European Medicines Agency

EMEA/H/C/298

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

HEXAVAC

International Nonproprietary Name (INN): **Diphtheria, tetanus, acellular pertussis, inactivated poliomyelitis, hepatitis B (recombinant) and *Haemophilus influenzae* type b conjugate vaccine, adjuvanted**

Abstract

Active substance:	Purified adsorbed diptheria toxoid (PDT) Purified tetanus toxoid (PTT) Purified pertussis toxoid (PTxT) Purified pertussis filamentous haemagglutinin (FHA) Hepatitis B S surface antigen recombinant (HBsAG) Inactivated poliovirus (IPV): type 1 (Mahoney) type 2 (MEF 1) type 3 (Saukett) *Haemophilus influenzae* type b polysaccharide, conjugated to tetanus protein (PRP-T)
Pharmaco-therapeutic group (ATC Code):	Bacterial and viral vaccines, combined (J07CA)
Currently approved therapeutic indication(s):	This combined vaccine is indicated for primary and booster vaccination of children against diphtheria, tetanus, pertussis, hepatitis B caused by all known subtypes of viruses, poliomyelitis and invasive infections caused by *Haemophilus influenzae* type b.
Authorised presentations:	See the Module "All authorised presentations"
Marketing Authorisation Holder:	AVENTIS PASTEUR MSD, SNC 8, rue Jonas Salk F-69007 Lyon France
Date of issue of Marketing Authorisation valid throughout the European Union:	23 October 2000
Orphan medicinal product designation date:	Not applicable

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Hexavac is a hexavalent vaccine which contains combined antigens derived from *Corynebacterium diphtheriae*, *Clostridium tetani*, *Bordetella pertussis*, hepatitis B virus, polio virus and *Haemophilus influenzae* type b. It is developed for primary and booster vaccination of children against the viruses and bacteria mentioned above.

The approval was based on results from clinical trials, which investigated the immunogenicity and reactogenicity of Hexavac when administered according to specific primary and booster vaccination schedules. These studies showed the protective efficacy of Hexavac against the above diseases in infants.

The most common adverse events were transient local reactions (pain, redness, swelling at the injection site) and systemic reactions (loss of appetite, fever, drowsiness, irritability).

The following adverse effects were reported very rarely: allergic reaction, chills, fatigue, hypotonic-hyporesponsive episode, malaise, oedema, pallor, swelling or oedema of the entire limb(s), transient local lymph node swelling, convulsions (febrile and non febrile), encephalitis, encephalopathy with acute brain oedema, eyes rolling, Guillain Barré Syndrome, hypotonia, neuritis, abdominal pain, meteorism, nausea, petechiae, purpura, purpura thrombocytopenic, thrombocytopenia, agitation, sleep disorder, dyspnoea or Stridor inspiratory, angioedema, erythema, pruritus, rash, urticaria and flushing.

The CHMP, on the basis of quality, efficacy and safety data submitted, considéres that the overall benefit /risk ratio for Hexavac remains favourable in the approved indication.

For detailed conditions for the use of this product, scientific information or procedural aspects please refer to the relevant modules.