QUADRACEL®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why does my child need Quadracel?

Quadracel is a vaccine. It is used to help prevent whooping cough (pertussis), tetanus, diphtheria and polio, in infants and children.

For more information, see Section 1. Why does my child need Quadracel? in the full CMI.

2. What should I know before my child is given Quadracel?

Do not use if your child ever had an allergic reaction to Quadracel or any of the ingredients listed at the end of the CMI.

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

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

3. What if my child is taking other medicines?

Some medicines may interfere with Quadracel 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 Quadracel is given?

Quadracel is given by a doctor or nurse as an injection into muscle.

More instructions can be found in Section 4. How is Quadracel given? in the full CMI.

5. What should I know after my child is given Quadracel?

Things you should do	• Keep an updated record of vaccinations. • Keep follow-up appointments with your doctor or clinic.
Looking after your medicine	Quadracel is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store Quadracel: • keep in the fridge between 2-8°C. Do not freeze.

For more information, see Section 5. What should I know after my child is given Quadracel? in the full CMI.

6. Are there any side effects?

Common side effects include local reaction around the injection site (redness, swelling, and tenderness), vomiting, fever, crying, decreased eating, diarrhoea, fussiness, decreased activity, sleepiness, listlessness or blisters at the injection site. Serious side effects include abscess at the injection site, sudden signs of allergic reactions such as rash, itching or hives on the skin and shortness of breath, convulsion with or without high temperature, unusual muscle slackness, pale skin or bluish appearance to finger nails or lips, large injection site reactions including limb swelling.

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

QUADRACEL®

Active ingredient(s): *Diphtheria toxoid, Tetanus toxoid, Pertactin, Pertussis filamentous haemagglutinin, Pertussis fimbriae 2 + 3, Pertussis toxoid, and Poliovirus.*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

1. Why does my child need Quadracel?
2. What should I know before my child is given Quadracel?
3. What if my child is taking other medicines?
4. How Quadracel is given?
5. What should I know after my child is given Quadracel?
6. Are there any side effects?
7. Product details

1. Why does my child need Quadracel?

Quadracel contains the active ingredients Diphtheria toxoid, Tetanus toxoid, Pertactin, Pertussis filamentous haemagglutinin, Pertussis fimbriae 2 + 3, Pertussis toxoid, and Poliovirus. Quadracel is a combination vaccine used to help prevent four diseases, whooping cough (pertussis), tetanus, diphtheria and polio, in infants and children. Polio, whooping cough, tetanus and diphtheria cause significant sickness and sometimes death in unvaccinated infants, children, and adults.

This vaccine is for use in children up to 6 years of age, and is used in infants from the age of 2 months who are at the greatest risk from these diseases.

How Quadracel works

Quadracel works by causing the body to produce its own protection against whooping cough, tetanus, diphtheria, and polio. It does this by making substances called antibodies in the blood, which fight the bacteria and toxins that cause these diseases. If a vaccinated person comes into contact with these bacteria and toxins, the body is usually ready to destroy them.

Most children will produce enough antibodies against these diseases. However, as with all vaccines, 100% protection cannot be guaranteed.

The vaccine will not give your child any of these diseases.

The chance of a severe reaction from Quadracel is very small, but the risks from not being vaccinated against these diseases may be very serious.

2. What should I know before my child is given Quadracel?

Warnings

Do not use Quadracel if your child:

- is allergic to Diphtheria toxoid, Tetanus toxoid Pertactin, Pertussis filamentous haemagglutinin, Pertussis fimbriae 2 + 3, Pertussis toxoid, and Poliovirus, or any of the ingredients listed at the end of this leaflet.
- had an anaphylactic or other allergic reaction to a previous dose of this vaccine or another vaccine designed to protect against whooping cough, tetanus, diphtheria and polio.
- had a serious nervous system disorder within 7 days after a previous whooping cough vaccine.
- has progressive nervous system disorder such as infant spasm, uncontrolled epilepsy. The vaccination may be considered only after a treatment has been established and the condition is stabilised.
- an illness with febrile or acute infection. The vaccination shall be postponed until after the child has recovered.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if your child:

- has reacted to Quadracel or any other vaccine with any of the following:
  - life-threatening allergic reaction.
  - shock-like state or being unresponsive for a long period of time. Symptoms include shallow breathing, breathing which stops temporarily, skin pale when compared to normal healthy skin colour.
  - convulsions with or without high temperature within 3 days.
  - high temperature (greater than 40.5°C).
  - persistent crying lasting for more than 3 hours within 48 hours.
- has or had any medical conditions, especially the following:
  - lowered immunity due to diseases (such as HIV/AIDS or cancer) or medicines used to treat cancer including radiation therapy.
  - a higher risk of convulsion than the general population.
  - a bleeding disorder.
- has fainted with previous injections. Fainting can occur following, or even before, any needle injections

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 pharmacist 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.

Tell your doctor if your child has been treated with medicines that may affect the body's natural defenses (immune system) such as chemotherapy. Response to vaccines may not be optimal.

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

4. How Quadracel is given?

How much to use

- Quadracel is given by a doctor or nurse as an injection into muscle.
- For infants under the age of 12 months, Quadracel is given as an injection into the upper thigh muscle. In older children who have started walking, the vaccine is usually injected into the upper arm muscle.

When to use Quadracel

- The primary immunisation schedule is one 0.5 mL dose given at 2, 4 and 6 months of age. A booster dose may be given at 15 months to 6 years of age.

If your child misses a dose of Quadracel

If your child misses a dose, talk to your doctor and arrange another visit as soon as possible.

If your child received too much Quadracel

Overdose is most unlikely because your doctor or nurse gives the injections. If you have any concerns, ask your doctor.

5. What should I know after my child is given Quadracel?

Things you should do

- Keep an updated record of your child's vaccinations.
- Keep follow-up appointments with your doctor or clinic.

  It is important your child has follow-up doses of Quadracel at the appropriate times to make sure the vaccine has the best chance of providing protection against whooping cough, tetanus, diphtheria, and polio.

Call your doctor straight away if your child:

- does not feel well after having Quadracel

Remind any doctor, dentist or pharmacist you visit your child had Quadracel.

Looking after your child's medicine

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

- Keep Quadracel where children cannot reach it.
- Keep Quadracel in the original pack until it is time for it to be given.
- Keep Quadracel in the refrigerator, between 2°C and 8°C. Do not freeze Quadracel. Freezing destroys the vaccine.

Getting rid of any unwanted medicine

If your child no longer needs to use this vaccine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this vaccine after the expiry date.

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 doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• local reaction around the injection site such as redness, swelling, and tenderness • blisters at the injection site • fussiness • decreased activity • decreased eating • crying or screaming • fever • vomiting • diarrhoea • sleepiness • listlessness	**Speak to your doctor if your child has any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• abscess at the injection site • sudden signs of allergic reactions such as rash, itching or hives on the skin and shortness of breath • convulsions with or without high temperature • pale skin or bluish appearance to finger nails or lips	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you**

Serious side effects	What to do
• unusual muscle slackness • large injection site reactions including limb swelling	**notice any of these serious side effects.**

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

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

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 in Australia or in New Zealand at https://pophealth.my.site.com/carmreportnz/s/. By reporting side effects, you can help provide more information on the safety of this vaccine.

Always make sure you speak to your doctor or pharmacist before you decide to stop giving any medicines to your child.

7. Product details

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

What Quadracel contains

Active ingredient (main ingredient)	• 20 microgram pertussis toxoid • 20 microgram pertussis filamentous haemagglutinin • 5 microgram pertussis fimbriae Types 2+3 • 3 microgram pertussis pertactin • at least 30 IU (15 LF) diphtheria toxoid • at least 40 IU (5 LF) tetanus toxoid • 29 D-antigen Units Poliovirus inactivated type 1, Vero (Mahoney) • 7 D-antigen Units Poliovirus inactivated type 2, Vero (MEF-1) • 26 D-antigen Units Poliovirus inactivated type 3, Vero (Saukett)
Other ingredients (inactive ingredients)	• aluminium phosphate • phenoxyethanol • polysorbate 80 Quadracel may also contain traces of the following: • bovine serum albumin • formaldehyde • glutaral • neomycin • streptomycin sulfate • polymyxin B sulfate
Potential allergens	No

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.

Your child should not receive this vaccine if they are allergic to any of these ingredients.

What Quadracel looks like

Quadracel is a sterile, uniform, white to off-white suspension for injection.

AUST R 385069 (pre-filled syringe)

Who distributes Quadracel

Distributed in Australia by:

sanofi-aventis australia pty ltd

International Tower 3, Level 23

300 Barangaroo Avenue

Sydney NSW 2000

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

Distributed in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics

PO Box 62027

Sylvia Park Auckland 1644

Freecall: 0800 283 684

Email: medinfo.australia@sanofi.com

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