INFANRIX HEXA
Patient Information Leaflet

SCHEDULING STATUS:

S2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

INFANRIX HEXA

Combined diphtheria-tetanus-acellular pertussis, hepatitis B, enhanced inactivated polio vaccine and *Haemophilus influenzae* type b vaccine.

Powder and suspension for injection.

Read all of this leaflet carefully before your child receives INFANRIX HEXA.

- Keep this leaflet until your child has finished the complete vaccination course. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- INFANRIX HEXA has been prescribed for your child and you should not share medicines with other people.

WHAT INFANRIX HEXA CONTAINS:

INFANRIX HEXA contains immunogenic agents that will stimulate an immune response to diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and *Haemophilus influenzae* type b.

After reconstitution, 1 dose (0,5 ml) contains:

Diphtheria toxoid[1]	not less than 30 International Units (IU)
Tetanus toxoid[1]	not less than 40 International Units (IU)

Bordetella pertussis antigens	
Pertussis toxoid (PT)[1]	25 µg
Filamentous Haemagglutinin (FHA)[1]	25 µg
Pertactin (PRN)[1]	8 µg
Hepatitis B surface antigen (HBs)[2,3]	10 µg
Poliovirus (inactivated) (IPV)	
type 1 (Mahoney strain)[4]	40 D-antigen Unit
type 2 (MEF-1 strain)[4]	8 D-antigen unit
type 3 (Saukett strain)[4]	32 D-antigen unit
Haemophilus influenzae type b polysaccharide	10 µg
(polyribosylribitol phosphate, PRP)[3]	
conjugated to tetanus toxoid as carrier protein	approximately 25 µg

[1]adsorbed on aluminium hydroxide, hydrated ($Al(OH)_3$)	0,5 mg Al^{3+}
[2]produced in yeast cells (*Saccharomyces cerevisiae*) by recombinant DNA technology	
[3]adsorbed on aluminium phosphate ($AlPO_4$)	0,32 mg Al^{3+}

[4]propagated in VERO cells

The other ingredients in INFANRIX HEXA are: Lactose, sodium chloride (NaCl), water for injections and Medium 199 (as stabilizer containing amino acids, mineral salts and vitamins). Potassium chloride, disodium phosphate, monopotassium phosphate, polysorbate 20 and 80, glycine, formaldehyde, neomycin sulphate and polymyxin B sulphate are also present in tiny amounts.

WHAT INFANRIX HEXA IS USED FOR:

INFANRIX HEXA is a vaccine used to protect your child against six diseases: diphtheria, tetanus (lockjaw), pertussis (whooping cough), hepatitis B, poliomyelitis (polio) and *Haemophilus influenzae* type b.

How the vaccine works:

- INFANRIX HEXA helps your child's body to make its own protection (antibodies). This will protect your child against these diseases.
- INFANRIX HEXA may not fully protect all children who are vaccinated.
- INFANRIX HEXA cannot cause the diseases that it protects against.

BEFORE YOU ARE GIVEN INFANRIX HEXA:

INFANRIX HEXA should not be given:

- if your child is allergic (hypersensitive) to INFANRIX HEXA, or any ingredient contained in this vaccine. The active substances and other ingredients in INFANRIX HEXA are listed above. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue
- if your child has previously had an allergic reaction to any vaccine against diphtheria, tetanus, pertussis (whooping cough), hepatitis B, poliomyelitis (polio) or *Haemophilus influenzae* type b diseases
- if your child experienced problems of the nervous system within 7 days after previous vaccination with a vaccine against pertussis (whooping cough) disease.

Check with your doctor if you think any of these apply to your child.

Take special care with INFANRIX HEXA:

- if your child has a severe infection with a high temperature. In these cases the vaccination will be postponed until recovery. A minor infection such as a cold should not be a problem, but talk to your doctor first.
- if after previously having INFANRIX HEXA or another vaccine against pertussis (whooping cough) disease, your child had any problems, especially:
  - a high temperature (over 40 °C) within 48 hours of vaccination
  - a collapse or shock-like state within 48 hours of vaccination
  - persistent crying lasting 3 hours or more within 48 hours of vaccination
  - seizures/fits with or without a high temperature within 3 days of vaccination
- if your child is suffering from neurological disorders, including infantile spasms, uncontrolled epilepsy or progressive encephalopathy (a disease of the brain)
- if your child has a bleeding problem or bruises easily
- if your child has a tendency to seizures/fits due to a fever, or if there is a history in the family of this
- 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 was born prematurely (before or at 28 weeks of pregnancy)
- children with a weakened immune system, for example due to HIV infection or due to medicines that suppress the immune system, may not get the full benefit from INFANRIX HEXA
- fainting can occur following, or even before, any needle injection, therefore tell the doctor or nurse if your child fainted with a previous injection
- high incidence of fever (> 39,5 °C) was reported in infants receiving INFANRIX HEXA and pneumococcal conjugate vaccine compared to infants receiving INFANRIX HEXA alone

- increased reporting rates of fits (with or without fever) and collapse or shock-like state were observed with concomitant administration of INFANRIX HEXA and pneumococcal conjugate vaccines.

Important information about some of the ingredients of INFANRIX HEXA:

Patients who are intolerant to lactose should note that INFANRIX HEXA contains a small amount of lactose. If you have been told by your doctor that your child has intolerance to some sugars, contact your doctor before your child is given INFANRIX HEXA.

INFANRIX HEXA contains traces of neomycin and polymyxin. Tell your doctor if your child has had an allergic reaction to these antibiotics.

Using other medicines with INFANRIX HEXA:

Always tell your healthcare professional if you are taking any other medicines. (This includes complementary or traditional medicines.)

HOW TO RECEIVE INFANRIX HEXA:

- The doctor or nurse will give the recommended dose of INFANRIX HEXA to your child.
- Usually, your child will receive a total of two or three injections with an interval of at least one month between each one. Each injection is given on a separate visit.
- INFANRIX HEXA is given as an injection of 0,5 ml into a muscle.
- You will be informed when your child should come back for the next injection.
- If additional injections (or “boosters”) are necessary, the doctor or nurse will tell you.

If your child misses a dose of INFANRIX HEXA:

If your child misses a scheduled injection, it is important that you make another appointment.

Make sure your child finishes the complete vaccination course. If not, your child may not be fully protected against the diseases.

POSSIBLE SIDE EFFECTS:

INFANRIX HEXA can cause side effects.

Not all side effects reported for INFANRIX HEXA are included in this leaflet. Should your child's general health worsen, ir if your child experiences any untoward effects while using INFANRIX HEXA, please consult your doctor, pharmacist or other healthcare professional for advice.

Allergic reactions:

Severe allergic reactions may occur. These can be recognised by:

- itchy rash of the hands and feet
- swelling of the eyes and face
- difficulty in breathing or swallowing
- sudden drop in blood pressure and loss of consciousness.

These reactions will usually occur before leaving the doctor's surgery. However, if your child gets any of these symptoms you should contact a doctor urgently.

➔ These are all very serious side effects. If your child has them, he/she may have had a serious allergic reaction to INFANRIX HEXA. Your child may need urgent medical attention or hospitalisation.

See your doctor immediately or go to the casualty deprtment at your nearest hospital, if your child has any of the following serious side effects:

- collapse

- times when they lose consciousness or have a lack of awareness
- fits - this may be when they have a fever.

These side effects usually happen within 2 to 3 days after vaccination with other vaccines against whooping cough.

➔ These are all serious side effects. Your child may need urgent medical attention.

Other side effects include:

Frequent side effects include:

- loss of appetite
- unusual crying, feeling irritable or restless
- pain, redness and swelling where the injection was given
- fever of 38 °C or higher
- feeling tired
- feeling nervous
- being sick (vomiting)
- diarrhoea
- fever higher than 39 °C
- swelling larger than 5 cm where the injection was given
- hard lump where the injection was given
- itching.

Less frequent side effects include:

- upper respiratory tract infection
- feeling sleepy
- cough

- large swelling of the vaccinated limb.

Other side effects include:

- bronchitis
- rash
- swollen glands in the neck, armpit or groin (lymphadenopathy)
- bleeding or bruising more easily than normal (thrombocytopenia)
- temporarily stopping breathing (apnoea)
- in babies born very prematurely (at or before 28 weeks of gestation) longer gaps than normal between breaths may occur for 2-3 days after vaccination
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioneurotic oedema)
- swelling of whole injected limb
- blister where the injection was given
- hives (urticaria)
- skin rash (dermatitis).

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

STORAGE AND DISPOSING OF INFANRIX HEXA:

Store in a refrigerator (+2 °C to +8 °C).

Store in the original package in order to protect from light.

Do not freeze. Freezing destroys the vaccine.

Store all medicines out of reach of children.

Do not use INFANRIX HEXA after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF INFANRIX HEXA:

The diphtheria, tetanus, acellular pertussis, hepatitis B, inactivated poliomyelitis (DTPa-HBV-IPV) component is presented in a glass syringe.

The Hib component is presented in a glass vial.

Both components must be mixed together before your child receives the vaccine.

INFANRIX HEXA is available in packs of 1, 10, 20 and 50 (with or without needles).

IDENTIFICATION OF INFANRIX HEXA:

The diphtheria, tetanus, acellular pertussis, hepatitis B, inactivated poliomyelitis (DTPa-HBV-IPV) component is a turbid white suspension. Upon storage, a white deposit and clear supernatant can be observed.

The Hib component is a white powder.

REGISTRATION NUMBER:

36/30.1/0347

NAME AND ADDRESS OF REGISTRATION HOLDER:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

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