HEXAXIM®

DTPa-hepB-IPV-Hib

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

Consumer Medicine Information

What is in this leaflet

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for your child. Do not pass it on to others.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

What Hexaxim is and what it is used for

Hexaxim (DTPa-hepB-IPV-Hib) is a vaccine 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 can be 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 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 (inflammed). 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.

Remember that no vaccine can provide complete, lifelong protection in all people who are vaccinated.

Before your child is given Hexaxim

When your child must not be given Hexaxim

Do not give 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 any of the ingredients listed in FURTHER INFORMATION
  - 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.

Before your child is given Hexaxim

Tell your doctor 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-Barre 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 defences) 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.
- is born prematurely. Lower responses to the vaccine may be observed in relation with immaturity of the immune system. However, according to national recommendations, vaccination should not be delayed. In addition, longer gaps than normal between breaths may occur for 2 -3 days after vaccination.
- 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.
- has fainted when having a previous injection. Fainting can occur before or following needle injection.

Taking other medicines

Please tell your doctor if your child is taking or has recently taken any other medicines, including medicines obtained without prescription.

Having other vaccines

Your doctor will advise you if Hexaxim is to be given with another vaccine.

How Hexaxim is given

Hexaxim is administered to your child by your doctor or nurse.

Hexaxim is injected into the muscle in the upper part of your child's leg or upper arm.

First course of vaccination (primary vaccination)

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

Additional injections (booster)

After the first course of injections, your child may require a booster dose, in accordance with local recommendations. Your doctor will advise you if your child requires a booster dose.

If you forget one dose of Hexaxim

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

It is important to follow the instructions from the doctor or nurse 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, pharmacist or nurse.

Possible side effects

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

Serious allergic reactions

Serious allergic reactions are a very rare possibility (may affect up to 1 in 10,000 people) after receiving any vaccine.

Signs and symptoms of serious allergic reactions usually develop quickly after the injection is given and while the child is still in the clinic or doctor's surgery

If any of these symptoms occur after leaving the place where your child has received Hexaxim, you must consult a doctor IMMEDIATELY:

- difficulty in breathing
- blueness of the tongue or lips
- a rash
- swelling of the face or throat
- low blood pressure causing dizziness or collapse.

Other side effects:

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

Very common (may affect more than 1 in 10 people):

- pain, redness or swelling at the injection site
- loss of appetite
- crying
- sleepiness
- vomiting
- irritability
- fever (temperature 38°C or higher)

Common (may affect up to 1 in 10 people):

- abnormal crying (prolonged crying)
- diarrhoea
- injection site hardness

Uncommon (may affect up to 1 in 100 people):

- allergic reaction
- lump at the injection site
- high fever (temperature 39.6°C or higher)

Rare (may affect up to 1 in 1000 people):

- 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.

Very rare (may affect up to 1 in 10,000 people):

- 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).
- serious allergic reaction (anaphylactic reaction)
- fits (convulsions) with or without fever

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 discolouration of the skin, redness, small areas of bleeding under the skin 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 the need for treatment.

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

Storing Hexaxim

Hexaxim is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store Hexaxim

- Keep out of reach and sight of children.
- Keep Hexaxim in the original pack until it is time for it to be given.
- **Keep it in the refrigerator, store at 2°C to 8°C. Do not freeze Hexaxim.**

Do not use Hexaxim after the expiry date which is stated on the carton after EXP.

Do not use Hexaxim if the packaging is torn or shows signs of tampering.

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.

Further Information

What Hexaxim contains

Each 0.5 ml dose of Hexaxim contains:

- At least 20 IU of diphtheria toxoid
- At least 40 IU of tetanus toxoid
- 25 micrograms of pertussis toxoid and 25 micrograms of pertussis filamentous haemagglutinin
- 10 micrograms of hepatitis B surface antigen
- 40 D antigen Units of poliovirus Type 1, 8 D antigen Units of poliovirus Type 2, 32 D antigen Units of poliovirus Type 3
- 12 micrograms of Haemophilus type B polysaccharide conjugated to 22- 36 micrograms of tetanus protein

The other ingredients include dibasic sodium phosphate-, mono basic potassium phosphate-, trometamol, sucrose, essential amino acids (cystine, tyrosine, arginine hydrochloride, histidine, isoleucine, leucine, lysine hydrochloride, methionine, phenylalanine, threonine, tryptophan and valine) and water for injections.

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

The manufacture of this product includes exposure to bovine 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.

What Hexaxim looks like and contents of the pack

Hexaxim is provided as a fully liquid suspension for injection in pre-filled syringe (0.5 mL).

Hexaxim is available in a pack containing 1 pre-filled syringe with 1 or 2 needles.

Hexaxim is available in a pack containing 10 pre-filled syringes with 10 or 20 needles.

Not all pack sizes may be marketed.

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

Name and Address of Sponsor

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