European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

PROCOMVAX

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

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What is PROCOMVAX?

PROCOMVAX is a vaccine, which is available as a suspension for injection. It contains proteins from *Haemophilus influenzae* type b ('Hib', a bacterium that can cause meningitis) and parts of the hepatitis B virus as active substances.

What is PROCOMVAX used for?

PROCOMVAX is used to vaccinate infants aged between six weeks and 15 months against 'invasive' disease caused by Hib (such as bacterial meningitis) and infection with the hepatitis B virus.
The medicine can only be obtained with a prescription.

How is PROCOMVAX used?

The vaccination schedule is three doses of PROCOMVAX, ideally at two, four, and 12 to 15 months of age. Children who receive one dose of a hepatitis B vaccine at or shortly after birth can be given PROCOMVAX. The vaccine must only be given by injection into a muscle.

How does PROCOMVAX work?

PROCOMVAX is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against diseases. PROCOMVAX contains small amounts of:

- a protein purified from Hib, attached to a carrier (a protein purified from the outer membrane of the bacterium *Neisseria meningitidis*);
- surface antigen (proteins from the surface) of the hepatitis B virus. These are produced by a method known as 'recombinant DNA technology': they are made by a yeast that has received a gene (DNA), which makes it able to produce the proteins.

When an infant is given the vaccine, the immune system recognises the parts of the bacteria and viruses as 'foreign' and makes antibodies against them. The immune system will then be able to produce antibodies more 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 active substances are 'adsorbed', meaning that they are fixed onto aluminium compounds, and the vaccine contains an 'adjuvant' (a compound containing aluminium) to stimulate a better response.
PROCOMVAX is a combination of components that have been available in the European Union (EU) in other vaccines for a number of years.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

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How has PROCOMVAX been studied?
PROCOMVAX has been studied in one main study involving 882 infants. The study compared the effects of PROCOMVAX with those of separate vaccines containing the same active substances. In both groups, the infants were vaccinated at two, four, and 12 to 15 months of age. The main measure of effectiveness whether protective levels of antibodies to Hib and hepatitis B virus had developed at one and two months after vaccination.
The results of further studies were used to support the use of PROCOMVAX, both in infants who had and who had not received hepatitis B vaccination in the past.

What benefit has PROCOMVAX shown during the studies?
In the main study, the responses both to PROCOMVAX and to the separate vaccines were low in terms of levels of antibodies against Hib. However, the company provided further information from other studies to show that three doses of PROCOMVAX produced adequate levels of protection.
The main study also showed that PROCOMVAX produced adequate levels of protection against hepatitis B virus. This conclusion was confirmed with the results from seven additional studies supplied by the company.
The additional studies showed that protection against hepatitis B from PROCOMVAX was adequate in infants who had and who had not received hepatitis B vaccination in the past.

What is the risk associated with PROCOMVAX?
The most common side effects seen with PROCOMVAX are reactions at the injection site, including pain, soreness, erythema (redness) and swelling. Other common side effects are fever, anorexia (loss of appetite), vomiting, diarrhoea, irritability, somnolence (sleepiness), crying (including unusual high-pitched crying and prolonged crying) and otitis media (infection of the middle ear). For the full list of all side effects reported with PROCOMVAX, see the Package Leaflet.
PROCOMVAX should not be used in infants who may be hypersensitive (allergic) to any of the active substances or any of the other ingredients. Infants who show signs of hypersensitivity (allergic reaction) after an injection should not receive further injections of the vaccine. PROCOMVAX is not recommended for infants younger than six weeks of age, because of a risk of a reduced protective response to Hib. Vaccination with PROCOMVAX should be postponed in infants with moderate or severe sudden fever until they have recovered.
As for all vaccines, if PROCOMVAX is used in very premature babies, there is a risk of the babies experiencing apnoea (brief pauses in breathing). Their breathing should be monitored for up to three days after vaccination.

Why has PROCOMVAX been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that PROCOMVAX's benefits are greater than its risks for vaccination against invasive disease caused by Hib and against infection caused by all known subtypes of hepatitis B virus in infants six weeks to 15 months of age. The Committee recommended that PROCOMVAX be given marketing authorisation.

Other information about PROCOMVAX:
The European Commission granted a marketing authorisation valid throughout the EU to Sanofi Pasteur MSD S.N.C. for PROCOMVAX on 7 May 1999. The marketing authorisation was renewed on 7 May 2004.

The full EPAR for PROCOMVAX can be found here.

This summary was last updated in 02-2008.

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