

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations)

- 1986

This medicine is dispensed with a doctor'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 hemagglutinin (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 entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor 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 to yours.

1. What is this medicine intended for?

Active immunisation in infants from the age of 2 months to 5 years against diphtheria, 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 this medicine

Infanrix-IPV-Hib should not be given if:

- your child is sensitive (allergic) to the active ingredients or any of the other ingredients of this medicine (see list 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 doctor first.

This vaccine 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 the vaccine.

Special warnings about using this medicine

Tell your doctor or pharmacist before your child is given Infanrix-IPV-Hib, if:

- after previously vaccination with Infanrix-IPV-Hib or another vaccine against pertussis 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 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.

Drug interactions

Tell your doctor or pharmacist if your child is taking, or has recently taken other medicines, including nonprescription medications and dietary supplements. 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 doctor 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 this medicine's ingredients

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 to use this medicine?

Always use this medicine according to your doctor's instructions.

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine. The usually recommended dose for your child is 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 doctor 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 as recommended by your doctor.

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

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Infanrix IPV-Hib may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of 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 (seizures)

If you notice any of the effects 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 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 you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home

page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il/>

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated 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 throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredients, this 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 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 (0.5 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: 10 doses. Needles may be included in the pack.

License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel Street, Petach Tikva.

Manufacturer: GlaxoSmithKline Biologicals S.A, Rixensart, Belgium.

Registration number of the medicine in the Ministry of Health's National Drug
Registry: 112-53-29413

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