

INFANRIX-Hib™

Combined diphtheria, tetanus, acellular pertussis (DTPa) and Haemophilus influenza type b vaccine

What Is In This Leaflet?

This leaflet answers some of the common questions about INFANRIX-Hib vaccine. It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines and vaccines have risks and benefits. Your doctor has weighed the possible risks of your child having INFANRIX-Hib against the expected benefits.

If you have any concerns about INFANRIX-Hib talk to your doctor, nurse or pharmacist.

Keep this leaflet with this vaccine. You may need to read it again.

What Is INFANRIX-Hib Used For

INFANRIX-Hib is a vaccine used to immunise against diphtheria, tetanus, pertussis (whooping cough) and Haemophilus influenza type b in children from 15 months old.

INFANRIX-Hib is not intended for use in adults.

Diphtheria, pertussis, tetanus and Haemophilus influenza type b are life-threatening diseases caused by bacterial and viral infections. The vaccine works by causing the body to produce its own protection (antibodies) against these diseases.

Diphtheria

Diphtheria is a bacterium that lives in the airways of humans and can also affect the skin. Generally, the airways become inflamed (swollen) causing severe breathing difficulties and sometimes suffocation. The bacteria release a toxin (poison) which can cause nerve damage, heart problems and death. The risk of serious complications and death is greater in the very young and elderly.

Tetanus

Tetanus bacteria enter the body through wounded skin. Wounds that are especially prone to infection are burn wounds, fractures, deep wounds or wounds contaminated with soil, dust, horse manure or wood splinters. The bacteria release toxins, which can cause muscle stiffness, painful spasms, fits and death. The spasm can be strong enough to cause bone fractures of the spine.

Pertussis (whooping cough)

Pertussis is highly infectious. It affects the breathing tract causing severe spells of coughing that may interfere with normal breathing. The coughing is often accompanied by a "whooping" sound. The cough may last for 1-2 months or longer. Pertussis can also cause inner ear infections, long lasting bronchitis, pneumonia, fits, brain damage and death. The risk of severe complications and death is greatest in infants under 6 months of age.

Haemophilus influenza type b (Hib)

This is a common bacterium that causes a range of serious diseases in young children, such as pneumonia, bone infections and skin infections. The most serious disease this bacterium can cause is meningitis.

This vaccination does not protect against other types of *H. influenzae*. Note that Haemophilus influenza is not "the flu" which is caused by viruses.

Meningitis can be caused by different bacteria and also viruses. Infanrix-hib only protects against meningitis caused by Haemophilus influenzae type b. It does not protect against meningitis caused by other bacteria or by viruses.

Vaccination is the best way of protecting against these diseases. INFANRIX-Hib vaccine cannot give a child diphtheria, tetanus, pertussis infection or Haemophilus influenza type b. The vaccine will not protect against diseases caused by other types of bacteria or organisms.

Before Receiving INFANRIX-Hib

INFANRIX-Hib Must Not Be Given If:

- your child has had an allergic reaction to INFANRIX-Hib, or any ingredient contained in this vaccine. The ingredients are listed at the end of this leaflet. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.
- your child has had an allergic reaction to any other diphtheria, tetanus, pertussis or Haemophilus influenza type b vaccine.
- your child has had a rare severe effect on the brain within 7 days of having the pertussis vaccination, e.g. fits/seizures (but not seizures from high fever), unconsciousness, confusion.
- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering.

If you are not sure whether INFANRIX-Hib should be given, talk to your doctor or nurse.

Tell your doctor if:

- your child has any medical conditions, such as:
 - a bleeding disorder. Sometimes INFANRIX-Hib may need to be given differently in people with bleeding problems
 - an immune deficiency condition (e.g. are HIV positive)
 - brain disease or central nervous system (CNS) disease such as epilepsy (fits/seizures) or has had fits/seizures with a high fever (febrile convulsions)
- your child has allergies to any other medicines or substances, such as dyes, foods or preservatives.
- your child has a severe infection with a high temperature. A minor infection such as a cold should not be a problem, but talk to your doctor or nurse about this before being vaccinated.
- after having been given INFANRIX-Hib or another vaccine containing diphtheria, tetanus, pertussis, your child had problems such as:
 - high temperature (over 40.5°C) within 2 days of vaccination
 - a collapse or shock-like state within 2 days of vaccination
 - crying lasting 3 hours or more within 2 days of vaccination
 - convulsions/fits with or without fever within 3 days of vaccination.
- your child is receiving any other medication or vaccines.

Some vaccines may be affected by other vaccines or medicines. Your doctor, nurse or pharmacist will be able to tell you what to do if INFANRIX-Hib is to be given with another vaccine or medicine.

Giving INFANRIX-Hib

How INFANRIX-Hib Is Given

The doctor or nurse will give INFANRIX-Hib as an injection. If you have any concerns about how this vaccine is to be given, talk to your doctor, nurse or pharmacist.

How Much Is Given

The dose of INFANRIX-Hib is 0.5mL

How Is It Given

The Ministry of Health recommends that the same limb be used each time this vaccination is given. For infants and children with bleeding problems, the dose may need to be given under the skin (subcutaneously).

The vaccine should never be given intravenously (into the vein).

When It Will Be Given

INFANRIX-Hib is given as a total of four or five doses. Each dose is given on a separate visit.

It is important to return at the recommended times for follow up doses.

If A Dose Is Missed

If a scheduled dose is missed, talk to your doctor or nurse and arrange another visit as soon as possible.

While Getting INFANRIX-Hib

Things you must do

Keep your child's visits with the doctor or clinic. It is important INFANRIX-Hib doses are given at the correct times. This will ensure the best effect of the vaccine in protecting your child against diphtheria, tetanus Haemophilus influenza type b infection and pertussis (whooping cough).

Side Effects

Tell your doctor, nurse or pharmacist as soon as possible if your child does not feel well during or after having had a dose of INFANRIX-Hib.

INFANRIX-Hib helps protect most children from diphtheria, tetanus, pertussis and Haemophilus influenza type b infection, but it may have unwanted side effects in some children. All medicines and vaccines can have side effects. Sometimes they are serious; most of the time they are not. Some side effects may need medical treatment. However, the chance of your child having a serious side effect is less than the chance of your child having a permanent injury from the infections.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Most unwanted effects with INFANRIX-Hib are mild and usually clear up within a few days. These effects, as with other vaccines, generally occur around the injection site.

Common effects

Tell your doctor if you notice any of the following that are troublesome or ongoing after vaccination:

- redness, swelling, soreness around the injection site
- fever (between 38°C and 40°C)
- loss of appetite, vomiting or diarrhoea
- restlessness, unusual crying (for more than an hour).
- sleepiness

Serious effects

As with all vaccines given by injection there is a very small risk of serious allergic reaction. Contact your doctor immediately or go to the Accident and Emergency department of your nearest hospital if any of the following happens:

- swelling of limbs, face, eyes, inside of nose, mouth or throat
- shortness of breath, breathing or swallowing difficulties
- hives, itching (especially of the hands or feet), reddening of skin (especially around the ears), or severe skin reactions

- unusual tiredness or weakness that is sudden and severe, muscular aches and pains
- convulsions/fits, collapse, shock-like state or periods of unconsciousness
- fever over 40°C
- crying for 3 hours or more.

The above are signs of an allergic reaction. Allergy to INFANRIX-Hib is rare. Any such severe reactions will usually occur within the first few hours of vaccination.

Other side effects, not listed above, can also occur during or soon after a dose of INFANRIX-Hib such as respiratory infections and middle ear infections. **Check with your doctor or nurse if you notice any other effects.**

Do not be alarmed by this list of possible side effects. Your child may not experience any of them.

Storage

INFANRIX-Hib is usually stored at the doctor's clinic or surgery, or at the pharmacy. But if you need to store INFANRIX-Hib always:

- Keep both parts of the INFANRIX-Hib vaccination in the refrigerator stored between +2°C and +8°C. **THE PACK SHOULD NEVER BE FROZEN. FREEZING DESTROYS THE VACCINE.**
- Keep the vaccine out of the reach of children.
- Keep INFANRIX-Hib in the original pack to protect it from light.
- The vaccination is given as soon as the powder and liquid are mixed. Throw away any that is not used immediately.

Ask your pharmacist what to do with any left over INFANRIX-Hib that has expired or has not been used.

Product Description

What it looks like

INFANRIX-Hib comes in 2 parts. A powder in a glass vial (small bottle). A white slightly milky liquid in a glass vial or syringe and a pellet (Hib)

Ingredients

The active ingredients of INFANRIX-Hib are non-infectious substances from tetanus, diphtheria bacteria, Haemophilus influenza type b and purified proteins of pertussis bacteria. The vaccine cannot cause these diseases.

After mixing the powder and liquid, each 0.5mL dose contains:

- 30 IU of diphtheria toxoid
- 40 IU of tetanus toxoid
- 25mcg of pertussis toxoid, 25mcg of filamentous haemagglutinin and 8mcg of pertactin
- 10mcg of purified capsular polysaccharide of Haemophilus influenzae type b polysaccharide bound to 30mcg tetanus toxoid.

Inactive ingredients in the vaccine are: aluminium hydroxide, 2-phenoxyethanol, sodium chloride and water.

INFANRIX-Hib does not contain any infectious material.

Further Information

INFANRIX-Hib is only available if prescribed by a doctor.

INFANRIX-Hib comes in packs of 1 or 10.

Distributor

Distributed In New Zealand by:

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