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 arm muscle, upper thigh or leg 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.
- 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.

More instructions can be found in Section 4. How is INFANRIX HEXA given? in the full CMI.

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

Things you should do	• Tell your doctor, nurse or pharmacist 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 or your child has breathing difficulties. • Contact your doctor immediately, or go to the emergency department, if you notice any signs of an allergic reaction, including swelling of the face, lips, tongue or other parts of the body, hives, sudden and severe unusual tiredness or weakness or a sudden drop in blood pressure. • Remind any doctor or pharmacist that your child visits that your child has been given INFANRIX HEXA.
Looking after the vaccine	• 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 while my infant or child is being given INFANRIX HEXA? in the full CMI.

6. Are there any side effects?

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.

Side effects can include: pain, redness, swelling, a hard lump around the injection site, fever between 38°C and 39.5°C, generally feeling unwell, runny nose or loss of appetite, unusual crying (for more than 1 hour), nausea, vomiting, diarrhoea, headache, sleepiness, tiredness, nervousness, restlessness, fussiness or difficulty sleeping, skin rash, bruising, or purple or red-brown spots visible through the skin (purpura). For more information, including what to do if your child has 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 receiving 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 medicines?
4. How is INFANRIX HEXA given?
5. What should I know while 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 bronchitis, 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 (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 your child 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)
    - allergy 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.

From vaccination, 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 or nurse if your child has received another vaccine recently.

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

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 much is given

- The dose of INFANRIX HEXA is 0.5 mL.

How is it 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.

If too much INFANRIX HEXA is given

If you think that too much INFANRIX HEXA has been given, urgent medical attention may be required.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), 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 while my child is being given INFANRIX HEXA?

Things you should do

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.

Looking after the vaccine

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

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 INFANRIX HEXA in the original pack until it is time for it to be given
- INFANRIX HEXA should be used immediately after opening.

Keep it where young children cannot reach it.

Getting rid of any unwanted vaccine

If you no longer need to use 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 your child experiences 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, nurse or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
General disorders and administration site conditions: • 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. **Respiratory disorders:** • upper respiratory tract infection, bronchitis, runny or blocked nose. **Gastrointestinal disorders:** • vomiting • diarrhoea • loss of appetite. **Skin and subcutaneous tissue disorders:** • skin rash, bruising, or purple or red-brown spots visible through the skin (purpura).	**Speak to your doctor if your child has any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
General disorders and administration site conditions: • fever greater than 39.5°C • crying for 3 hours or more • collapse, or periods of unconsciousness or lack of awareness. **Nervous system disorders:** • seizures (convulsions) or fits. **Immune system disorders and allergic reactions:** • 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. **Respiratory disorders:** • respiratory infections • bronchitis. 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).	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

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

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

Reporting side effects

After you have received medical advice for any side affects your child experienced, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this vaccine.

Always make sure you speak to your doctor, nurse or pharmacist before you decide to stop your child taking any medicines.

7. Product details

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

What INFANRIX HEXA contains

Active ingredients (main ingredients)	• ≥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
Other ingredients (inactive ingredients)	• aluminium hydroxide hydrate • aluminium phosphate • lactose • sodium chloride (salt) • medium 199 • water for injections The following ingredients are present as residues: • neomycin sulfate • polymyxin B sulfate

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

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.

What INFANRIX HEXA looks like

INFANRIX HEXA (AUST R 132881) 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 Australia Pty Ltd

Level 4, 436 Johnston Street,

Abbotsford, Victoria, 3067

Phone: 1800 033 109

www.gsk.com.au

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

©2025 GSK group of companies or its licensor.

This leaflet was prepared on 29 August 2025.

Version 11.0