HAUTE AUTORITÉ DE SANTÉ

INFECTIOUS DISEASES
New medicinal product
October 2017

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

VAXELIS, hexavalent vaccine against diphtheria, tetanus, poliomyelitis, pertussis, *Haemophilus influenzae* type b infections, hepatitis B

No clinical benefit demonstrated for the primary and booster vaccination in infants

Main points

- VAXELIS is a hexavalent vaccine which has Marketing Authorisation for the primary and booster vaccination against diphtheria, tetanus, poliomyelitis, pertussis, *Haemophilus influenzae* type b infections and hepatitis B, in infants from 6 weeks of age.
- There are two other hexavalent vaccines authorised in France for the primary and booster vaccination in infants: INFANRIX HEXA and HEXYON. The immunogenicity of VAXELIS is not inferior to that of INFANRIX HEXA and its safety profile is comparable despite a higher frequency of local reactions and fever.

Therapeutic strategy

- In infants, vaccination against pertussis, diphtheria, tetanus and poliomyelitis is advised with two injections of combined vaccine containing the acellular pertussis component and the tetanus and diphtheria components at normal concentration (DTCaPolio) at 2 and 4 months of age, followed by a booster at 11 months of age.
  Vaccination against invasive infections with *Haemophilus influenzae* type b is recommended according to the same methods with a pentavalent vaccine combining the DTCaPolio and Hib components.
  Vaccination against hepatitis B is also recommended in every infant according to a regimen of 3 doses, respecting an interval of at least 5 months between the 2nd and 3rd dose.
- The use of a hexavalent vaccine combining the DTCaPolio, Hib and hepatitis B components enables these diseases to be immunised against in a single injection at the ages of 2, 4 and 11 months according to the vaccination schedule in effect.
- **Role of the medicinal product in the therapeutic strategy**
  VAXELIS can be used for the primary vaccination and booster vaccination in infants according to the regimens figured in the vaccination schedule.

Clinical data

- The immunogenicity data reveal a satisfactory vaccine response (above the predefined protective thresholds) as well as the non-inferiority of VAXELIS compared with INFANRIX HEXA for all the vaccine components.
- No immunogenicity data are available in immunocompromised infants or infants over 15 months of age, or on the interchangeability with the HEXYON and INFANRIX HEXA hexavalents.
- The safety profile of the VAXELIS vaccine can be considered as satisfactory and close to that of the INFANRIX HEXA vaccine despite the higher frequency of local reactions and fever.

Benefit of the medicinal product

- The actual clinical benefit* of VAXELIS is substantial.
- VAXELIS does not provide any clinical added value** (CAV level V) compared with the other available hexavalent vaccines.
- Recommends inclusion on the list of reimbursable products for supply by pharmacists and for hospital use.

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This document was created on the basis of the Transparency Committee Opinion of 11 October 2017 (CT-16299) and is available at **www.has-sante.fr**

* The actual clinical benefit (ACB) of a medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the ACB, which can be substantial, moderate, low or insufficient for reimbursement of the medicinal product for hospital use.

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV (equivalent to “no CAV”) means “no clinical added value”.