Vaxelis

Consumer Medicine Information (CMI) summary

The full CMI on the later pages has more details. If you are worried about having your child receive this vaccine, speak to your child's doctor or nurse.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why is my child receiving Vaxelis?

Vaxelis is a vaccine given to help protect your child against diphtheria, tetanus (lockjaw), pertussis (whooping cough), hepatitis B, polio and Hib (*Haemophilus influenzae* type b).

For more information, see Section 1. Why is my child receiving Vaxelis? in the full CMI.

2. What should I know before my child receives Vaxelis?

Do not use if your child has had shortness of breath or swelling of the face after a previous dose of Vaxelis, has ever had an allergic reaction to Vaxelis or any of the ingredients listed at the end of the CMI, has suffered from a severe reaction affecting the brain (encephalopathy) within 7 days of a prior dose of a pertussis vaccine or has an uncontrolled condition or severe illness affecting the brain and nervous system (uncontrolled neurologic disorder) or uncontrolled epilepsy.

Talk to your doctor if your child has or has had any other medical conditions or is taking any other medicines.

For more information, see Section 2. What should I know before my child receives Vaxelis? in the full CMI.

3. What if my child is taking other medicines?

Some medicines may interfere with Vaxelis and affect how it works.

A list of these medicines is in Section 3. What if my child is taking other medicines? in the full CMI.

4. How will my child receive Vaxelis?

Vaxelis is given by your child's doctor or nurse as an injection into the muscle.

More instructions can be found in Section 4. How will my child receive Vaxelis? in the full CMI.

5. What should I do after my child receives Vaxelis?

Things you should do	Tell your child's doctor or nurse immediately after your child receives the vaccine and if your child has • difficulty in breathing. • blueness of the tongue or lips. • swelling of the face or throat. • low blood pressure causing dizziness or collapse. • a rash associated with any of the above symptoms

For more information, see Section 5. What should I do after my child receives Vaxelis? in the full CMI.

6. Are there any side effects?

Very common side effects include decreased appetite, irritability, crying more than usual, vomiting, sleepiness or drowsiness, fever (temperature 38°C or higher), pain, redness, swelling at the injection site. Serious side effects can include signs of allergy such as: difficulty in breathing, blueness of the tongue or lips, swelling of the face or throat, low blood pressure causing dizziness or collapse, a rash associated with any of the other signs of allergy.

For more information, including what to do if your child has any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Vaxelis

Active ingredient(s): diphtheria, tetanus, pertussis, hepatitis B, poliovirus and Hib (*Haemophilus influenzae* type b)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Vaxelis. **You should also speak to your doctor or nurse if you would like further information or if you have any concerns or questions about using Vaxelis.**

Where to find information in this leaflet:

1. Why is my child receiving Vaxelis?
2. What should I know before my child receives Vaxelis?
3. What if my child is taking other medicines?
4. How will my child receive Vaxelis ?
5. What should I do after my child receives Vaxelis?
6. Are there any side effects?
7. Product details

1. Why is my child receiving Vaxelis?

Vaxelis is a vaccine, that helps to protect your child against diphtheria, tetanus (lockjaw), pertussis (whooping cough), hepatitis B, polio and Hib (*Haemophilus influenzae type b*). Vaxelis may be 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 should I know before my child receives Vaxelis?

Warnings

Do not allow your child to receive 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 to Vaxelis vaccine or any diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B or Hib containing vaccines, or any of the ingredients listed at the end of this leaflet.
- 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.

Always check the ingredients to make sure your child can be given this vaccine.

Check with your doctor 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:
  - fever of 40°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 normally 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 stabilized.
- 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 pregnancy). In these infants, longer gaps than normal between breaths may occur for 2 to 3 days after vaccination.

After vaccination, your child may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

3. What if my child is taking other medicines?

Tell your doctor or nurse if your child is taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

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.

Check with your doctor or nurse if you are not sure about what medicines, vitamins or supplements your child is taking and if these affect Vaxelis.

4. How will my child receive Vaxelis ?

How much 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 6. Are there any 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, if an additional injection (booster) is necessary, the doctor or nurse 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 or nurse.

5. What should I do after my child receives Vaxelis?

Call your doctor straight away if your child has:

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

Driving or using machines

It is expected that Vaxelis would have no or negligible influence on the ability to use bicycles and other such machines.

Looking after your child's vaccine:

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

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

Keep it where young children cannot reach it.

Getting rid of any unwanted vaccine

Medicines including vaccines should not be disposed of via wastewater or household waste. If your child no longer needs this vaccine or it is out of date, take it to any pharmacy for safe disposal. These measures will help to protect the environment.

Do not use this vaccine after its expiry date that is on the carton after EXP.

6. Are there any side effects?

All medicines including vaccines can have side effects. If your child experiences any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your child's doctor or nurse if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• decreased appetite • irritability • crying • vomiting • sleepiness or drowsiness • fever (temperature 38°C or higher) • pain, redness, swelling at the injection site • diarrhoea • hard mass, lump (nodule) at the injection site • bruising at the injection site • 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	**Speak to your doctor if your child has any of these side effects and they worry you.**
• floppiness	

Serious side effects

Serious side effects	What to do
Serious allergic reactions: • difficulty in breathing • blueness of the tongue or lips • swelling of the face or throat • low blood pressure causing dizziness or collapse • a rash associated with any of the above symptoms 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 and can occur after receiving any vaccine. Other serious side effects: • floppiness and unresponsive or unconscious and/or paleness or bluish skin • fits (convulsions) with or without fever • extensive swelling of the vaccinated limb	**Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or nurse if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects your child experienced, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this vaccine.

7. Product details

This vaccine is only available with a doctor's prescription.

What Vaxelis contains

Active ingredient (main ingredient)	• Diphtheria Toxoid[1] not less than 20 IU[6] • Tetanus Toxoid[1] not less than 40 IU[6] • *Bordetella pertussis* 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) 29 D antigen units[5] ○ Type 2 (MEF-1) 7 D antigen units[5] ○ Type 3 (Saukett) 26 D antigen units[5] • *Haemophilus influenzae* type b polysaccharide ○ (Polyribosylribitol Phosphate) 3 micrograms ○ Conjugated to meningococcal protein[2] 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] these antigen quantities are strictly the same as those previously expressed as 40-8-32 D-antigen units, for virus type 1, 2 and 3 respectively, when measured by another suitable immunochemical method [6] or equivalent activity determined by an immunogenicity or antigenicity evaluation.
Other ingredients (inactive ingredients)	Dibasic sodium phosphate and monobasic sodium phosphate, water for injections
Potential allergens	Glutaraldehyde, formaldehyde, neomycin, streptomycin, polymyxin B, and bovine serum albumin

Do not allow your child to receive this vaccine if he/she is allergic to any of these ingredients.

What Vaxelis looks like

Vaxelis 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 (AUST R 363251) or vial (AUST R 364413).

Pack size of 1 or 10 pre-filled syringes, without attached needles.

Pack size of 10 vials.

Not all pack sizes may be marketed.

Who distributes Vaxelis

Sanofi-Aventis Australia pty ltd

Tower 3 International Towers Sydney,

Level 23, 300 Barangaroo Avenue,

Barangaroo NSW 2000

Tel: 1800 818 806

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