

INFANRIX®-IPV

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

CONSUMER MEDICINE INFORMATION LEAFLET

WHAT IS IN THIS LEAFLET

This leaflet answers some of the common questions about INFANRIX®-IPV 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®-IPV against the expected benefits.

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

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

WHAT INFANRIX®-IPV IS USED FOR

INFANRIX®-IPV is a vaccine used in infants from 6 weeks of age and over to prevent four diseases, diphtheria, tetanus, pertussis (whooping cough) 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. Poliomyelitis is an 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.

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®-IPV vaccine cannot give your child diphtheria, tetanus, pertussis or polio infection. The vaccine will not protect against diseases caused by other types of bacteria, viruses or organisms.

BEFORE VACCINATION

INFANRIX®-IPV SHOULD NOT BE GIVEN IF:

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

in INFANRIX®-IPV 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®-IPV 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 inactivated polio containing vaccine (such as 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®-IPV 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®-IPV 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 sulfate and polymyxin sulfate.

- after having INFANRIX®-IPV or another pertussis-containing vaccine (such as INFANRIX® or Triple Antigen™) your child had any problems, especially:
 - ◆ a high temperature (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

TAKING OTHER MEDICINES

Tell your doctor or nurse if your child 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 medicines. Your doctor, nurse or pharmacist will be able to

tell you what to do if INFANRIX®-IPV is to be given with another medicine.

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®-IPV is to be given with another vaccine.

HOW INFANRIX®-IPV IS GIVEN

The doctor or nurse will give INFANRIX®-IPV 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®-IPV is 0.5mL.

HOW IT IS GIVEN

INFANRIX[®]-IPV 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. Each dose of INFANRIX[®]-IPV is for single use only. Any residual vaccine must be discarded.

The vaccine should never be given intravenously.

WHEN IT IS GIVEN

INFANRIX[®]-IPV 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[®]-IPV should not be given at birth.

It is also recommended that children up to 6 years of age receive a single booster (follow up) dose of INFANRIX[®]-IPV.

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[®]-IPV

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[®]-IPV are given at the correct times. This will ensure the best effect of the vaccine in protecting your child against diphtheria, tetanus, pertussis 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[®]-IPV vaccine.

INFANRIX[®]-IPV helps protect most children from diphtheria, tetanus, pertussis 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[®]-IPV are mild and usually clear up within a few days. These effects, as with other vaccines, generally occur around the injection site.

MILD EFFECTS

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

- ◆ 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)

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
- **Contact your doctor immediately or take your child to the casualty department of your nearest hospital if any of the following happens:**
 - ◆ sudden sign of allergy such as rash, itching or hives on the skin, swelling of limbs, face, eyes, lips, mouth, throat or other part of the body

- ◆ shortness of breath, breathing or swallowing difficulties
- ◆ 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®-IPV vaccine is rare. Any such severe reactions will usually occur within the first few hours of vaccination.

- **Other events reported after INFANRIX®-IPV vaccination, but not necessarily related to the vaccine include:**
 - ◆ coughing, respiratory infections, bronchitis or viral
 - ◆ infection of the middle ear that may cause earache and temporary hearing loss
 - ◆ toothache, sore throat

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

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

PRODUCT DESCRIPTION

WHAT IT LOOKS LIKE

INFANRIX®-IPV comes in a prefilled syringe. It is a white, slightly milky liquid.

INGREDIENTS

The active ingredients of INFANRIX®-IPV are non-infectious substances from tetanus, diphtheria bacteria, purified proteins of pertussis bacteria and inactivated poliovirus. **The vaccine cannot cause these diseases.** Each 0.5mL dose contains:

- 30IU (25Lf U) of diphtheria toxoid
- 40IU (10Lf U) of tetanus toxoid
- 25mcg of pertussis toxoid, 25mcg of filamentous haemagglutinin and 8mcg of 69 kilodalton outer membrane protein (pertactin)
- 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

The inactive ingredients in the vaccine are: aluminium hydroxide, phenoxyethanol, sodium chloride (salt), polysorbate 80, neomycin (traces), polymyxin (traces), 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®-IPV is only available if prescribed by a doctor.

INFANRIX®-IPV comes in a prefilled syringe (AUST R 80847) or as a glass vial* (AUST R 80848)

MANUFACTURER

GlaxoSmithKline Beecham Biologicals
Rue de l'Institut 89,
1330 Rixensart, Belgium.

DISTRIBUTED IN AUSTRALIA BY

GlaxoSmithKline Australia Pty Ltd
1061 Mountain Highway
Boronia VIC 3155

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* The vial presentation is not currently marketed in Australia.