

QUADRACEL[®]

Pertussis Vaccine – Acellular and Diphtheria and Tetanus Toxoids (Adsorbed) Combined with Inactivated Poliovirus Types 1, 2 and 3 (MRC-5 Cell)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about QUADRACEL. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines, including vaccines, have risks and benefits. Your doctor has weighed the risks of your child having QUADRACEL against the benefits they expect it will have.

If you have any concerns about this vaccine, ask your doctor, nurse or pharmacist.

Keep this leaflet.

You may need to read it again.

What QUADRACEL is used for

QUADRACEL is a vaccine used to help prevent whooping cough, tetanus, diphtheria and polio.

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.

Polio, whooping cough, tetanus and diphtheria cause significant sickness and sometimes death in unvaccinated infants, children, and adults.

How it 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.

It usually takes several weeks after vaccination to develop protection against these diseases. Protection requires 3 doses of this vaccine or this vaccine used alternately with other vaccines protecting against the same diseases. A booster dose may be required between 15 months of age and six years.

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.

Before you are given QUADRACEL

When your child must not be given it

Do not give QUADRACEL to a child who has:

- an allergy to QUADRACEL 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, polio, or *Haemophilus influenzae* type b.
- had a serious nervous system disorder within 7 days after a previous whooping cough vaccine.
- 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.

Symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rash, itching or hives

Do not use QUADRACEL after the expiry date printed on the pack.

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

If you are not sure whether your child should have QUADRACEL, talk to your doctor or pharmacist.

Before your child is given it

Tell your doctor if your child has reacted to previous vaccination with any of the following:

- life-threatening allergic reaction
- shock-like state or being unresponsive for a long period of time
- convulsions with or without high temperature
- high temperature (greater than 40.5°C)
- persistent crying lasting for more than 3 hours

Tell your doctor if your child has or has had any medical conditions, especially the following:

- lowered immunity due to diseases (such as HIV/AIDS or cancer) or medicines (such as medicines used to treat cancer including radiation therapy)
- a higher risk of convulsions than the general population
- a bleeding disorder or taking blood-thinning medicines

Tell your doctor if your child has allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Having other vaccines

Tell your doctor if your child has had any vaccines in the last 4 weeks.

Your doctor will advise you if QUADRACEL is to be given with another vaccine as a separate injection.

How QUADRACEL is given

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.

QUADRACEL should not be injected directly into the veins.

How much is given and when it is given

The primary immunisation schedule is one 0.5mL 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

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

After having QUADRACEL

Things you must 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.

Side effects

Tell your doctor or pharmacist as soon as possible if your child does not feel well after having QUADRACEL.

QUADRACEL may have unwanted side effects in a few people. All medicines, including vaccines, can have side effects. Sometimes they are serious, most of the time they are not. Your child may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- local reaction around the injection site such as redness, tenderness, pain or discomfort, or swelling
- flushing or redness of the skin
- fussiness
- decreased activity
- decreased eating
- crying or screaming
- fever
- vomiting
- diarrhoea
- sleepiness

These are the more common side effects of QUADRACEL. Mostly these are mild and short-lived.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- abscess at the injection site
- sudden signs of allergic reactions such as rash, itching or hives on the skin swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- convulsions with or without high temperature
- the child becomes pale, limp and unresponsive
- pale skin or bluish appearance to finger nails or lips
- unusual muscle slackness
- nervous system disorders that may result in headache and fever, progressing to hallucinations, confusion, paralysis of part or all the body, disturbances of behaviour, speech and eye movements, stiff neck and sensitivity to light.

These are very serious side effects. Your child may need urgent medical attention or hospitalisation.

All of these side effects are very rare.

Very rarely children may experience swelling of the whole arm after the booster (4th) dose. This reaction occurs very rarely in association with all vaccines with similar active ingredients to QUADRACEL. It is a short-lived reaction, which resolves spontaneously without any permanent damage.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making your child feel unwell.

Do not be alarmed by this list of possible side effects.

Your child may not experience any of them.

Storing QUADRACEL

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

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

Product description

What it looks like

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

Ingredients

Active ingredients:

- 20 µg pertussis toxoid
- 20µg pertussis filamentous haemagglutinin
- 5µg pertussis fimbriae Types 2+3
- 3µg pertussis pertactin
- ≥30 IU diphtheria toxoid
- ≥40 IU tetanus toxoid

- 40 DAgU Poliovirus inactivated type 1
- 8 DAgU Poliovirus inactivated type 2
- 32 DAgU Poliovirus inactivated type 3

Other ingredients:

- aluminium phosphate
- phenoxyethanol
- polysorbate 80
- albumin – bovine serum
- polymyxin B sulfate
- neomycin
- formaldehyde
- glutaraldehyde
- water for injections

QUADRACEL does not contain thiomersal, lactose, sucrose, gluten, tartrazine or any other azo dyes.

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.

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Sanofi Pasteur Limited
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