



EMA/859285/2015  
EMA/H/C/003982

## EPAR summary for the public

---

### Vaxelis

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

This is a summary of the European public assessment report (EPAR) for Vaxelis. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Vaxelis.

For practical information about using Vaxelis, patients should read the package leaflet or contact their doctor or pharmacist.

### What is Vaxelis and what is it used for?

Vaxelis is a vaccine containing active substances derived from diphtheria, tetanus, pertussis and *Haemophilus influenzae* type-b bacteria, the hepatitis B virus, and inactivated polioviruses. It is used in babies and toddlers aged from six weeks to protect against the following infectious diseases:

- diphtheria (a highly contagious disease that affects the throat and skin, and can cause damage to the heart and other organs);
- tetanus (lockjaw, usually caused by infection of a wound);
- pertussis (whooping cough);
- hepatitis B (a viral liver infection);
- poliomyelitis (polio, a disease that affects the nerves and can lead to muscle weakness or paralysis);
- invasive diseases (such as pneumonia and meningitis) caused by *H. influenzae* type-b bacteria (Hib).



## How is Vaxelis used?

Vaxelis is available in pre-filled syringes as a suspension for injection. It can only be obtained with a prescription. Vaccination with Vaxelis should be carried out according to official recommendations.

The recommended initial vaccination schedule is either two or three doses, given at least one month apart to children aged over six weeks. A booster dose should be given at least six months after the last of these initial doses. Vaxelis or an appropriate combination of other vaccines can be used for the booster dose. Vaxelis is given by injection into a muscle, normally in the upper thigh or the shoulder.

For further information, see the summary of product characteristics (also part of the EPAR).

## How does Vaxelis work?

Vaxelis is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) to defend itself against diseases. Vaxelis contains small amounts of materials derived from the viruses and bacteria it protects against.

When a child is given the vaccine, the immune system recognises the materials from the bacteria and viruses as foreign and makes antibodies against them. The immune system will then be able to produce antibodies quickly when the person is naturally exposed to the bacteria or viruses. This helps to protect against the diseases that these bacteria and viruses cause.

The vaccine is 'adsorbed' on aluminium compounds. This means that some of the active substances are fixed onto minute particles of aluminium compounds. This improves the ability to produce antibodies.

## What benefits of Vaxelis have been shown in studies?

Vaxelis has been studied in two main studies involving more than 2,500 infants and toddlers over six weeks of age who were given either two or three doses of the vaccine during their first six months of life. They then received a booster dose shortly after their first birthday. The effects of Vaxelis were compared with those of another vaccine, *Infanrix hexa*, designed to protect against the same six diseases as Vaxelis. In these studies, children also received other vaccines according to local vaccination schedules to protect against other childhood diseases such as rotavirus gastroenteritis, measles, mumps, rubella and varicella. The main measure of effectiveness was the production of antibody levels known to be protective against diphtheria, tetanus, poliomyelitis, hepatitis B and *H. influenzae* type b infections and expected to protect against pertussis.

Both studies showed that Vaxelis produces satisfactory levels of antibodies to protect against all of these six diseases in between 90 and 100% of children who completed the course of vaccination with Vaxelis.

## What are the risks associated with Vaxelis?

The most common side effects with Vaxelis include pain, swelling and redness at the site of injection, irritability, crying, sleepiness, fever, reduced appetite and vomiting. For the full list of all side effects reported with Vaxelis, see the package leaflet.

Vaxelis must not be used in children who have ever had an allergic reaction to Vaxelis or a vaccine containing the same components, including substances used during the manufacture of the vaccine and which may be found at extremely low levels (such as the antibiotics neomycin or streptomycin). It must not be used in children who have ever had encephalopathy (a brain disease) of unknown cause within seven days of receiving a vaccine containing pertussis components. It must not be used in children who have an uncontrolled or severe illness affecting the brain or nervous system, such as

uncontrolled epilepsy (fits), unless the condition has stabilised with treatment and the benefit of vaccination clearly outweighs the risk. For the full list of restrictions, see the package leaflet.

### **Why is Vaxelis approved?**

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Vaxelis's benefits are greater than its risks and recommended that it be approved for use in the EU. The Committee considered that Vaxelis has been shown to produce satisfactory antibody levels against diphtheria, tetanus, pertussis, hepatitis B virus, polioviruses and Hib. These antibody levels have been previously shown to protect against these diseases. With regard to safety, the CHMP considered that overall its safety profile is similar to other vaccines.

### **What measures are being taken to ensure the safe and effective use of Vaxelis?**

A risk management plan has been developed to ensure that Vaxelis is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Vaxelis, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the [summary of the risk management plan](#).

### **Other information about Vaxelis**

The European Commission granted a marketing authorisation valid throughout the European Union for Vaxelis on 15 February 2016.

The full EPAR and risk management plan summary for Vaxelis can be found on the Agency's website: [ema.europa.eu/Find\\_medicine/Human\\_medicines/European\\_public\\_assessment\\_reports](http://ema.europa.eu/Find_medicine/Human_medicines/European_public_assessment_reports). For more information about treatment with Vaxelis, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 02-2016.