

INFANRIX HEXA

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about receiving this vaccine, speak to your doctor or pharmacist.

1. Why is my child being given INFANRIX HEXA?

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

For more information, see Section [1. Why is my child being given INFANRIX HEXA?](#) in the full CMI.

2. What should I know before my child is given INFANRIX HEXA?

Do not use if your child has ever had an allergic reaction to INFANRIX HEXA or any of the ingredients listed at the end of the CMI.

Talk to your doctor if your child has any other medical conditions or takes any other medicines.

For more information, see Section [2. What should I know before my child is given INFANRIX HEXA?](#) in the full CMI.

3. What if my child is taking other medicines?

Some medicines may interfere with INFANRIX HEXA and affect how it works. A list of these medicines is in Section [3. What if my child is taking other medicines?](#) in the full CMI.

4. How is INFANRIX HEXA given?

- INFANRIX HEXA is given as a 0.5 mL injection into the upper leg muscle or the upper arm muscle.
- INFANRIX HEXA is usually given as a total of two or three doses with an interval of at least one month between each injection.
- A booster dose may be given. The healthcare professional will tell you.
- Each dose is given on a separate visit. INFANRIX HEXA should not be given at birth.

More instructions can be found in Section [4. How is INFANRIX HEXA given?](#) in the full CMI.

5. What should I know when my child is being given INFANRIX HEXA?

Things you should do	<ul style="list-style-type: none">• Tell your doctor, nurse or pharmacist immediately if you or your child 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.• Tell your doctor, nurse or pharmacist, or go to the emergency department if you notice any signs of an allergic reaction, including itchy skin rash, shortness of breath or swelling of the face or tongue or severe skin reactions.• Keep your child's follow-up visits with the doctor or clinic. It is important that follow-up doses of INFANRIX HEXA are given at the correct times.
Looking after your vaccine	<ul style="list-style-type: none">• INFANRIX HEXA is usually stored at the doctor's clinic or surgery, or at the pharmacy• If you need to store INFANRIX HEXA, store in the refrigerator between 2°C and 8°C. Do not freeze.

For more information, see Section [5. What should I know when my child is being given INFANRIX HEXA?](#) in the full CMI.

6. Are there any side effects?

All vaccines can have side effects. If your child does experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. Side effects which have been reported include 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).

As with all vaccines given by injection there is a very small risk of serious allergic reaction. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

INFANRIX HEXA

Active ingredients: *diphtheria toxoid, tetanus toxoid, pertussis toxoid, filamentous haemagglutinin and pertactin, Hepatitis B, Inactivated Poliovirus and Haemophilus influenzae type b*

Consumer Medicine Information (CMI)

This leaflet provides important information about INFANRIX HEXA. **You should also speak to your doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about your child being given INFANRIX HEXA.**

Where to find information in this leaflet:

- [1. Why is my child being given INFANRIX HEXA?](#)
- [2. What should I know before my child is given INFANRIX HEXA?](#)
- [3. What if my child is taking other vaccines?](#)
- [4. How is INFANRIX HEXA given?](#)
- [5. What should I know when my child is being given INFANRIX HEXA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why is my child being given INFANRIX HEXA?

INFANRIX HEXA contains the active ingredients of non-infectious substances from diphtheria bacteria, tetanus, purified proteins of pertussis bacteria, the surface protein of the hepatitis B virus (HBsAg, derived from genetically engineered yeast cells), inactivated poliovirus and *Haemophilus influenzae type b*.

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 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 (e.g. from a human bite, sharing razors or toothbrushes, or working with human blood or body fluids)
- injection (e.g. 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 wheelchair. 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 cause 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 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.

2. What should I know before my child is given INFANRIX HEXA?

Warnings

Your child should not be given INFANRIX HEXA if:

- your child is allergic to INFANRIX HEXA or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can receive this vaccine
- your child is allergic to any other diphtheria, tetanus, hepatitis B, inactivated polio or *Haemophilus influenzae* type b vaccine.

Check with your doctor if 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
- has experienced any problems after receiving INFANRIX HEXA or another pertussis-containing vaccine, especially:
 - a high temperature (over 40.5°C) within 48 hours 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 (seizures/fits) with or without a fever within 3 days of vaccination

- a disease of the brain within 7 days after previous vaccination with a pertussis containing vaccine.
- has any medical conditions 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)
 - allergies to the antibiotics neomycin and polymyxin.

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

During treatment, your child may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

3. What if my child is taking other medicines?

Tell your doctor, nurse or pharmacist if your child is taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with INFANRIX HEXA and affect how it works, such as:

- medicines which suppress the immune system, such as high-dose steroids.

Having other vaccines

Tell your doctor, nurse or pharmacist if your child has received another vaccine recently.

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.

4. How is INFANRIX HEXA 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 it is given

- INFANRIX HEXA is given as a 0.5 mL injection into either the upper arm muscle or the upper leg muscle.

- **The vaccine should never be injected into the skin or into a vein (intravenously).**

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.
- 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 influenzae type b, as well as diphtheria, tetanus and pertussis, is required.

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

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.

If your child has been given too much INFANRIX HEXA

If you think that your child has been given too much INFANRIX HEXA, they may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **0800 POISON** or **0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know when my child is being given INFANRIX HEXA?

Things you must do

Keep your child's follow-up visits with the doctor or clinic. It is important that 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.

Looking after your vaccine

INFANRIX HEXA vaccine is usually stored at the doctor's clinic or surgery, or at the pharmacy.

If you need to store INFANRIX HEXA:

- store it in the refrigerator between 2°C and 8°C. **THE PACK SHOULD NEVER BE FROZEN. FREEZING DESTROYS THE VACCINE**

- store in the original pack. INFANRIX HEXA should not be used 8 hours after opening.

Follow the instructions in the carton on how to take care of your vaccine properly.

Keep it where young children cannot reach it.

Getting rid of any unwanted vaccine

If your child no longer needs to receive this vaccine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this vaccine after the expiry date.

6. Are there any side effects?

All vaccines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>General disorders and administration site conditions:</p> <ul style="list-style-type: none"> • 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) • sleepiness, nervousness, irritability, restlessness, fussiness or difficulty sleeping. <p>Respiratory disorders:</p> <ul style="list-style-type: none"> • upper respiratory tract infection, bronchitis, runny or blocked nose. <p>Gastrointestinal disorders:</p> <ul style="list-style-type: none"> • vomiting • diarrhoea • loss of appetite. <p>Skin and subcutaneous tissue disorders:</p> <ul style="list-style-type: none"> • skin rash, bruising, or purple or red-brown spots visible through the skin (purpura). 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>General disorders and administration site conditions:</p> <ul style="list-style-type: none"> • fever greater than 39.5°C • crying for 3 hours or more 	<p>Call your doctor straight away, or go straight to the Emergency Department at</p>

<ul style="list-style-type: none"> collapse, or periods of unconsciousness or lack of awareness. <p>Nervous system disorders:</p> <ul style="list-style-type: none"> seizures (convulsions) or fits. <p>Immune system disorders and allergic reactions:</p> <ul style="list-style-type: none"> 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 the 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. <p>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.</p> <p>Respiratory disorders:</p> <ul style="list-style-type: none"> respiratory infections bronchitis. <p>If 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).</p>	<p>your nearest hospital if you notice any of these serious side effects.</p>
---	--

Tell your doctor or pharmacist if you notice anything else that may be making your child feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects via <https://pophealth.my.site.com/carmreportnz/s/>.

By reporting side effects, you can help provide more information on the safety of this vaccine.

Always make sure you speak to your doctor or pharmacist before you decide to stop giving any of your child's medicines or vaccines.

7. Product details

This vaccine is only available with a doctor's prescription.

What INFANRIX HEXA contains

<p>Active ingredients (main ingredients)</p>	<ul style="list-style-type: none"> ≥30 IU (25 LfU) of diphtheria toxoid ≥40 IU (10 Lf U) of tetanus toxoid 25 micrograms of pertussis toxoid, 25 micrograms of filamentous haemagglutinin and 8 micrograms of pertactin 10 micrograms 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 micrograms of purified capsular polysaccharide of Hib covalently bound to approximately 20-40 micrograms of tetanus toxoid
<p>Other ingredients (inactive ingredients)</p>	<ul style="list-style-type: none"> aluminium hydroxide hydrate aluminium phosphate lactose Medium 199 sodium chloride (salt) water for injections <p>The following ingredients are present as residues:</p> <ul style="list-style-type: none"> neomycin sulphate polymyxin B sulfate

Your child should not be given this vaccine if they are allergic to any of these ingredients.

The manufacture of this vaccine 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.

What INFANRIX HEXA looks like

INFANRIX HEXA (TT50-6438) 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.

Who distributes INFANRIX HEXA

GlaxoSmithKline NZ Ltd
Private Bag 106600
Downtown

Auckland 1143
New Zealand

Phone: (09) 367 2900
Facsimile: (09) 367 2910

Trade marks are owned by or licensed to the GSK group of companies.

©2025 GSK group companies or its licensor.

This leaflet was prepared on 1 August 2025.

Version 3