

Package leaflet: Information for the user**Vaxelis®****suspension for injection in pre-filled syringe**

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

Read all of this leaflet carefully before your child is vaccinated with this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for your child only. Do not pass it on to others.
- If your child get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What is Vaxelis and what it is used for

Vaxelis is a vaccine, which helps to protect your child against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and serious diseases caused by *Haemophilus influenzae* type b. Vaxelis is given to children from the age of six weeks.

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

- Diphtheria: a bacterial infection that usually first affects the throat, causing pain and swelling which can lead to suffocation. The bacteria also make a toxin (poison) that can damage the heart, kidneys and nerves.
- Tetanus (often called lock jaw): 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): 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: 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): 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 infections): serious bacterial infections causing 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

- Vaxelis will only help to prevent these diseases caused by the bacteria and viruses targeted by the vaccine. Vaxelis does not protect your child against diseases caused by other bacteria and viruses that may cause similar symptoms.
- The vaccine does not contain any live bacteria or viruses and it cannot cause any of the infectious diseases against which it protects.
- As with any vaccine, Vaxelis may not protect 100% of children who receive the vaccine.

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

To make sure that Vaxelis is suitable for your child, it is important to talk to 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, pharmacist or nurse to explain.

Do not use Vaxelis if your child:

- has had shortness of breath or swelling of the face (anaphylactic reaction) after administration of a previous dose of Vaxelis.
- is allergic (hypersensitive)
 - to Vaxelis vaccine or any diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B or Hib containing vaccines,
 - to any ingredients listed in section 6,
 - to glutaraldehyde, formaldehyde, neomycin, streptomycin, polymyxin B (antibiotics) and bovine serum albumin, as these substances are used during the manufacturing process.
- has 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, pharmacist or nurse before vaccination if your child:

- has a moderate to severe acute disease, with or without fever (e.g. sore throat, cough, cold or flu). Vaccination with Vaxelis may need to be delayed until your child is better.
- has had any of the following events after receiving a vaccine against pertussis (whooping cough), as the decision to give further doses of pertussis containing vaccine will need to be carefully considered:
 - had a fever of 40.5°C or above within 48 hours not due to another identifiable cause.
 - became floppy, unresponsive or unconscious after the previous vaccination, within 48 hours of vaccination.
 - cried continuously and could not be comforted for more than 3 hours within 48 hours of vaccination.
 - had a fit (convulsions) with or without fever, within 3 days of vaccination.
- previously had Guillain-Barré syndrome (temporary loss of feeling and movement) after being given a vaccine containing tetanus toxoid (an inactivated form of tetanus toxin). Your doctor will decide whether to give Vaxelis to your child.
- is receiving a treatment (such as steroids, chemotherapy or radiotherapy) or has a disease that suppresses or weakens the body's ability to fight infections. It is recommended to postpone vaccination until the end of such treatment or disease. However, children with long standing problems with their immune system such as HIV infection (AIDS) may still be given Vaxelis but the protection may not be as good as in children with a healthy immune system.

- suffers from any undiagnosed illness of the brain or epilepsy which is not controlled. Your doctor or nurse will assess the potential benefit offered by vaccination, once the condition is stabilised.
- suffers from fits during a fever, or there is family history of fits occurring during a fever.
- has any problems with bleeding for a long time after minor cuts, or bruises easily. Your doctor will advise you whether your child should receive Vaxelis.
- was born very prematurely (at or before 28 weeks of gestation). In these infants, longer gaps than normal between breaths may occur for 2 to 3 days after vaccination.

Other medicines or vaccines and Vaxelis

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

Vaxelis can be given at the same time as other vaccines such as pneumococcal vaccines, measles-mumps-rubella-varicella (MMRV) vaccines, rotavirus vaccines, or meningococcal B or C vaccines.

Your doctor or nurse will give these injections at different sites and will use different syringes and needles for each injection.

Driving and using machines

It is expected that Vaxelis will have no or negligible influence on the ability to drive and use machines.

Vaxelis contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How Vaxelis is given

Vaxelis will be given to your child by a doctor or nurse 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).

Your doctor or nurse will inject Vaxelis into your child's thigh (in infants from the age of 6 weeks) or arm (in children older than one year).

The recommended dose is as follows:

First course of vaccination (primary vaccination)

Your child will receive two or three injections given at least one month apart. Your doctor or nurse will tell you when your child should come back for their next injection as per the local vaccination program.

Additional injection (booster)

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 your child misses a dose of Vaxelis

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.

4. Possible side effects

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

Serious allergic reactions

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
- low blood pressure causing dizziness or collapse.

When these signs or symptoms 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 very rare (may affect up to 1 in 10,000 people) and can occur after receiving any vaccine.

Other side effects

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

- Very common side effects (may affect more than 1 in 10 people) are:
 - decreased appetite
 - irritability
 - crying
 - vomiting
 - sleepiness or drowsiness
 - fever (temperature 38°C or higher)
 - pain, redness, swelling at the injection site
- Common side effects (may affect up to 1 in 10 people) are:
 - diarrhoea
 - hard mass, lump (nodule) at the injection site
 - bruising at the injection site
- Uncommon side effects (may affect up to 1 in 100 people) are:
 - rash
 - warmth, rash at the injection site
 - increased appetite
 - stomach pain
 - excessive sweating
 - cough
 - nasal congestion and runny nose
 - paleness
 - sleep disorders including inability to get adequate sleep
 - restlessness
 - swollen glands in the neck, armpit or groin
 - feeling tired
 - floppiness
- Rare side effects (may affect up to 1 in 1,000 people) are:
 - allergic reaction, serious allergic reaction (anaphylactic reaction)
 - extensive swelling of the vaccinated limb
- Side effects with frequency not known (frequency cannot be estimated from the available data) are:
 - fits (convulsions) with or without fever
 - floppiness and unresponsive or unconscious and/or paleness or bluish skin

Reporting of side effects

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. You can also report side effects directly via the national reporting system (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Medicines and Healthcare products Regulatory Agency (MHRA):
Yellow Card Scheme at <https://www.mhra.gov.uk/yellowcard> or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Vaxelis

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

Store in a refrigerator (2°C - 8°C). Do not freeze. Keep the vaccine in the outer carton in order to protect from light.

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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist 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 Vaxelis contains

The active substances per dose (0.5 mL):

Diphtheria Toxoid ¹	not less than 20 IU ⁶
Tetanus Toxoid ¹	not less than 40 IU ⁶
<i>Bordetella pertussis</i> antigens ¹	
Pertussis Toxoid (PT)	20 micrograms
Filamentous Haemagglutinin (FHA)	20 micrograms
Pertactin (PRN)	3 micrograms
Fimbriae Types 2 and 3 (FIM)	5 micrograms
Hepatitis B surface antigen ^{2,3}	10 micrograms
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
<i>Haemophilus influenzae</i> type b polysaccharide (Polyribosylribitol Phosphate) Conjugated to meningococcal protein ²	3 micrograms 50 micrograms

¹ adsorbed on aluminium phosphate (0.17 mg Al³⁺)

² adsorbed on amorphous aluminium hydroxyphosphate sulfate (0.15 mg Al³⁺)

³ produced in yeast (*Saccharomyces cerevisiae*) by recombinant DNA technology

⁴ produced in Vero cells

⁵ or equivalent antigenic quantity determined by a suitable immunochemical method

⁶ or equivalent activity determined by an immunogenicity evaluation.

Aluminium phosphate and amorphous aluminium hydroxyphosphate sulphate are included in the vaccine as adjuvants. Adjuvants are included to improve the immune response of vaccines.

The other ingredients are:

Sodium phosphate, water for injections

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

What Vaxelis looks like and contents of the pack

The normal appearance of the vaccine is a uniform, cloudy, white to off-white suspension, which may settle down during storage.

Vaxelis is provided as a suspension for injection in pre-filled syringe.

Pack size of 1 or 10 pre-filled syringes, without attached needle, with 1 separate needle or with 2 separate needles.

Multipack of 5 packs of 10 pre-filled syringes with no needle.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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The following information is intended for healthcare professionals only:

The pre-filled syringe should be shaken gently in order to obtain a homogeneous, whitish, cloudy suspension.

The suspension should be visually inspected, prior to administration, for foreign particulate matter and/or variation of physical appearance. If either is observed, discard the pre-filled syringe.

The needle must be fitted firmly on to the pre-filled syringe, rotating it by a one-quarter turn.

Vaxelis is for intramuscular injection only.

The recommended injection sites are the anterolateral aspect of the thigh or the deltoid region of the upper arm if there is adequate muscle mass. The anterolateral aspect of the thigh is the preferred site for infants under one year of age.