



Public Health
England

Use of Infanrix®-IPV+Hib in the infant primary immunisation schedule

Information for healthcare practitioners

Withdrawn June 2020



Aims of training resource

To provide information about the use of Infanrix®-IPV+Hib in the infant schedule:

- What Infanrix®-IPV+Hib vaccine is
- What immunisers need to know about this vaccine
- Reconstitution and administration
- Contraindications, precautions and potential adverse reactions

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Key messages

- Infanrix®-IPV+Hib will be provided for the infant primary immunisation schedule from summer 2014
- This vaccine protects against tetanus, diphtheria, pertussis, polio and Hib diseases
- It is safe and effective and is used in many countries worldwide
- Pediacel® will continue to be provided for the infant schedule – either vaccine (Pediacel® or Infanrix®-IPV+Hib) can be used



What is Infanrix®-IPV+Hib?

Infanrix®-IPV/Hib is a combined diphtheria, tetanus, acellular pertussis, inactivated poliomyelitis, *Haemophilus influenzae* type b (*Hib*) vaccine

It is given to infants to protect them against:

Diphtheria: an infection of the upper respiratory tract and sometimes the skin

Tetanus: an acute illness caused by the toxin which can cause muscle contractions, muscle rigidity and painful spasms

Pertussis (whooping cough): acute bacterial respiratory infection causing severe bouts of coughing

Polio: an acute viral infection of the nervous system which can cause paralysis

Hib: a bacterial infection which causes meningitis, pneumonia, epiglottitis, facial cellulitis and bone and joint infections



Infanrix®-IPV+Hib

- From Summer 2014, Infanrix®-IPV+Hib will be one of the two vaccines available for use in the primary infant vaccination schedule
- Generic name: diphtheria, tetanus, pertussis (acellular component), poliomyelitis (inactivated), *Haemophilus influenzae* type b conjugate vaccine
- Marketed by GlaxoSmithKline
- Licensed from 2 months of age
- Single dose pre-filled syringe containing DTaP/IPV (suspension for injection) and single dose vial containing Hib (lyophilized powder for injection)

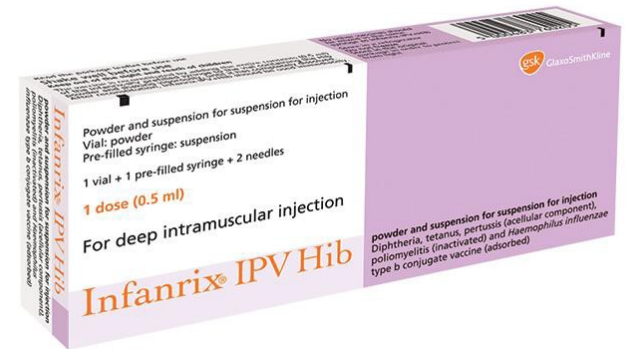


Image courtesy of GSK



Infanrix®-IPV+Hib composition

Active ingredients

- Diphtheria toxoid 30IU (International Units) (25Lf)
- Tetanus toxoid 40IU (10Lf)
- *Bordetella pertussis* antigens:
 - Pertussis toxoid 25 µg
 - Filamentous haemagglutinin 25 µg
 - Pertactin 8µg
- Poliovirus (inactivated):
 - type 1 poliovirus 40 D-antigen units (DU)
 - type 2 poliovirus 8DU
 - type 3 poliovirus 32DU
- *Haemophilus Influenzae* type B polysaccharide (polyribosylribitol phosphate) 10µg conjugated to 30µg of tetanus toxoid

Other ingredients

- Lactose
- Sodium chloride
- Aluminium hydroxide (as adjuvant)
- Medium 199 (as stabilizer including amino acids, mineral salts, vitamins and other substances)
- Water for injections

Trace amounts of:

- neomycin sulphate
- polymyxin sulphate
- polysorbate 80



Infanrix®-IPV+Hib presentation

- The *Haemophilus influenzae* type b vaccine is supplied as a lyophilized (freeze dried) white powder in a glass vial
- The diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine is supplied as a cloudy white suspension in a pre-filled (0.5 mL) syringe
- **The contents of the pre-filled syringe must be combined with the contents of the vial to make a single dose of 0.5ml of cloudy white suspension**



Storage of Infanrix®-IPV+Hib

Infanrix®-IPV+Hib must be stored in accordance with manufacturer's instructions

- Store between +2°C and +8°C
- **Do not freeze. Discard if the vaccine has been frozen**
- Store in original packaging to protect from light
- After reconstitution immediate use is recommended





Infanrix®-IPV+Hib schedule

3 dose schedule

- First dose at two months of age
- Second dose at three months of age (at least four weeks after the first)
- Third dose at four months of age (at least four weeks after the second)

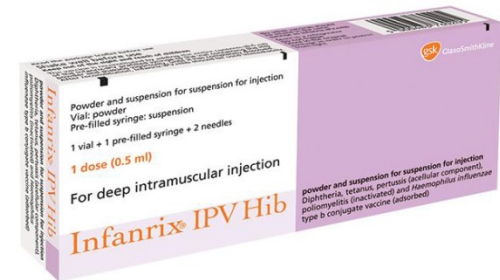
If the course is interrupted, it should be resumed and completed as soon as possible. There is no need to start the course again as immunological memory from the remaining dose(s) is likely to be maintained

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Administration of Infanrix®-IPV+Hib®

- Infanrix®-IPV+Hib should be administered by intramuscular injection
- Infanrix®-IPV+Hib can be administered at the same time as other childhood vaccines
- Ideally, a course started with Infanrix®-IPV+Hib or Pediacel® should be completed with the same vaccine. If not possible, whichever primary vaccine is available should be used





Preparation and administration of Infanrix®-IPV+Hib

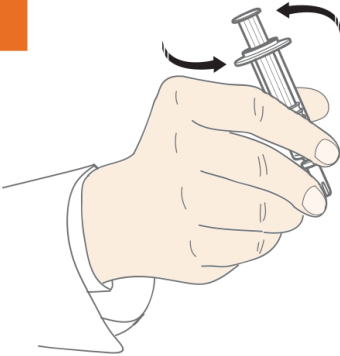
- During storage of the DTaP-IPV suspension, a white deposit and clear fluid above this deposit may be observed in the syringe. This is not a sign of deterioration
- The pre-filled syringe should be shaken well
- The DTaP-IPV suspension in the pre-filled syringe, the Hib powder in the vial and the reconstituted vaccine should be visually inspected for any foreign particulate matter and/or abnormal physical appearance prior to administration. If either is observed, the vaccine should be discarded
- The vaccine is reconstituted by adding the entire contents of the pre-filled syringe of DTaP-IPV suspension to the vial containing the Hib powder
- The mixed vaccine should then be injected immediately

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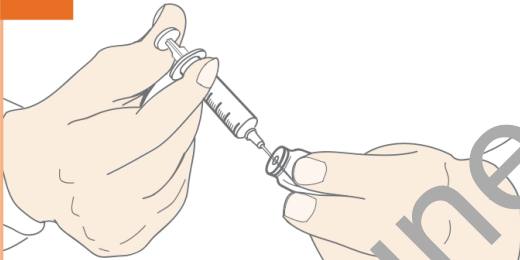
Preparation and administration of Infanrix®-IPV+Hib

1



Shake the pre-filled DTaP-IPV syringe. Place the green needle onto the syringe.

2



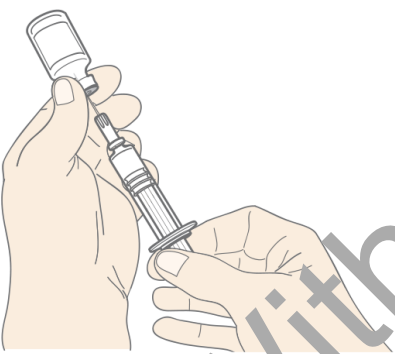
Inject the contents of the syringe into the Hib glass vial.

3



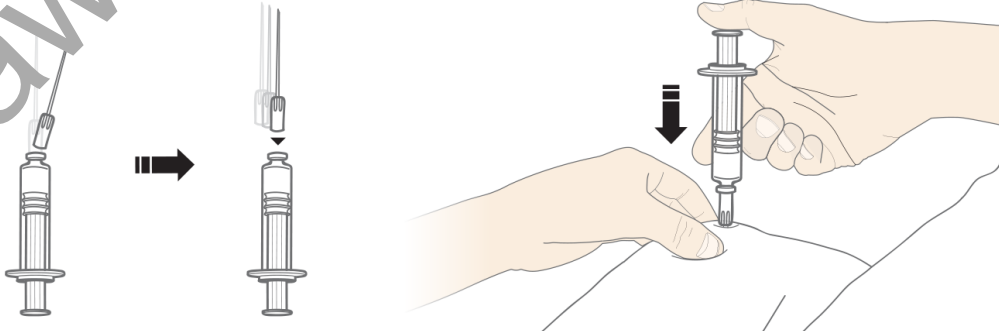
With the needle still inserted, shake the Hib vial vigorously and visually inspect.

4



Withdraw the entire mixture back into the syringe and visually inspect.

5

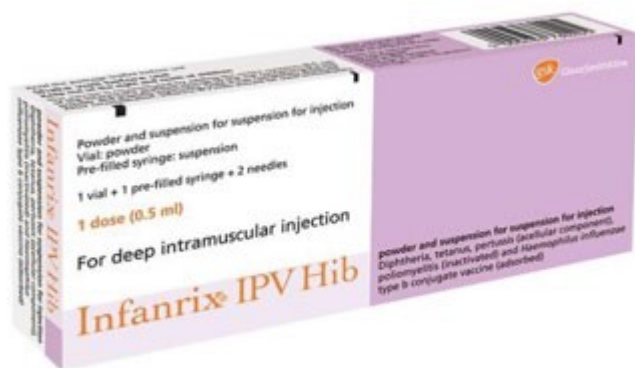


Place the blue needle onto the filled syringe and administer the vaccine into the anterolateral aspect of the thigh

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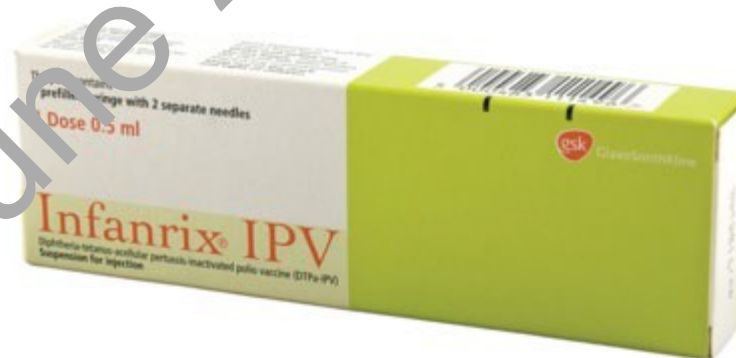


Beware of product confusion!



Contains Hib

For infant primary schedule



Does not contain Hib

For pre-school booster



Contraindications

Contraindications to Infanrix®-IPV+Hib are the same as for Pediacel® vaccine:

Neither vaccine should be given to those who have had:

- a confirmed anaphylactic reaction to a previous dose of a diphtheria, tetanus, pertussis, polio or Hib-containing vaccine, or
- a confirmed anaphylactic reaction to any of the components of the vaccine

There are very few children who cannot receive Infanrix®-IPV+Hib and Pediacel® vaccines

When there is doubt, appropriate advice should be sought from a consultant paediatrician, immunisation co-ordinator or consultant in communicable disease control rather than withholding the vaccine

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Precautions

- These are the same as for Pediacel® and relevant Green Book chapters should be consulted for further information
- Immunisation may be deferred if child is acutely unwell or if:
 - evidence of current neurological deterioration, including poorly controlled epilepsy
 - child experiences encephalopathy or encephalitis within 7 days of immunisation
 - a seizure associated with a fever occurs within 72 hours of an immunisation

In any of these occur, child should be referred for investigation to see if underlying cause can be identified and then immunised once cause identified or condition has stabilised

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Adverse reactions

Types and rates of adverse reactions following Infanrix®-IPV+Hib are similar to Pediacel® vaccine

The most common adverse reactions observed are:

- Fever
- Pain, redness and swelling at injection site
- Loss of appetite
- Irritability, crying, restlessness
- Sleepiness
- Diarrhoea and vomiting

As for all vaccines, report any suspected adverse reactions via the Yellow Card scheme (<http://yellowcard.mhra.gov.uk>)



Resources

- Green Book diphtheria, tetanus, pertussis, polio and Hib chapters
- “Vaccine Update” March, April, May and June 2014 editions – (vaccination newsletter for health professionals and immunisation practitioners available at: <https://www.gov.uk/government/collections/vaccine-update>)
- “Use of Infanrix®-IPV+Hib in the infant schedule - Information for Healthcare Professionals” – available on PHE website at <https://www.gov.uk/government/collections/immunisation>