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For the use of a Registered Medical Practitioner Only

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

HEXAXIM®

suspension for injection in pre-filled syringe

Read all of this leaflet carefully before your child is vaccinated because it contains important information for him/her.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If your child gets any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Hexaxim is and what it is used for

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

Hexaxim is indicated for primary and booster vaccination of infants and toddlers from six weeks of age against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases caused by *Haemophilus influenzae* type b (Hib).

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 highly infectious illness that affects the airways. It causes severe coughing that may lead to problems with breathing. The coughing often has a "whooping" sound. The cough may last for one to two months or longer. Whooping cough can also cause ear infections, chest infections (bronchitis) which may last a long time, lung infections (pneumonia), fits, brain damage and even death.
- Hepatitis B is caused by the hepatitis B virus. It causes the liver to become swollen (inflamed). In some people, the virus can stay in the body for a long time, and can eventually lead to serious liver problems, including liver cancer.
- 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), which can lead to brain damage, deafness, epilepsy, or partial blindness. Infection can also cause inflammation and swelling of the throat, leading to difficulties in swallowing and breathing, and infection can affect other parts of the body such as the blood, lungs, skin, bones, and joints.

Important information about the protection provided

- Hexaxim will only help to prevent 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.
- The vaccine does not contain any live bacteria or viruses and it cannot cause any of the infectious diseases against which it protects.
- This vaccine does not protect against infections caused by other types of *Haemophilus influenzae* nor against meningitis due to other micro-organisms.
- Hexaxim will not protect against hepatitis infection caused by other agents such as hepatitis A, hepatitis C and hepatitis E.
- Because symptoms of hepatitis B take a long time to develop, it is possible for unrecognised hepatitis B infection to be present at the time of vaccination. The vaccine may not prevent hepatitis B infection in such cases.
- As with any vaccine, Hexaxim may not protect 100% of children who receive the vaccine.

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 talk to your doctor if any of the points below apply to your child. If there is anything you do not understand, ask your doctor to explain.

Do not use Hexaxim if your child:

- has had respiratory disorder or swelling of the face (anaphylactic reaction) after administration of Hexaxim.
- has had an allergic reaction
  - to the active substances,
  - to any of the excipients 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 containing vaccines.
- suffered from a severe reaction affecting the brain (encephalopathy) within 7 days of a prior dose of a pertussis vaccine (acellular or whole cell pertussis).
- has an uncontrolled condition or severe illness affecting the brain and nervous system (uncontrolled neurologic disorder) or uncontrolled epilepsy.

Warnings and precautions

Talk to your doctor before vaccination if your child:

- 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.
- has had any of the following events after receiving a pertussis vaccine, as the decision to give further doses of pertussis containing vaccine will need to be carefully considered:
  - fever of 40°C or above within 48 hours 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.
  - fits (convulsions) with or without fever, occurring within 3 days of vaccination.
- previously had Guillain-Barré syndrome (temporary inflammation of nerves causing pain, paralysis and sensitivity disorders) or brachial neuritis (severe pain and decreased mobility of arm and shoulder) after being given a vaccine containing tetanus toxoid (an inactivated form of tetanus toxin). In this case, the decision to give any further vaccine containing tetanus toxoid should be evaluated by your doctor.
- is having a treatment that suppresses her/his immune system (the body's natural defenses) or has any disease that causes the weakness of the immune system. In these cases the immune response to the vaccine may be decreased. It is normally recommended to wait until the end of the treatment or disease before vaccinating. However children with long standing problems with their immune system such as HIV infection (AIDS) may still be given Hexaxim but the protection may not be as good as in children whose immune system is healthy.
- suffers from an acute or chronic illness including chronic renal insufficiency or failure (inability of the kidneys to work properly).
- suffers from any undiagnosed illness of the brain or epilepsy which is not controlled. 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.

Other medicines or vaccines and Hexaxim

Tell your doctor if your child is taking, has recently taken or might take any other medicines or vaccines.

Hexaxim can be given at the same time as other vaccines such as pneumococcal vaccines, measles-mumps-rubella vaccines, rotavirus vaccines, meningococcal group A, C, W-135 and Y conjugate vaccine.

When given at the same time with other vaccines, Hexaxim will be given at different injection sites.

3. How to use Hexaxim

Hexaxim will be given to your child by a doctor trained in the use of vaccines and who are equipped to deal with any uncommon severe allergic reaction to the injection (see section 4 Possible side effects).

Hexaxim is given as an injection into a muscle (intramuscular route IM) in the upper part of your child's leg or upper arm. The vaccine will never be given into a blood vessel or into or under the skin.

The recommended dose is as follows:

<u>First course of vaccination (primary vaccination)</u>

Your child will receive three injections given at an interval of one to two months (at least four weeks apart). This vaccine should be used according to the local vaccination programme.

<u>Additional injections (booster)</u>

After the first course of injections, your child will receive a booster dose, in accordance with local recommendations, at least 6 months after the last dose of the first course. Your doctor will tell you when this dose should be given.

If you forget one dose of Hexaxim

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

It is important to follow the instructions from the doctor 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 this vaccine, ask your doctor.

4. Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them.

Serious allergic reactions (anaphylactic reaction)

If any of these symptoms occur after leaving the place where your child received his/her injection, you must consult a doctor IMMEDIATELY:

- difficulty in breathing
- blueness of the tongue or lips
- a rash
- swelling of the face or throat
- sudden and serious malaise with drop in blood pressure causing dizziness and loss of consciousness, accelerated heart rate associated with respiratory disorders

When these signs or symptoms (signs or symptoms of anaphylactic reaction) occur they usually develop quickly after the injection is given and while the child is still in the clinic or doctor's surgery.

Serious allergic reactions are a rare possibility (may affect up to 1 in 1,000 people) after receiving this vaccine.

Other side effects

If your child experiences any of the following side effects, please tell your doctor.

- Very common side effects (may affect more than 1 in 10 people) are:
  - loss of appetite (anorexia)
  - crying
  - sleepiness (somnolence)
  - vomiting
  - pain, redness or swelling at the injection site
  - irritability
  - fever (temperature 38°C or higher)
- Common side effects (may affect up to 1 in 10 people) are:
  - abnormal crying (prolonged crying)
  - diarrhoea
  - injection site hardness (induration)
- Uncommon side effects (may affect up to 1 in 100 people) are:
  - allergic reaction
  - lump (nodule) at the injection site
  - high fever (temperature 39.6°C or higher)
- Rare side effects (may affect up to 1 in 1,000 people) are:
  - rash
  - 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.
  - fits (convulsions) with or without fever.
- Very rare side effects (may affect up to 1 in 10,000 people) are:
  - 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).

Potential side effects

Other side effects not listed above have been reported occasionally with other diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B or Hib containing vaccines and not directly with Hexaxim:

- Temporary inflammation of nerves causing pain, paralysis and sensitivity disorders (Guillain-Barré syndrome) and severe pain and decreased mobility of arm and shoulder (brachial neuritis) have been reported after administration of a tetanus containing vaccine.
- Inflammation of several nerves causing sensory disorders or weakness of limbs (polyradiculoneuritis), facial paralysis, visual disturbances, sudden dimming or loss of vision (optic neuritis), inflammatory disease of brain and spinal cord (central nervous system, demyelination, multiple sclerosis) have been reported after administration of a hepatitis B antigen containing vaccine.
- Swelling or inflammation of the brain (encephalopathy/encephalitis).
- 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 one or both feet and lower limbs which may occur along with bluish discoloration of the skin (cyanosis), redness, small areas of bleeding under the skin (transient purpura) and severe crying following vaccination with Haemophilus influenzae type b containing vaccines. If this reaction occurs, it is mainly after first injections and within the first few hours following vaccination. All symptoms should disappear completely within 24 hours without need for treatment.

Reporting of side effects

If your child gets any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hexaxim

Keep this vaccine out of the sight and reach of children.

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

Store in a refrigerator (2°C - 8°C). Do not freeze.

Shelf life of the product is 36 months.

Keep the vaccine in the outer carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your doctor how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Hexaxim contains

Components[1]	Quantity per dose (0.5 mL)
Active Ingredients:	
Diphtheria toxoid	30 Lf (≥ 20 IU[2])
Tetanus toxoid	10 Lf (≥ 40 IU[2])
Bordetella pertussis antigens Pertussis toxoid Filamentous haemagglutinin	 25 µg 25 µg
Poliovirus (inactivated)[3] Type 1 (Mahoney) Type 2 (MEF-1) Type 3 (Saukett)	 40 DU[4] 8 DU[4] 32 DU[4]
Hepatitis B surface antigen5	10 µg
Haemophilus influenzae type b polysaccharide (polyribosylribitol phosphate) conjugated to Tetanus protein (PRP-T)	12 µg 22-36 µg
Inactive Ingredients:	
Aluminium hydroxide, hydrated	0.6 mg Al^{3+}
Buffers Disodium hydrogen phosphate Potassium dihydrogen phosphate Essential amino acids Trometamol Saccharose	 1.528 mg 1.552 mg 1.115 mg 0.1515 mg 10.625 mg
Water for injections	Up to 0.5 mL

[1] NaOH, acetic acid or HCl can be used for pH adjustment. These components are only present in trace amount.
[2] As lower confidence limit (p = 0.95)
[3] Produced on Vero cells
[4] Or equivalent antigenic quantity determined by a suitable immunochemical method
[5] Produced in yeast Hansenula polymorpha cells by recombinant DNA technology
[6] Essential amino acids including L-phenylalanine

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

What Hexaxim looks like and contents of the pack

Hexaxim is provided as a suspension for injection in pre-filled syringe (0.5 ml) in prefilled syringe with 2 separate needles or 0.5 ml in vial) –box of 1 or 10

All pack sizes may not marketed.

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

Hexaxim® is registered trademark of Sanofi Pasteur France.

This leaflet was last revised in Dec 2021

The following information is intended for healthcare professionals only:

- For syringes without attached needle, the needle must be fitted firmly to the syringe, rotating it by a one-quarter turn.
- Shake the pre-filled syringe so that the contents become homogeneous.
- Hexaxim should not be mixed with other medicinal products.
- Hexaxim must be administered intramuscularly. The recommended injection site is preferably the antero-lateral area of the upper thigh and the deltoid muscle in older children (possibly from 15 months of age).

The intradermal or intravenous routes must not be used. Do not administer by intravascular injection: ensure that the needle does not penetrate a blood vessel.

Manufactured by:

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