Package leaflet: Information for the user

Infanrix hexa, Powder and suspension for suspension for injection in a pre-filled syringe
Diphtheria (D), tetanus (T), pertussis (acellular, component) (Pa), hepatitis B (rDNA) (HBV), poliomyelitis (inactivated) (IPV) and *Haemophilus influenzae* type b (Hib) conjugate vaccine (adsorbed).

Read all of this leaflet carefully before your child receives 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 hexa is and what it is used for

Infanrix hexa is a vaccine used to protect your child against six 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.

- **Hepatitis B:** is caused by the hepatitis B virus. It makes the liver swollen. The virus is found in body fluids such as in the vagina, blood, semen or spit (saliva) of infected people.

- **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). 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.

How Infanrix hexa works
- Infanrix hexa helps your child's body make its own protection (antibodies). This will protect your child against these diseases.
- As with all vaccines, Infanrix hexa may not fully protect all children who are vaccinated.
- The vaccine cannot cause the diseases that it protects your child from.

2. What you need to know before your child receives Infanrix hexa

Infanrix hexa should not be given:

- if your child is allergic to:
  - Infanrix hexa or any of the ingredients of this vaccine (listed in section 6).
  - formaldehyde.
  - neomycin or polymyxin (antibiotics).

  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, hepatitis B, polio or *Haemophilus influenzae* type b.
- if your child has had problems of the nervous system 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.

Infanrix hexa 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 hexa.

Warnings and precautions

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

- if after previously having Infanrix hexa 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
- if your child has an undiagnosed or progressive disease of the brain or epilepsy which is not controlled. After control of the disease the vaccine can be given.
- if your child has a bleeding problem or bruises easily
- if your child tends to have fits when they have a fever, or if there is a history of this in the family.
- if your child should become unresponsive or experience seizures (fits) after the vaccination, please contact your doctor immediately. See also section 4 Possible side effects.

- if your baby was born very prematurely (at or before 28 weeks of gestation) longer gaps than normal between breaths may occur for 2-3 days after vaccination. These babies may require respiratory monitoring for 48-72h following the administration of the first two or three doses of Infanrix hexa.

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 hexa.

Other medicines and Infanrix hexa
Your doctor may ask you to give your child a medicine that lowers fever (such as paracetamol) before or immediately after Infanrix hexa is given. This can help to lower some of the side effects (febrile reactions) of Infanrix hexa.

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

Infanrix hexa contains neomycin and polymyxin
This vaccine contains neomycin and polymyxin (antibiotics). Tell your doctor if your child has had an allergic reaction to these ingredients.

3. How Infanrix hexa is given

How much is given
- Your child will have a total of two or three injections with at least 1 month between each injection.
- You will be told by the doctor or nurse when your child should come back for their next injections.
- If additional injections (boosters) are necessary, the doctor will tell you.

How the vaccine is given
- Infanrix hexa will be given as an injection into a muscle.
- The vaccine should never be given into a blood vessel or into the skin.

If your child misses a dose
- If your child misses an injection which is due, 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.**

4. Possible side effects

Like all medicines, this vaccine 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:
- 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.

These signs usually start very soon after the injection has been given. Talk to a doctor straight away if they happen after leaving the doctor's surgery.

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

- collapse
- times when they lose consciousness or have a lack of awareness
- fits – this may be when they have a fever

These side effects have happened very rarely with Infanrix hexa as with other vaccines against whooping cough. They usually happen 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 tired, loss of appetite, high temperature of 38°C or higher, swelling, pain, redness where the injection site was given, unusual crying, feeling irritable or restless.

Common (these may occur with up to 1 in 10 doses of the vaccine): diarrhoea, being sick (vomiting), high temperature of more than 39.5°C, swelling larger than 5 cm or hard lump where the injection was given, feeling nervous.

Uncommon (these may occur with up to 1 in 100 doses of the vaccine): upper respiratory tract infection, feeling sleepy, cough, large swelling at the injected limb.

Rare (these may occur with up to 1 in 1,000 doses of the vaccine): bronchitis, rash, swollen glands in the neck, armpit or groin (lymphadenopathy), bleeding or bruising more easily than normal (thrombocytopenia), 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 face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema), swelling of the whole injected limb, blisters.

Very rare (these may happen with up to 1 in 10,000 doses of the vaccine): itching (dermatitis).

Experience with hepatitis B vaccine

In extremely rare cases the following side effects have been reported with hepatitis B vaccine: paralysis, numbness or weakness of the arms and legs (neuropathy), inflammation of some nerves, possibly with pins and needles or loss of feeling or normal movement (Guillain-Barré syndrome), swelling or infection of the brain (encephalopathy, encephalitis), infection around the brain (meningitis).
The causal relationship to the vaccine has not been established.
Bleeding or bruising more easily than normal (thrombocytopenia) has been reported with hepatitis B vaccines.

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 hexa

- 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. The expiry date refers to the last day of that month.

- Store in a refrigerator (2°C – 8°C).
- Store in the original package in order to protect from light.
- Do not freeze. Freezing destroys the vaccine.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines your child no longer uses. These measures will help protect the environment.

6. Contents of the pack and other information

What Infanrix hexa contains

The active substances are:

Diphtheria toxoid[1]	not less than 30 International Units (IU)
Tetanus toxoid[1]	not less than 40 International Units (IU)
Bordetella pertussis antigens	
Pertussis toxoid[1]	25 micrograms
Filamentous Haemagglutinin[1]	25 micrograms
Pertactin[1]	8 micrograms
Hepatitis B surface antigen[2,3]	10 micrograms
Poliovirus (inactivated)	
type 1 (Mahoney strain)[4]	40 D-antigen unit
type 2 (MEF-1 strain)[4]	8 D-antigen unit
type 3 (Saukett strain)[4]	32 D-antigen unit
Haemophilus influenzae type b polysaccharide (polyribosylribitol phosphate)[3] conjugated to tetanus toxoid as carrier protein	10 micrograms approximately 25 micrograms

[1]adsorbed on aluminium hydroxide, hydrated ($Al(OH)_3$) 0.5 milligrams Al^{3+}
[2]produced in yeast cells (*Saccharomyces cerevisiae*) by recombinant DNA technology
[3]adsorbed on aluminium phosphate ($AlPO_4$) 0.32 milligrams Al^{3+}
[4]propagated in VERO cells

The other ingredients are:
Hib powder: lactose anhydrous
DTPa-HBV-IPV suspension: sodium chloride (NaCl), medium 199 containing principally amino acids, mineral salts, vitamins and water for injections

What Infanrix hexa looks like and contents of the pack
- The diphtheria, tetanus, acellular pertussis, hepatitis B, inactivated poliomyelitis (DTPa-HBV-IPV) component is a white, slightly milky liquid presented in a pre-filled syringe (0.5 ml).
- The Hib component is a white powder presented in a glass vial.
- Both components are mixed together just before your child receives the injection. The mixed appearance is a white, slightly milky liquid.

- Infanrix hexa is available in packs of 1 and 10 with or without needles, and a multipack of 5 packs, each containing 10 vials and 10 pre-filled syringes, without needles.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

GlaxoSmithKline Biologicals s.a.

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This leaflet was last revised in 08/2019

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

The following information is intended for healthcare professionals only:

Upon storage, a clear liquid and white deposit may be observed in the pre-filled syringe containing the DTPa-HBV-IPV suspension. This is a normal observation.

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

The vaccine is reconstituted by adding the entire contents of the pre-filled syringe to the vial containing the powder. The mixture should then be well shaken until the powder is completely dissolved prior to administration.

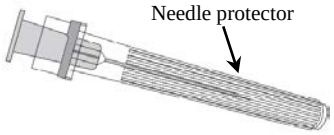
The reconstituted vaccine appears as a slightly more cloudy suspension than the liquid component alone. This is a normal observation.

The vaccine suspension should be inspected visually before and after reconstitution for any foreign particule matter and/or abnormal physical appearance. If either is observed, discard the vaccine.

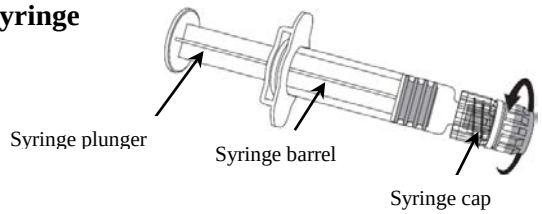
The pre-filled syringe can be supplied with either a ceramic coated treatment (CCT) of the luer tip or with a plastic rigid tip cap (PRTC) luer lock adaptor.

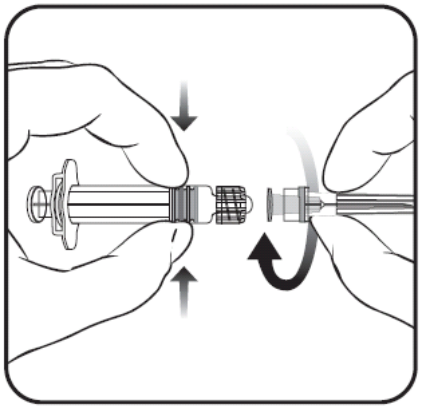
- ***Instructions for use of pre-filled syringe if supplied with a PRTC luer lock adaptor***

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. Reconstitute the vaccine as described above.

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