeding problem or bruise easily?
- Does your child have longstanding problems with their immune system due to any reason (including HIV infection)? Your child may still be given Infanrix-IPV but the protection against infections after having the vaccine may not be as good as in children with good immunity to infections.

Pregnancy and breast feeding

It is recommended that Infanrix-IPV should not be given during pregnancy or breast feeding.

Driving and operating machinery

Since Infanrix-IPV is not intended for persons above 13 years of age, the fact that sleepiness sometimes occurs after vaccination (see next section) should not be a problem. However, you should warn your child about sleepiness, especially if they ride a bicycle.

Taking other medicines and having other vaccines

If your child is taking any medicines that reduce immunity to infections or is having any other type of treatment (such as radiotherapy) that affects the immune system, Infanrix-IPV can still be given but the child's response to the vaccine may be poor. Therefore, whenever possible, vaccination is postponed until the treatment is over. Infanrix-IPV can be given at the same time but as a separate injection to vaccines against Hib disease (that is, against *Haemophilus influenzae* type b infections) and combined measles, mumps and rubella vaccines (MMR).

If necessary, Infanrix-IPV can be given at the same time as other vaccines or injections of immunoglobulins (antibodies) provided that these are given into a separate body site.

Any medicines that your child takes regularly should be continued after vaccination.

3. How Infanrix-IPV is given

Your child will receive a single injection of half a millilitre of Infanrix-IPV as a booster.

Please remember that Infanrix-IPV is only suitable for children who have previously had the recommended course of vaccinations against diphtheria, tetanus, pertussis and polio. Infanrix-IPV can be given to children who have previously received polio vaccine given by mouth.

If you are unsure whether your child has received these vaccines previously, you should ask your doctor, nurse or health visitor and they will advise you.

The nurse or doctor will give Infanrix-IPV as an injection usually into the muscle of the upper outer arm and will make sure that the vaccine is not given into a blood vessel. In young children, the injection may be given into the muscle of the thigh if preferred.

4. Possible side effects

Like all vaccines, Infanrix-IPV can have side effects.

Some children can have a severe allergic reaction to a vaccine. Very severe reactions are seen in less than 1 in 10,000 people who are vaccinated. Your child may be asked to stay in the surgery or vaccination area for a short time after vaccination to check that he or she does not have an immediate allergic reaction. Tell the doctor or nurse immediately if your child develops a rash (which may be raised and lumpy), tightness of the throat, swelling of the face or neck or shortness of breath. Other possible symptoms of a severe allergic reaction include a drop in blood pressure and unconsciousness. It is very important that your child has immediate medical treatment for any severe allergic reaction. If the symptoms start after you have left the clinic, you should go to the nearest accident and emergency department.

In clinical studies, side effects that occurred in children after vaccination with Infanrix-IPV were:-

Very common (in more than 1 in 10 children vaccinated)

- Pain, redness or swelling at the site of the injection
- Fever
- Headache
- Generally feeling unwell
- Feeling sleepy
- Feeling irritable
- Loss of appetite
- Feeling restless
- Unusual crying.

Common (in less than 1 in 10 but more than 1 in 100 children vaccinated)

- Diarrhoea
- Feeling or being sick
- Feeling weak
- Extensive swelling of the arm or leg into which the vaccine was injected.

Uncommon (in less than 1 in 100 but more than 1 in 1000 children vaccinated)

- Swollen glands
- Rash
- Inability to sleep
- Runny nose
- Cough
- Inability to control the bladder
- Stomach pain
- Back pain.

Rare (in less than 1 in 1000 but more than 1 in 10,000 children vaccinated)

- Itching
- Earache
- Sore throat
- Eye pain.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. Storing Infanrix-IPV

Your doctor or nurse should make sure that Infanrix-IPV is stored between 2°C and 8°C (in a refrigerator) before it is given to your child and that it is not frozen. Freezing the vaccine will stop it working properly.

Your doctor or nurse should make sure that Infanrix-IPV is always kept out of the reach and sight of children.

There is an expiry date on the pack. The doctor or nurse will check that this date has not been passed. The date for last use corresponds to the last day of the month mentioned.

6. Further information on Diphtheria, Tetanus, Whooping cough, and Polio diseases

- **Diphtheria:** Diphtheria infection usually occurs through the airways and less often through the skin. A tough membrane can form in the throat and the airways can 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 likely to be infected with tetanus bacteria are burns, broken bones that break through the skin, deep wounds or any wound, even if minor that gets contaminated with soil, dust, animal manure/dung or wood splinters. The bacteria release a toxin (poison), which can cause muscle stiffness, painful muscle spasms, fits and even suffocation and death.
- **Pertussis (whooping cough):** Pertussis is a highly infectious illness and can affect people of all ages although it is most common in very young children (under two years). The disease affects the airways causing severe spells of coughing that may interfere with normal breathing. In small children who get the infection, 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, permanent damage to the airways, pneumonia, fits, brain damage and even death.
- **Poliomyelitis (polio):** Poliomyelitis, sometimes called simply "polio" is a viral infection that can have variable effects. In its severest form, polio infection causes paralysis of the muscles (muscles cannot move), including those muscles needed for breathing and walking and can be fatal. The limbs affected by the disease may be permanently deformed.

7. Specific information for the Healthcare Professional

Upon storage, a white deposit and clear supernatant can be observed in the syringe. This does not constitute a sign of deterioration.

The syringe should be well shaken in order to obtain a homogeneous turbid white suspension and then inspected visually for any foreign particulate matter and/or abnormal physical appearance. In the event of either being observed, discard the container.

A blue, 25mm, 23G needle and an orange, 16mm, 25G needle have been provided for vaccine administration. The vaccine needs to be injected to the appropriate depth in order for it to be effective. Choose the most appropriate needle for your patient to ensure the vaccine reaches the muscle.

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