

# INFANRIX<sup>®</sup> HepB

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

## CONSUMER MEDICINE INFORMATION LEAFLET

### WHAT IS IN THIS LEAFLET

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

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

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

### WHAT INFANRIX HepB IS USED FOR

INFANRIX HepB is a vaccine used to prevent four diseases, diphtheria, tetanus, pertussis (whooping cough), and hepatitis B. 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 is an infectious disease 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.

Vaccination is the best way to protect against these diseases. INFANRIX HepB vaccine cannot give your child diphtheria, tetanus, pertussis or hepatitis B infection. The vaccine will not protect against diseases caused by other types of bacteria or organisms. If a person is already infected with the hepatitis B virus at the time of vaccination, INFANRIX HepB may not prevent the disease in these people.

## **BEFORE VACCINATION**

### **INFANRIX HepB SHOULD NOT BE GIVEN IF :**

- your child has had an allergic reaction to INFANRIX HepB, or any ingredient contained in this vaccine. The ingredients in INFANRIX HepB 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.

If your child had INFANRIX HepB 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, pertussis, or hepatitis B containing vaccine (such as Engerix-B, H-B-Vax II, Infanrix® or Triple Antigen vaccine).
- your child has had a severe reaction defined as prolonged seizures (fits) and/or unconsciousness within 7 days following injection of INFANRIX HepB or any other pertussis-containing vaccine (such as Infanrix® or Triple Antigen 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 HepB 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 HepB 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 kidney problem
  - ◆ allergy to yeast
- after having INFANRIX HepB or another pertussis-containing vaccine (such as Infanrix® or Triple Antigen) your child had any problems, especially:
  - ◆ a 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 (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 HepB is to be given with another vaccine or medicine.*

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## HOW INFANRIX HepB IS GIVEN

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

## HOW IT IS GIVEN

INFANRIX HepB 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. 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.*

## WHEN IT IS GIVEN

INFANRIX HepB 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 HepB should not be given at birth. A hepatitis B vaccine alone (eg. Engerix-B or H-B-Vax-II) should be given at birth.

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

A booster dose of INFANRIX HepB may be given when the child is 18 months old if boosting with hepatitis B, as well as diphtheria, tetanus and pertussis, is required. In cases where boosting with hepatitis B at 18 months is not required, a diphtheria, tetanus and pertussis vaccine, such as Infanrix<sup>®</sup>, should be used.

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.

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## WHILE USING INFANRIX HepB

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### 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 HepB are given at the correct times. This will ensure the best effect of the vaccine in

protecting your child against diphtheria, tetanus, pertussis, and hepatitis B infection.

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## SIDE EFFECTS

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**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 HepB vaccine.**

INFANRIX HepB helps protect most children from diphtheria, tetanus, pertussis, and hepatitis B 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 HepB 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, abdominal pain, or loss of appetite
- ◆ sleepiness, tiredness, nervousness, mood swings, restlessness, or difficulty sleeping
- ◆ skin rash, bruising, or purple or red-brown spots visible through the skin (purpura).

**MORE SERIOUS EFFECTS THAT MAY OCCUR RARELY**

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

- ◆ crying for 3 hours or more
- ◆ collapse, or periods of unconsciousness or lack of awareness

- ◆ seizures (convulsions) or fits
- ◆ fever over 39.5°C

*These side effects have occurred with other pertussis-containing vaccines.*

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

- ◆ bronchitis

Other side effects not listed above, can also occur during or soon after a dose of INFANRIX HepB. **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 HepB vaccine is usually stored at the doctor's clinic or surgery, or at the pharmacy. But if you need to store INFANRIX HepB always:

- Keep INFANRIX HepB 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 HepB in the original pack until it is time for it to be given.

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

**PRODUCT DESCRIPTION**

**WHAT IT LOOKS LIKE**

INFANRIX HepB comes in glass vials and prefilled syringes. It is a white, slightly milky liquid.

**INGREDIENTS**

The active ingredients of INFANRIX HepB are non-infectious substances from tetanus, diphtheria bacteria, purified proteins of pertussis bacteria, and the surface protein of the hepatitis B virus (HBsAg, derived from genetically engineered yeast cells). **The vaccine cannot cause these diseases.** Each 0.5mL dose contains:

- 25Lf U of diphtheria toxoid
- 10Lf U of tetanus toxoid
- 25mcg of pertussis toxoid, 25mcg of filamentous haemagglutinin and 8mcg of 69 kilodalton outer membrane protein (pertactin)
- 10mcg of recombinant HBsAg protein.

The inactive ingredients in the vaccine are: aluminium hydroxide, aluminium phosphate, 2-phenoxyethanol, polysorbate 80, sodium chloride (salt) and water.

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 HepB is only available if prescribed by a doctor.

INFANRIX HepB comes in a glass vial (AUST R 67471) or as

a prefilled syringe (AUST R  
67472)

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**MANUFACTURER**

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