PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

HEXAXIM suspension for injection in pre-filled syringe

HEXAXIM suspension for injection in single dose vial

Diphtheria, tetanus, pertussis (acellular component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type B conjugate vaccine (adsorbed).

Contains sugar (11 mg sucrose per 0,5 mL vaccine).

Read all of this leaflet carefully before your child is vaccinated with HEXAXIM.

- Keep this leaflet. You may need to read it again.
- Ask your doctor, pharmacist, nurse or other health care provider if you need more information or advice.

What is in this leaflet:

1. What HEXAXIM is and what it is used for
2. What you need to know before HEXAXIM is given to your child
3. How HEXAXIM will be administered
4. Possible side effects
5. How to store HEXAXIM
6. Contents of the pack and other information

1. What HEXAXIM is and what it is used for

HEXAXIM (DTaP-IPV-HB-Hib) is a vaccine. Vaccines are used to protect against infectious diseases.

HEXAXIM helps to protect against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and serious diseases caused by *Haemophilus influenzae* type b. HEXAXIM is given to children from six weeks of age.

The vaccine works by causing the body to produce its own protection (antibodies) against the bacteria and viruses that cause these different infections:

- Diphtheria is an infectious disease that usually first affects the throat. In the throat, the infection causes pain and swelling which can lead to suffocation. The bacteria that cause the disease also make a toxin (poison) that can damage the heart, kidneys and nerves.
- Tetanus (often called lock jaw) is usually caused by the tetanus bacteria entering a deep wound. The bacteria make a toxin (poison) that causes spasms of the muscles, leading to inability to breathe and the possibility of suffocation.
- Pertussis (often called whooping cough) is a bacterial infection of the airways that can occur at any age but mostly affects infants and young children. Increasingly severe coughing spells that can last for several weeks are a characteristic of the disease. Coughing spells may be followed by a whooping noise.
- 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 (spit) of infected people.
- Poliomyelitis (often just called polio) is caused by viruses that affect the nerves. It can lead to paralysis or muscle weakness most commonly of the legs. Paralysis of the muscles that control breathing and swallowing can be fatal.
- *Haemophilus influenzae* type b infections (often just called Hib) are serious bacterial infections and can cause meningitis (inflammation of the outer covering of the brain), infections of the blood, lungs, inflammation of the tissue under the skin, inflammation of the joints and bones and inflammation of part of the back of the throat, causing difficulty in swallowing and breathing.

Important information about the protection provided:

- HEXAXIM will only help to prevent against these diseases if they are caused by the bacteria or viruses targeted by the vaccine. Your child could get diseases with similar symptoms if they are caused by other bacteria or viruses.
- HEXAXIM does not contain any live bacteria or viruses and it cannot cause any of the infectious diseases against which it protects.
- HEXAXIM does not protect against infections caused by other types of *Haemophilus influenzae* nor against meningitis due to other microorganisms.
- HEXAXIM will not protect against hepatitis infection caused by other agents such as hepatitis A, hepatitis C and hepatitis E or by other liver pathogens.
- Because of the long incubation period of hepatitis B, it is possible for unrecognised hepatitis B infection to be present at the time of immunisation. The vaccine may not prevent hepatitis B infection in such cases.
- Remember that no vaccine can provide complete, lifelong protection in all people who are vaccinated.

2. What you need to know before HEXAXIM is given to your child

To make sure that HEXAXIM is suitable for your child, it is important to tell your doctor or nurse if any of the points below apply to your child. If there is anything you do not understand, ask your doctor or nurse to explain.

Do not use HEXAXIM if your child:

- Has had an allergic (hypersensitive) reaction:
  - to any diphtheria, tetanus, pertussis (any vaccine which protects against whooping cough), hepatitis B, poliomyelitis or Hib vaccines,
  - to any of the other ingredients of HEXAXIM listed in section 6,
  - to glutaraldehyde, formaldehyde, neomycin, streptomycin or polymyxin B, as these substances are used during the manufacturing process,

- after previous administration of HEXAXIM or any other diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B or Hib vaccines.

- Has a moderate or high temperature or an acute illness (e.g. fever, sore throat, cough, cold or flu). Vaccination with HEXAXIM may need to be delayed until your child is better.
- Suffered from encephalopathy (cerebral lesions) within 7 days of a previous dose of a pertussis vaccine (acellular or whole pertussis).
- Has a progressive condition or severe illness affecting the brain (progressive neurological disorder, progressive encephalopathy (with unknown cause)) and nervous system, or uncontrolled epilepsy.

Warnings and precautions:

Tell your doctor or nurse before vaccination if your child:

- Follows a treatment that suppresses her/his immune defences or if your child presents with immunodeficiency: in these cases, the immune response to the vaccine may be decreased. It is then recommended to wait until the end of the treatment or disease before vaccinating. Nevertheless, vaccination of subjects with chronic immunodeficiency such as HIV infection is recommended even if the antibody response may be limited.
- Suffers from chronic renal failure (kidney disease).
- Presented with Guillain-Barré syndrome (abnormal sensitivity, paralysis) or brachial neuritis (paralysis, diffuse pain in the arm and shoulder) following receipt of a prior vaccine containing tetanus toxoid (vaccine against tetanus). The decision to give any further vaccine containing tetanus toxoid should be evaluated by your doctor.
- Suffers from multiple sclerosis (including visual disturbances, tingling, facial paralysis, numbness or weakness of muscles, trouble with coordination and balance). Your doctor will assess the potential benefit offered by vaccination.
- Has any problems with the blood that cause easy bruising or bleeding for a long time after minor cuts. Your doctor will advise you whether your child should have HEXAXIM.

- If any of the following events are known to have occurred in temporal relation to receipt of vaccine, the decision to give further doses of pertussis-containing vaccine should be carefully considered:
    - Fever of 40 °C or above within 48 hours of vaccination not due to another identifiable cause.
    - Collapse or shock-like state with hypotonic-hyporesponsive episode (drop in energy) within 48 hours of vaccination.
    - Persistent, inconsolable crying lasting 3 hours or more, occurring within 48 hours of vaccination.
    - Convulsions with or without fever, occurring within 3 days of vaccination.

Fainting can occur following, or even before, any needle injection. Therefore, tell your doctor or nurse your child fainted with a previous injection.

Other medicines and HEXAXIM:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

HEXAXIM can be given at the same time as other vaccines, such as pneumococcal polysaccharide conjugated vaccine, measles-mumps-rubella vaccines and/or varicella-containing vaccines or rotavirus vaccines.

Using HEXAXIM with a meningococcal conjugate vaccine have shown no clinically relevant interference with the immune response to each of the HEXAXIM antigens.

Your health care provider will give the injections at different sites and will use separate syringes and needles for each injection.

HEXAXIM contains phenylalanine, potassium and sodium:

HEXAXIM contains 85 micrograms phenylalanine in each 0,5 mL dose. Phenylalanine may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.
HEXAXIM contains less than 1 mmol potassium (39 mg) and less than 1 mmol sodium (23 mg) per dose, that is to say essentially “potassium-free” and “sodium-free”.

3. How HEXAXIM will be administered

Your health care provider (e.g. doctor/nurse) will administer HEXAXIM to your child.
The vaccination should be given by medical or health care providers who are trained in the use of vaccines and who are equipped to deal with any uncommon severe allergic reaction to the injection (see section 4).
Your doctor will inject HEXAXIM into a muscle in the upper part of your child’s leg or upper arm.

Dosage

First course of vaccination (primary vaccination):

Your child will receive three injections of half a millilitre given at an interval of one to two months (at least four weeks apart) or two injections of half a millilitre given at an interval of at least eight weeks apart, according to the local vaccination schedule.

Additional injections (booster):

After vaccination with 2 or 3 doses, when indicated by the local vaccination schedule, your child should receive a booster dose, at least 6 months after the last dose of the primary vaccination. Your doctor will tell you when this dose should be given.

If your child receives more HEXAXIM than he/she should:

Since a health care provider will administer HEXAXIM, he/she will control the dosage. However, in the event of overdosage, your doctor will manage the symptoms of the overdosage.

If your child misses a dose of HEXAXIM:

If your child misses a scheduled injection, it is important that you discuss it with your health care provider, who will decide when to give the missed dose.

It is important to follow the instructions from your health care provider, so that your child completes the course of injections. If not, your child may not be fully protected against the diseases.

If you have any further questions on the use of HEXAXIM, ask your health care provider.

4. Possible side effects

HEXAXIM can have side effects.

Not all side effects reported for HEXAXIM are included in this leaflet. Should your child's general health worsen or if your child experiences any untoward effects after being given HEXAXIM, please consult your health care provider for advice.

If any of the following happens after leaving the place where your child received his/her injection, you must tell a doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If your child has them, he/she have had a serious reaction to HEXAXIM.

When these signs or symptoms occur, they usually develop quickly after the injection is given and while your child is still at the clinic or doctor's surgery.

Tell a doctor immediately or go to the casualty department at your nearest hospital if you notice the following:

- Convulsions (abnormal, involuntary contraction of the muscles) with or without fever.
- Episodes when your child goes into a shock-like state or is pale, floppy and unresponsive for a period of time (hypotonic reactions or hypotonic-hyporesponsive episodes (HHE)).

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

Tell your doctor if you notice your child experiences any of the following:

Frequent side effects:

- Loss of appetite (anorexia).
- Crying.
- Somnolence (problems sleeping).
- Vomiting.
- Injection site pain, injection site redness (erythema), injection site swelling, injection site hardness (induration).
- Irritability.
- Fever (temperature 38 °C or higher).
- Abnormal crying (prolonged crying).
- Diarrhoea.

Less frequent side effects:

- Injection site nodule.
- Fever (temperature 39,6 °C or higher).
- Large reactions at the injection site (larger than 5 cm), including extensive limb swelling from the injection site beyond one or both joints. These reactions start within 24 – 72 hours after vaccination, may be associated with redness, warmth, tenderness or pain at the injection site, and get better within 3 – 5 days without the need for treatment.

Potential side effects

Other side effects not listed above that have been reported with other vaccines containing the same active substances as HEXAXIM:

- Guillain-Barré syndrome (abnormal sensitivity, paralysis) and brachial neuritis (paralysis, diffuse pain in the arm and shoulder) have been reported after administration of a tetanus toxoid-containing vaccine.
- Swelling of one or both lower limbs. This may occur along with bluish discolouration of the skin (cyanosis), redness, small areas of bleeding under the skin (transient purpura) and severe crying. If this reaction occurs, it does so mainly after first (primary) injections and is seen within the first few hours following vaccination. All symptoms will disappear completely within 24 hours without the need for treatment.
- Tingling, numbness or weakness of the arms and/or legs (polyradiculoneuritis), facial paralysis, visual disturbances, sudden dimming or loss of vision (optic neuritis), trouble with coordination and balance (central nervous system demyelination, multiple sclerosis) have been reported after administration of a hepatitis B antigen-containing vaccine.
- 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.
- Inflammation of the brain (encephalopathy/encephalitis).

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

Reporting of side effects:

If your child gets any side effects, talk to a doctor, pharmacist or nurse.

You can also report any side effects to:

- The Pharmacovigilance Unit at Sanofi: za.drugsafety@sanofi.com (email) or 011 256 3700 (tel), or
- SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s

publications: https://www.sahpra.org.za/Publications/Index/8

By reporting side effects, you can help provide more information on the safety of HEXAXIM

5. How to store HEXAXIM

Store in a refrigerator (+2 °C to +8 °C). Vaccine components are stable at temperatures up to 25 °C for 72 hours, whereafter HEXAXIM should be used or discarded.

Do not freeze.

Shake before use.

Protect from light.

Keep in original packaging until required for use.

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What HEXAXIM contains:

The active substance in each 0,5 mL adjuvanted dose contains*:

Diphtheria toxoid	≥ 20 IU[1] (30 Lf)
Tetanus toxoid	≥ 40 IU[2,3] (10 Lf)
Bordetella pertussis antigens	
Pertussis toxoid	25 µg
Filamentous haemagglutinin	25 µg
Poliovirus (inactivated)[4]	
Type 1 (Mahoney)	40 D antigen units[5]
Type 2 (MEF-1)	8 D antigen units[5]

Type 3 (Saukett)	32 D antigen units[5]
Hepatitis B surface antigen	10 µg[6]
Haemophilus influenzae type b polysaccharide	
(polyribosylribitol phosphate)	12 µg
conjugated to tetanus protein	22 – 36 µg

[*] Adsorbed on Al(OH)[3]

[1] As lower confidence limit (p = 0,95) and not less than 30 IU as mean value

[2] As lower confidence limit (p = 0,95)

[3] Or equivalent activity determined by an immunogenicity evaluation

[4] Produced on Vero cells

[5] Or equivalent antigenic quantity determined by a suitable immunochemical method

[6] Surface antigen of hepatitis B virus produced from recombinant strain of the yeast Hansenula polymorpha

The other ingredients are:
Disodium hydrogen phosphate, potassium dihydrogen phosphate, trometamol, sucrose, essential amino acids including L-phenylalanine, sodium hydroxide and/or acetic acid and/or hydrochloric acid (for pH adjustment), and water for injections

The vaccine may contain traces of glutaraldehyde, formaldehyde, neomycin, streptomycin and polymyxin B.

What HEXAXIM looks like and contents of the pack:

After shaking, the normal appearance of HEXAXIM is a whitish, cloudy suspension.

Containers and devices	Container element	Nature

Syringe (without attached needle or with one or two separate needles)	Syringe	Colourless, transparent type I glass
	Plunger stopper	Grey bromobutyl
	Tip-Cap	Black chlorobromobutyl
Needle	25G - 5/8 and 23G-1	Stainless steel
Vial (no needles supplied with vials)	Vial	Colourless, transparent type I glass
	Stopper with flip-off cap	Grey bromobutyl Light blue aluminium

List of presentations:

Container	**Volume per container**	**Number of doses per container**	**Number of containers per box**
Pre-filled syringe	0,5 ml	1	1 or 10
Vial	0,5 ml	1	1 or 10

Not all pack sizes may be marketed.

Holder of certificate of registration and manufacturer:

sanofi-aventis south africa (pty) ltd

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