PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed according to a physician's prescription only

Infanrix IPV-Hib

Powder and suspension for suspension for injection

Each dose (0.5 ml) contains:

diphtheria toxoid	– NLT 30 IU
tetanus toxoid (T)	– NLT 40 IU
pertussis toxoid (PT)	– 25 mcg
filamentous haemagglutinin (FHA)	– 25 mcg
pertactin (PRN)	– 8 mcg
inactivated Polio Virus type 1	– 40 DU
inactivated Polio Virus type 2	– 8 DU
inactivated Polio Virus type 3	– 32 DU
haemophilus influenzae type b polysaccharide (PRP)	– 10 mcg
conjugated to tetanus toxoid as carrier protein	– approximately 25 mcg

For the list of the inactive and allergenic ingredients in the medicine, see section 2 – "Important information about some of the ingredients in the medicine" and section 6 – "Additional information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Active immunisation in infants from the age of 2 months to 5 years against diptheria, tetanus, pertussis, poliomyelitis and Haemophilus influenza type b.

Booster dose for children who have previously been immunised with DTP, Polio and Hib antigens.

Therapeutic group: Bacterial and viral vaccines combined

How the vaccine works?

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

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 the vaccine.

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

2. BEFORE USING THE MEDICINE

Do not use Infanrix IPV-Hib if:

- your child is sensitive (allergic) to the active ingredients or to any of the additional ingredients contained in 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 and tongue.
- your child experienced problems of the nervous system within 7 days after previous vaccination against pertussis disease.
- 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 physician first.

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

Special warnings regarding use of the medicine

Before your child is given Infanrix IPV-Hib, tell the physician 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 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 tendency to seizures/fits due to a fever, or if there is a family history of this.

- 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 physician or pharmacist before your child is given Infanrix IPV-Hib.
Fainting can occur following, or even before, any needle injection. Therefore tell the physician or nurse if your child fainted with a previous injection.

Drug interactions

If your child is taking, or has recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist. Especially if your child is taking any of the following:

- medicines to fight infections 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 physician or pharmacist for advice before taking any medicine.

Infanrix IPV-Hib will never be given to women who are pregnant or breast-feeding as it is only used in children.

Important information about some of the ingredients in the medicine

This medicine contains para-aminobenzoic acid, phenylalanine, sodium and potassium

This medicine contains para-aminobenzoic acid. It may cause allergic reactions (possibly delayed), and exceptionally, bronchospasm.

This medicine contains 0.036 microgram phenylalanine in each dose. Phenylalanine may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

This medicine contains less than 1 mmol potassium (39 mg) per dose, i.e. essentially 'potassium-free'.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions.
Check with the physician or pharmacist if you are uncertain about the preparation dosage and treatment regimen.
The dosage and treatment regimen will be determined by the physician only.
The recommended dosage for your child is usually three injections during the first six months of life, with an interval of at least one month between consecutive doses.
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 physician will tell you. These booster injections will be given at least 6 months after the last injection of the initial vaccination course.

Do not exceed the recommended dose.

- Infanrix IPV-Hib is always injected into a muscle, 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.

Adhere to the treatment regimen recommended by your physician.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Infanrix IPV-Hib may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

The following side effects may happen with this vaccine:

Allergic reactions

If your child has an allergic reaction, **see your physician 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 physician 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 physician straight away if your child has any of the following serious side effects:

- collapse
- loss of consciousness
- lack of awareness
- fits (seizures)

If you notice any of the effects above, **see your physician 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 side effects

These may occur with **more than 1 in 10** doses 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 side effects

These may occur with **up to 1 in 10** doses of the vaccine:

- diarrhoea or vomiting
- hard lump at the injection site
- large swelling at the injection site

Uncommon side effects

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 side effects

These may occur with **up to 1 in 1,000** doses of the vaccine:

- skin rash
- itching

Very rare side effects

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 to 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 two days of the injection and go away after four days.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il/

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store in a refrigerator (between 2°C to 8°C). Do not freeze.
- Store in the original package to protect from light.
- Do not discard medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredients, the medicine also contains:
  lactose, sodium chloride, medium 199 (containing amino acids (including phenylalanine), mineral salts (including sodium and potassium), vitamins (including para-aminobenzoic acid) and other substances), aluminium (as aluminium hydroxide), water for injection.
- What the medicine looks like and the contents of the package:
  The Infanrix IPV component of the Infanrix IPV-Hib vaccine is a white, slightly milky suspension presented in a pre-filled syringe (0.5 ml).
  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.

  Pack size: 1 and 10 doses of vials + pre-filled syringes. Needles may be included in the pack.
  Not all package sizes may be marketed.

- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: GlaxoSmithKline Biologicals S.A., Rixensart, Belgium.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 112-53-29413

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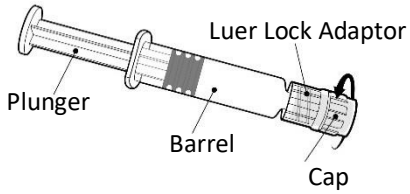
Infanrix IPV-HIB PT V3C

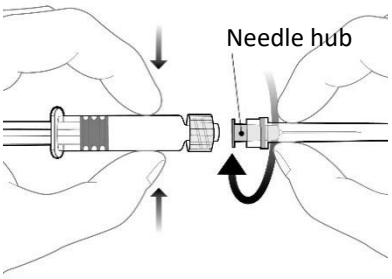
The following information is intended for healthcare professionals only:
Infanrix-IPV+Hib should not be mixed with other vaccines or medicinal products in the same syringe.
Upon storage of the DTPa-IPV suspension, a white deposit and clear supernatant can be observed in the syringe. This is not a sign of deterioration.
The pre-filled syringe should be well shaken to obtain a homogeneous suspension. The DTPa-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 DTPa-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 DTPa-IPV suspension
2. Attach a needle to the pre-filled syringe of DTPa-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 needle with an appropriate size needle for injection and administer the vaccine.
6. If the vaccine is not administered immediately, shake the solution vigorously again before injection.

Instructions for the pre-filled syringe



Hold the syringe by the barrel, not by the plunger.
Unscrew the syringe cap by twisting it anticlockwise.



To attach the needle, connect the hub to the Luer Lock Adaptor and rotate a quarter turn clockwise until you feel it lock.
Reconstitute the vaccine as described above.
Do not pull the syringe plunger out of the barrel. If it happens, do not administer the vaccine.

Disposal

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