INFANRIX hexa

Combined Diphtheria-Tetanus-acellular Pertussis (DTPa), Hepatitis B, Inactivated Poliovirus and Haemophilus influenzae type b Vaccine

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you are given INFANRIX hexa.

This leaflet answers some of the common questions about INFANRIX hexa 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 hexa against the expected benefits.

If you have any concerns about your child receiving INFANRIX hexa talk to your doctor, nurse or pharmacist.

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

What INFANRIX hexa is used for

INFANRIX hexa is a vaccine used to prevent six diseases: diphtheria, tetanus, pertussis (whooping cough), hepatitis B, poliomyelitis (polio) and *Haemophilus influenzae* type b (Hib). The vaccine works by causing the body to produce its own protection (antibodies) against these diseases.

Diphtheria, tetanus, pertussis and Hib are all serious life-threatening diseases caused by bacterial infection. Hepatitis B and poliomyelitis are infectious diseases caused by viral infection.

Diphtheria
Diphtheria mainly affects the airways and sometimes the skin. Generally the airways become inflamed (swollen) causing severe breathing difficulties and sometimes suffocation. The bacteria also 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 (Lockjaw)
Tetanus bacteria enter the body through wounded skin. Wounds that are especially prone to infection are burns, fractures, deep wounds or wounds contaminated with soil, dust, horse manure or wood splinters. The bacteria release a toxin (poison), which can cause muscle stiffness, painful muscle spasms, fits and death. The spasms can be strong enough to cause bone fractures of the spine. The death rate is 10% of cases.

Pertussis (Whooping cough)
Pertussis is a highly infectious illness. The disease 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 chest infections (bronchitis), lung infections (pneumonia), fits, brain damage and death. The risk of severe complications and death is greatest in infants under 6 months of age. The death rate is 0.5% for infants under 6 months of age.

Hepatitis B
Hepatitis B is caused by the hepatitis B virus. It causes the liver to be become swollen (inflamed). The virus is found in body fluids such as blood, semen, vaginal secretions, or saliva of infected people. The virus can enter the bloodstream through:

- an infected mother passing the virus onto her baby during or shortly after birth
- sores, cuts or tiny wounds coming into contact with infected fluids (eg from a human bite, sharing razors or toothbrushes, or working with human blood or body fluids)
- injection (eg needlestick injury, or sharing needles for IV drug use)
- sexual intercourse

Some people infected with hepatitis B may not look or feel sick. But others will get symptoms, which may not be seen for 6 weeks to 6 months after infection. Sometimes people will only have mild flu-like symptoms, but other people can become very ill. They may be extremely tired, and have dark urine, pale faeces, yellowish skin and/or eyes (jaundice), and other symptoms possibly requiring hospitalisation.

Most adults fully recover from the disease. However, some people, particularly children, who may not have had symptoms, can remain infected. They are called hepatitis B virus carriers. Hepatitis B carriers can infect others throughout their lives.

Babies infected with hepatitis B at birth almost always become carriers. Often they do not show symptoms, and seem healthy for many years. However, after 30, 40 or 50 years they can become sick and develop symptoms. For all chronic hepatitis B carriers there is a risk of serious liver disease, such as cirrhosis (liver scarring) and liver cancer.

There is no specific treatment for hepatitis B.

Poliomyelitis (Polio)
Polio is a viral infection that can have variable effects. Often it causes only a mild illness but in some people it causes permanent injury or death.

In its severest form, polio infection causes paralysis of the muscles (unable to move), including those needed for breathing and walking. Polio infection can leave a person unable to breathe without the help of an iron lung machine, unable to walk without leg braces, or confined to a wheel chair. The limbs affected by the disease may be painfully twisted (deformed).

***Haemophilus influenzae* type b (Hib)**
Hib most frequently causes brain inflammation (swelling), which is generally seen in infants under 18 months of age. The death rate is 5-10% of infants in this age group. In 15-30% of surviving infants there will be some type of serious complication such as: mental retardation, cerebral palsy, deafness, epilepsy or partial blindness. Hib can also causes inflammation of the throat, which is mostly seen in children over 18 months of age. This occasionally causes death by suffocation. Less commonly, the bacteria can also infect the blood, heart, lungs, bones, joints, and tissues of the eyes and mouth.

Vaccination is the best way to protect against these diseases. INFANRIX hexa vaccine cannot give your child diphtheria, tetanus, pertussis, hepatitis B, Hib or polio infection.

The vaccine will not protect against diseases caused by other types of bacteria, viruses or organisms.

If a person is already infected with the hepatitis B virus at the time of vaccination, INFANRIX hexa may not prevent the disease in these people.

Before INFANRIX hexa is given

When INFANRIX hexa must not be given

INFANRIX hexa should not be given if your child has had an allergic reaction to:

- INFANRIX hexa or any of the active ingredients in the vaccine
- any of the ingredients listed at the end of this leaflet.
- any other diphtheria, tetanus, hepatitis B, inactivated polio or *Haemophilus influenzae* type b vaccine (such as ENGERIX-B, H-B-Vax II™, INFANRIX, Triple Antigen™, Tripacel™ or IPOL™ vaccine, HIBERIX).

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

If your child had INFANRIX hexa before and became unwell, tell your doctor, nurse or pharmacist before the next dose is given.

INFANRIX hexa should not be given if:

- your child experienced a disease of the brain within 7 days after previous vaccination with a pertussis containing vaccine.
- 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 vaccination.
- the expiry date printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

If you are not sure whether your child should have INFANRIX hexa vaccine, talk to your doctor or nurse. Do not give this vaccine to anyone else; your doctor has prescribed it specifically for your child.

Before you are given it

Before INFANRIX hexa is given tell your doctor or nurse if:

- your child has any medical problems such as:
  - brain disease or central nervous system (CNS) disease (for example epilepsy etc.)
  - a bleeding problem or bruises easily
  - lowered immunity due to medical treatment or a medical condition
  - a tendency to febrile convulsions (seizures/fits due to a fever or high body temperature)
  - a family history of seizures/fits
  - a family history of Sudden Infant Death Syndrome (SIDS)

- allergy to the antibiotics: neomycin and polymyxin.
- after having INFANRIX hexa or another pertussis-containing vaccine your child had any problems, especially:
  - a high temperature (over 40.0°C) within 48 hours of vaccination
  - a collapse or shock-like state within 48 hours of vaccination
  - crying lasting 3 hours or more within 48 hours of vaccination
  - convulsions (seizures/fits) with or without a fever within 3 days of vaccination
- your child has allergies to any other medicines or substances, such as dyes, foods or preservatives
- your child has received another vaccine recently, or is having any prescription or OTC (over-the-counter) medicines. In particular, mention if your child is being given medicines which suppress the immune system, such as high-dose steroids

Fainting can occur following, or even before, any needle injection, therefore tell the doctor or nurse if your child fainted with a previous injection.

Higher incidence of fever (>39.5°C) was reported in infants receiving INFANRIX hexa and Prevenar compared to infants receiving INFANRIX hexa alone.

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 hexa is to be given with another vaccine or medicine.

Increased reporting rates of fits (with or without fever) and collapse or shock-like state were observed in infants receiving INFANRIX hexa and pneumococcal conjugate vaccine (e.g. Prevenar) at the same visit compared to infants receiving INFANRIX hexa alone.

How INFANRIX hexa is given

The doctor or nurse will give INFANRIX hexa 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 hexa is 0.5 mL.

How it is given

INFANRIX hexa will be injected into the upper leg muscle or the upper arm muscle.

The vaccine should never be injected into a vein, artery or the skin.

When it is given

INFANRIX hexa is usually given as a total of two or three doses with an interval of at least one month between each injection.

If additional injections (boosters) are necessary, the doctor or nurse will tell you.

Each dose is given on a separate visit. INFANRIX hexa should not be given at birth.

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

INFANRIX hexa can be given as a booster dose when the child is 18 months old when boosting with hepatitis B and/or poliovirus and/or *Haemophilus influenza* type b, as well as diphtheria, tetanus and pertussis, is required.

You should discuss with your doctor what is needed for your child.

If a dose is missed

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

While INFANRIX hexa is given

Keep your child's follow-up visits with the doctor or clinic. It is important the follow-up doses of INFANRIX hexa are given at the correct times. This will ensure the best effect of the vaccine in protecting your child against diphtheria, tetanus, pertussis, hepatitis B, poliovirus infection and *Haemophilus influenzae* type b.

Side effects

Tell your doctor or nurse as soon as possible if your child does not feel or look well during or after being given INFANRIX hexa vaccine.

INFANRIX hexa helps protect most children from diphtheria, tetanus, pertussis, hepatitis B, poliovirus infection and *Haemophilus influenzae* type b, but it may have unwanted side effects in a few 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. The chance of your child having a serious side effect is very much less than the chance of your child having a permanent injury from the natural infections.

Do not be alarmed by the following lists of side effects. Your child may not experience any of them.

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

Most unwanted effects with INFANRIX hexa are mild and usually clear up within a few days. These effects, as with other vaccines, generally occur around the injection site. Side effects are more likely to occur with booster dosing.

Tell your doctor if your child has any of the following that are troublesome or ongoing:

- pain, redness, swelling, a hard lump, bruising or itching around the injection site
- fever between 38°C and 39.5°C
- unusual crying (for more than 1 hour)
- vomiting, diarrhoea
- loss of appetite
- sleepiness, nervousness, irritability restlessness, fussiness or difficulty sleeping
- upper respiratory tract infection, bronchitis, runny or blocked nose
- skin rash, bruising, or purple or red-brown spots visible through the skin (purpura)

The above list includes the more common side effects of your medicine.

See your doctor immediately if you notice any of the following:

- fever greater than 39.5°C
- crying for 3 hours or more
- collapse, or periods of unconsciousness or lack of awareness
- seizures (convulsions) or fits
- your child has breathing difficulties, please contact your doctor. This may be more common in the first three days following vaccination if your child is born prematurely (before or at 28 weeks of pregnancy).

The above list includes serious side effects that may require medical attention.

Contact your doctor immediately or take your child to the casualty 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
- sudden drop in blood pressure and loss of consciousness

These are signs of an allergic reaction. As with all vaccines given by injection there is a very small risk of such reactions. Allergy to INFANRIX hexa vaccine is rare. Any such severe reactions will usually occur within the first few hours of vaccination.

Other events reported after INFANRIX vaccination, but may not be necessarily related to the vaccine include:

- respiratory infections or bronchitis

Other side effects not listed above, can also occur during or soon after a dose of INFANRIX hexa.

Check with your doctor or nurse if your child has any other effects.

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

After being given INFANRIX hexa

Storage

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

- Keep INFANRIX hexa 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.
- INFANRIX hexa should not be used 8 hours after opening.
- Keep INFANRIX hexa in the original pack until it is time for it to be given.

Disposal

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

Product description

What it looks like

INFANRIX hexa comes in two parts. The first part is a white, milky liquid (0.5 mL) in a pre-filled syringe that consists of the combined diphtheria, tetanus, pertussis, hepatitis B and inactivated poliovirus vaccine.

The second part is the Hib vaccine and is a white pellet in a separate glass vial. These parts are mixed together before use.

When both parts are mixed the vaccine looks like a white, cloudy/milky liquid.

Ingredients

The active ingredients of INFANRIX hexa are non-infectious substances from tetanus, diphtheria bacteria, purified proteins of pertussis bacteria, the surface protein of the hepatitis B virus (HBsAg, derived from genetically engineered yeast cells) and inactivated poliovirus.

The vaccine cannot cause these diseases.

Each 0.5 mL dose contains:

- ≥30 IU (25 LfU) of diphtheria toxoid
- ≥40 IU (10 Lf U) of tetanus toxoid
- 25 µg of pertussis toxoid, 25 µg of filamentous haemagglutinin and 8 µg of pertactin
- 10 µg of recombinant HBsAg protein.
- 40 D-antigen units of poliovirus Type 1, 8 D-antigen units of poliovirus Type 2 and 32 D-antigen units of poliovirus Type 3
- 10 µg of purified capsular polysaccharide of Hib covalently bound to approximately 20-40 µg of tetanus toxoid.

The inactive ingredients in the vaccine are:

- aluminium hydroxide
- aluminium phosphate
- lactose
- sodium chloride (salt)
- water for injections.

The following ingredients are present as residues:

- Medium 199
- potassium chloride
- formaldehyde
- glycine
- sodium phosphate dibasic dehydrate
- potassium phosphate monobasic
- neomycin sulphate
- polymyxin B sulfate
- polysorbate 20 and 80

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

Further Information

INFANRIX hexa is only available if prescribed by a doctor.

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Manufacturer

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