EMA/35341/2023
EMEA/H/C/006304

VacPertagen (*pertussis vaccine (recombinant, acellular, component, adsorbed)*)

An overview of VacPertagen and why it is authorised in the EU

What is VacPertagen and what is it used for?

VacPertagen is a vaccine used as a booster to protect against pertussis (whooping cough) in adolescents aged 12 years and older and adults who were previously vaccinated against the disease.

It is also used in pregnant women to protect their infants against pertussis in the first months after birth.

VacPertagen contains two proteins from the pertussis bacteria as active substances.

How is VacPertagen used?

The vaccine can only be obtained with a prescription.

Vaccination with VacPertagen should be carried out according to official recommendations.

The recommended vaccination schedule is one dose, given by injection into a muscle, usually in the muscle of the upper arm. If used in pregnant women, the dose is given during the second or third trimester of pregnancy.

For more information about using VacPertagen, see the package leaflet or contact your doctor or pharmacist.

How does VacPertagen work?

VacPertagen is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against diseases. VacPertagen contains small amounts of two proteins from the pertussis bacteria it protects against. They have been inactivated so that they do not cause any disease.

When a person is given the vaccine, the immune system recognises the proteins from the bacteria as 'foreign' and makes defences (antibodies) against them. If, later on, the vaccinated person comes into contact with the bacteria causing pertussis, the immune system will recognise the proteins and be prepared to attack it. This helps to protect against whooping cough.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

When VacPertagen is given during pregnancy, antibodies will be transferred from the mother to the foetus. This will help protect infants against pertussis during the first months after birth.

The vaccine is 'adsorbed'. This means that some of the active substances are fixed onto aluminium compounds, to better stimulate the immune response.

What benefits of VacPertagen have been shown in studies?

VacPertagen has been evaluated in three main studies that measured how well VacPertagen triggers the production of antibodies against pertussis, at levels expected to protect against whooping cough. In these studies, VacPertagen was compared to a vaccine used to protect against whooping cough, tetanus and diphtheria.

The first study was in 450 adolescents aged 12 to 17 years of age and the second in 750 adults who received one dose of VacPertagen or a comparator vaccine as a booster vaccination. In each study 150 people received VacPertagen. The results showed that 28 days after vaccination, adults and adolescents had higher antibody levels than those who received the other vaccine indicating that VacPertagen is effective. In addition, antibodies persisted for up to 3 years in adults and 5 years in adolescents.

The third study in 240 pregnant women found that VacPertagen, which was given to 40 of the women, also led to higher antibody levels than the other vaccine 28 days after vaccination in the second or third trimester of pregnancy. Higher levels of pertussis antibodies were also passed from mothers to infants following vaccination with VacPertagen compared with the other vaccine and persisted at least until 2 months of age.

What are the risks associated with VacPertagen?

For the full list of side effects and restrictions with VacPertagen, see the package leaflet.

The most common side effects with VacPertagen (which may affect more than 1 in 10 people) include pain at the site of injection, headache, tiredness, muscle pain, pain in joints, malaise and nausea. Most of the reactions are mild in severity and resolve within a few days of onset.

VacPertagen must not be used in people who have ever had an allergic reaction to VacPertagen or another whooping cough vaccine, to one of the components of VacPertagen, or to formaldehyde (a substance used during the manufacture of the vaccine). It must not be used in people who have ever had encephalopathy (a brain disease) of unknown cause within seven days of receiving a vaccine containing pertussis components in the past. It must also not be used in people who have an illness affecting the brain or nervous system, such as uncontrolled epilepsy, unless the condition has stabilised with treatment and the benefit of vaccination clearly outweighs the risk.

Why is VacPertagen authorised in the EU?

VacPertagen has been shown to trigger higher antibody levels against pertussis when compared with another vaccine against whooping cough, tetanus and diphtheria. The vaccine is therefore expected to be effective for booster protection against whooping cough without including extra components for other diseases that are not targeted.

In pregnant women, the available data are limited, and there are uncertainties on the magnitude and duration of protection in newborns. The company will carry out additional studies to confirm the vaccine's effectiveness after marketing, and to confirm safety in pregnant women vaccinated with VacPertagen and the impact on the infant. Regarding safety overall, the vaccine's safety profile is

similar to those of other vaccines. The European Medicines Agency therefore decided that VacPertagen's benefits are greater than its risks and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of VacPertagen?

Recommendations and precautions to be followed by healthcare professionals and people receiving the vaccine for the safe and effective use of VacPertagen have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of VacPertagen are continuously monitored. Suspected side effects reported with VacPertagen are carefully evaluated and any necessary action taken to protect patients.

Other information about VacPertagen

VacPertagen received a marketing authorisation valid throughout the EU on 9 January 2026.

Further information on VacPertagen can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/vacpertagen.

This overview was last updated in 01-2026.