

INFANRIX® PENTA

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

CONSUMER MEDICINE INFORMATION LEAFLET

WHAT IS IN THIS LEAFLET

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

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

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

WHAT INFANRIX PENTA IS USED FOR

INFANRIX PENTA is a vaccine used to prevent five diseases, diphtheria, tetanus, pertussis (whooping cough), hepatitis B and poliomyelitis (polio). The vaccine works by causing the body to produce its own protection (antibodies) against these diseases.

Diphtheria, tetanus, and pertussis 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 30-40% 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 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. But 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, 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 deformed.

Vaccination is the best way to protect against these diseases. INFANRIX PENTA vaccine cannot give your child diphtheria, tetanus, pertussis, hepatitis B 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 PENTA may not prevent the disease in these people.

BEFORE VACCINATION

INFANRIX PENTA SHOULD NOT BE GIVEN IF:

- your child has had an allergic reaction to INFANRIX PENTA, or any ingredient contained in this vaccine. The ingredients in INFANRIX PENTA 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 had INFANRIX PENTA before and became unwell, tell your doctor, nurse or pharmacist before the next dose is given.
- your child experienced a disease of the brain within 7 days after previous vaccination with a pertussis containing vaccine.
- your child has had an allergic reaction to any other diphtheria, tetanus, hepatitis B or inactivated polio containing vaccine (such as Engerix[®]-B, H-B-Vax II[™], Infanrix[®], Triple Antigen[™], Tripacel[™] or IPOL[™] 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 PENTA 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 INFANRIX PENTA IS GIVEN TELL YOUR DOCTOR OR NURSE IF:

- your child has any medical problems such as:
 - ◆ brain disease or central nervous system (CNS) disease (ie. 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 Sudden Infant Death Syndrome (SIDS)
 - ◆ allergy to the antibiotics: neomycin and polymyxin.
- after having INFANRIX PENTA or another pertussis-containing vaccine (such as Infanrix[®] or Triple Antigen) your child had any problems, especially:
 - ◆ a high temperature (over 40.0°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 (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

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 PENTA is to be given with another vaccine or medicine.

HOW INFANRIX PENTA IS GIVEN

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

HOW IT IS GIVEN

INFANRIX PENTA will be injected into the upper leg

muscle in infants under 12 months of age. In children over 12 months of age the injection may be given in the upper arm muscle instead.

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

WHEN IT IS GIVEN

INFANRIX PENTA is usually given as a total of three doses as follows:

- First dose: 2 months of age
- Second dose: 4 months of age
- Third dose: 6 months of age

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

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.

WHILE USING INFANRIX PENTA

THINGS YOU MUST DO:

Keep your child's follow up visits with the doctor or clinic. It is important the follow-up doses of INFANRIX PENTA 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 and poliovirus infection.

SIDE EFFECTS

Tell your doctor or nurse as soon as possible if your child does not feel or look well during or after having had a dose of INFANRIX PENTA vaccine.

INFANRIX PENTA helps protect most children from diphtheria, tetanus, pertussis, hepatitis B and poliovirus infection, 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.

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

Most unwanted effects with INFANRIX PENTA 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.

MILD EFFECTS

- **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, runny nose or loss of appetite

- ◆ sleepiness, tiredness, nervousness, restlessness, fussiness or difficulty sleeping
- ◆ skin rash, bruising, or purple or red-brown spots visible through the skin (purpura)

MORE SERIOUS EFFECTS

- **Tell 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. 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).
- **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

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 PENTA vaccine is rare. Any such severe reactions will usually occur within the first few hours of vaccination.

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

- ◆ respiratory infections, bronchitis or viral infection
- ◆ infection of the middle ear that may cause earache and temporary hearing loss

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

STORAGE

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

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

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

PRODUCT DESCRIPTION

WHAT IT LOOKS LIKE

INFANRIX PENTA comes in a prefilled syringe or a vial. It is a white, slightly milky liquid.

INGREDIENTS

The active ingredients of INFANRIX PENTA 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 0.5mL dose contains:

- 30 IU (25 Lf U) of diphtheria toxoid
- 40 IU (10 Lf U) of tetanus toxoid
- 25mcg of pertussis toxoid, 25mcg of filamentous haemagglutinin and 8mcg of pertactin
- 10mcg 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

Date of Preparation:
7 May 2008

The inactive ingredients in the vaccine are: aluminium hydroxide, aluminium phosphate, 2-phenoxyethanol, neomycin (traces), polymyxin (traces), polysorbate 20, polysorbate 80, Medium 199, sodium chloride (salt), formaldehyde, glycine, potassium chloride, sodium phosphate dibasic dihydrate, potassium phosphate monobasic and water.

* The vial presentation is not currently marketed in Australia.

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 PENTA is only available if prescribed by a doctor.

INFANRIX PENTA comes in a prefilled syringe (AUST R 79079) or in a vial* (AUST R 79991).

MANUFACTURER

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DISTRIBUTED IN AUSTRALIA BY

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