Package leaflet: Information for the user

Infanrix-IPV+Hib vaccine
Powder and suspension for suspension for injection

Diphtheria (D), tetanus (T), pertussis (acellular component) (Pa), poliomyelitis (inactivated) (IPV) and *Haemophilus influenzae* type b (Hib) conjugate 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 Infanrix-IPV+Hib is and what it is used for

Infanrix-IPV+Hib is a vaccine used to protect your child against 5 diseases:

- **Diphtheria** - a serious bacterial infection that mainly affects the airways and sometimes the skin. The airways become swollen causing serious breathing problems. 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 disease 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 which may last a long time, lung infections, fits, brain damage and even death.
- **Polio -** a viral infection. Polio can make the muscles unable to move (paralysis of the muscles). This includes the muscles needed for breathing and walking. The arms or legs affected by the disease may be painfully twisted (deformed).
- ***Haemophilus influenzae* type b (Hib) -** can cause brain swelling (inflammation). This can lead to serious problems such as: mental slowness (retardation), cerebral palsy, deafness, epilepsy or partial blindness. It can also cause swelling of the throat. This can cause death by suffocation. Less commonly, the bacteria can also infect the blood, heart, lungs, bones, joints and tissues of the eyes and mouth.

Infanrix-IPV+Hib is for children between 2 months and 3 years old. It is not suitable for children older than 3 years.

How the vaccine works
Infanrix-IPV+Hib helps your child's body make its own protection (antibodies). This will protect your child against these diseases.

About the protection from Infanrix-IPV+Hib
- Infanrix-IPV+Hib will only protect against infections caused by the pathogens for which the vaccine has been developed.
- As with all vaccines, Infanrix-IPV+Hib may not fully protect all children who are vaccinated.
- Children with a weakened immune system (such as due to HIV infection) may not get the full benefit from Infanrix-IPV+Hib.
- The vaccine cannot cause the diseases that it protects your child from.

2. What you need to know before your child receives Infanrix-IPV+Hib

Infanrix-IPV+Hib should not be given
- if your child is allergic to Infanrix-IPV+Hib or any of the other ingredients of this medicine (listed in Section 6) or neomycin, polymyxin (types of antibiotics) or Polysorbate 80. The active substances and other ingredients in Infanrix-IPV+Hib are listed at the end of the leaflet. Signs of an allergic reaction may include itchy skin, rash, shortness of breath and swelling of the face and tongue.
- if your child experienced problems of the nervous system within 7 days after previous vaccination with a vaccine against pertussis (whooping cough) disease.
- 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. However, talk to your doctor first.

Infanrix-IPV+Hib 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 Infanrix-IPV+Hib.

Warnings and Precautions
Talk to your doctor or pharmacist before your child is given Infanrix-IPV+Hib
- if after previously having Infanrix-IPV+Hib or another vaccine against pertussis (whooping cough) disease, 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 having the vaccine
- 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 your child has a tendency to seizures/fits due to a fever, or if there is a family history of this
- if your child has a bleeding problem or bruises easily.

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 Infanrix-IPV+Hib.

Fainting can occur following, or even before, any needle injection, therefore tell the doctor or nurse if your child fainted with a previous injection.

Other medicines and Infanrix-IPV+Hib
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 taking any of the following:
- medicines to fight infection that affect the immune system. Infanrix-IPV+Hib may not work as well if your child is taking these medicines.

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

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.
Infanrix-IPV+Hib will never be given to people who are pregnant or breast-feeding as it is only used in children.

Infanrix-IPV+Hib contains sodium
This medicine contains less than 1 mmol sodium (23mg) per dose, that is to say essentially 'sodium-free'.

3. How Infanrix-IPV+Hib is given

How much is given
- The doctor will give the recommended dose of Infanrix-IPV+Hib to your child.
- Usually, your child will receive two or three injections with an interval of 1 month. It depends on official recommendation. The first injection can be given from the age of 2 months.
- You will be informed when your child should come back for their next injection.
- If additional injections (boosters) are necessary, the doctor will tell you. These booster injections will be given at least 6 months after the last injection of the initial vaccination course.

How the vaccine is given
- Infanrix-IPV+Hib is always injected into a muscle.
- This is usually in the thigh.
- The vaccine should not be given into a blood vessel

If your child misses a dose
- If your child misses a scheduled injection, it is important that you make another appointment.
- **Make sure your child finishes the complete vaccination course. If not, your child may not be fully protected against the diseases.**

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:
- face swelling
- low blood pressure
- difficulty breathing
- skin going blue

- 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 (these may occur with up to 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

If you notice any of the above, see your doctor straight away. These effects are very rare (these may occur with up to 1 in 10,000 doses of the vaccine).

Other side effects include:

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

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

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

- diarrhoea or being sick (vomiting)
- hard lump at the injection site
- large swelling at the injection site.

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

- swollen glands in the neck, armpit or groin (lymphadenopathy)
- coughing, chest infection (bronchitis) or runny nose
- upper respiratory tract infection such as a cold, tonsillitis or laryngitis
- rash, lumpy rash (hives)
- tiredness
- swelling of the injected limb and sometimes the nearby joint
- high temperature of 39.5°C or higher.

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

- skin rash
- itching.

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

- in babies born very prematurely (at or before 28 weeks of gestation) longer gaps than normal between breaths may occur for 2-3 days after vaccination
- temporarily stopping breathing (apnoea)
- swelling of the whole injected limb
- blisters at the injection site.

Booster doses of Infanrix-IPV+Hib may increase the risk of reactions at the injection site. These include swelling at the place of injection, swelling of the whole injected leg or arm and sometimes swelling at the nearby joint. These reactions usually begin within 2 days 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Infanrix-IPV+Hib

- Keep this medicine out of the sight and reach of children.
- Store in a refrigerator (2°C to 8°C).
- Do not freeze.
- Store in the original package in order to protect from light.
- 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 waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Content of the pack and other information

What Infanrix-IPV+Hib contains
The active substances are:

Diphtheria toxoid[1]	not less than 30 International Units (IU) (25 Lf)
Tetanus toxoid[1]	not less than 40 International Units (IU) (10 Lf)
Bordetella pertussis antigens	
Pertussis toxoid[1]	25 micrograms
Filamentous Haemagglutinin[1]	25 micrograms
Pertactin[1]	8 micrograms
Poliovirus (inactivated)	
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
Haemophilus influenzae type b polysaccharide (polyribosylribitol phosphate)	10 micrograms
conjugated to tetanus toxoid as carrier protein	approximately 25 micrograms
[1]adsorbed on aluminium hydroxide, hydrated	0.5 milligrams Al^{3+}

[2]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: lactose, sodium chloride (see also section 2, Infanrix-IPV+Hib contains sodium), Medium 199 (containing principally amino acids, mineral salts, vitamins), water for injections.

What Infanrix-IPV+Hib looks like and contents of the pack

- The Infanrix-IPV component of the Infanrix-IPV+Hib vaccine is a white, slightly milky suspension presented in a pre-filled syringe (0.5ml).
- The Hib component of the vaccine is a powder presented in a separate vial.
- Both components are mixed together just before your child receives the injection.
- Infanrix-IPV+Hib is available in packs of 1, 10, 20, 25, 40, 50 and 100.

- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder is:

SmithKline Beecham Ltd, Stockley Park West, Uxbridge, Middlesex UB11 1BT, UK

Manufacturer is:

GlaxoSmithKline Biologicals S.A.
Rixensart
Belgium

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

Infanrix-IPV+Hib: Česká republika, България, Deutschland, Ελλάδα, Österreich, Portugal, Slovenská republika, United Kingdom

INFANRIX-IPV+Hib: Hrvatska

Infanrix Polio+Hib: Suomi/Finland

Other formats:
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:
Product name **Infanrix-IPV+Hib**
Reference number 10592/0216
This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in 11/2017

Other sources of information
Detailed information on this medicine is available on the web site of: the Medicines and Healthcare Products Regulatory Agency (MHRA)

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The following information is intended for healthcare professionals only:

Infanrix-IPV+Hib should not be mixed with other vaccines or medicinal products in the same syringe.

Upon storage of the Infanrix-IPV suspension, a white deposit and clear supernatant can be observed in the syringe. This is not a sign of deterioration.

The pre-filled syringe should be well shaken to obtain a homogeneous suspension. The Infanrix-IPV suspension in the pre-filled syringe, the Hib powder in the vial and the reconstituted vaccine should be inspected visually for any foreign particulate matter and/or abnormal physical appearance prior to administration. In the event of either is observed, the vaccine should be discarded.

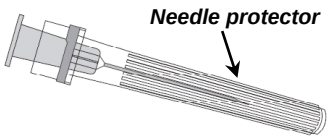
The vaccine is reconstituted by adding the entire contents of the pre-filled syringe of Infanrix-IPV suspension to the vial containing the Hib powder. The mixture should then be injected immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should normally not be longer than 8 hours at 2°C to 8°C (in a refrigerator). The full reconstitution instructions are:

1. Shake the pre-filled syringe containing the Infanrix-IPV suspension
2. Attach a 38 mm, 21 gauge (G) (green) needle to the pre-filled syringe of Infanrix-IPV and inject the contents of the syringe into the Hib vial.
3. With the needle still inserted, shake the Hib vial vigorously and examine for complete dissolution.
4. Withdraw the entire mixture back into the syringe.
5. Replace the 38 mm, 21G (green) needle with an appropriate size needle for injection and administer the vaccine. This 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 correct tissue. In most cases, this should be the 25 mm 23G (blue) needle provided, except in the smallest of babies, in which case a 16 mm, 25G (orange) needle should be used.
6. After reconstitution, Infanrix-IPV+Hib should be injected as soon as possible. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should normally not be kept longer than 8 hours at 2°C to 8°C (in a refrigerator). It should never be frozen.
7. If the vaccine is not administered immediately, shake the solution vigorously again before injection.

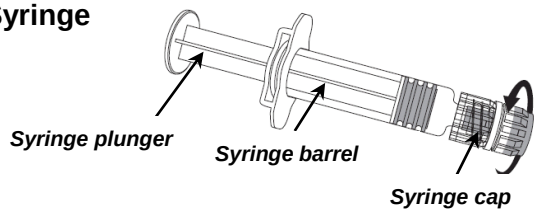
The pre-filled syringe can be supplied with either a ceramic coated treatment (CCT) of the luer tip or with a plastic rigid tip cap (PRTC) luer lock adaptor.

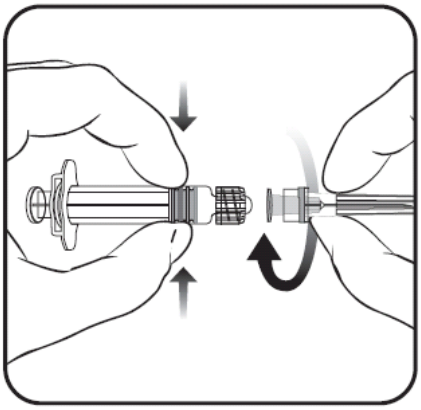
- ***Instructions for use of pre-filled syringe if supplied with a PRTC luer lock adaptor***

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. Reconstitute the vaccine as described above.

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