Unit: Technical Assessment Unit

Public assessment report for biological products

(Cervarix)

Administrative information:

Trade name of the medicinal product:	Cervarix
INN (or common name) of the active substance(s):	Human papilloma virus
Manufacturer of the finished product	GlaxoSmithKline Biologicals S.A., Parc de la Noire Epine, rue Flemming, 20-1300 Wavre – Belgium
Marketing Authorization holder	GlaxoSmithKline Biologicals S.A., Rue de l'Institut 89, B-1330 Rixensart – Belgium.
Applied Indication(s):	prevention of premalignant anogenital lesions (cervical, vulvar, vaginal and anal) and cervical and anal cancers causally related to certain oncogenic Human Papillomavirus (HPV) types.
Pharmaceutical form(s) and strength(s):	- Suspension for injection - Each one dose of 0.5 ml contains: Human Papillomavirus type 16 L1 protein 20 µg Human Papillomavirus type 18 L1 protein 20 µg
Route of administration	I.M.
Type of registration (EMA/FDA – Local)	EMA

List of abbreviations

GSK	GlaxoSmithKline Biologicals SA
EU	European Union

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1. **General introduction about the product including brief description of the AI, its mode of action and indications:**
   Cervarix is an adjuvanted non-infectious recombinant vaccine developed by GlaxoSmithKline Biologicals SA (GSK). It is approved in the European Union (EU) since 20 September 2007 via the Centralized Procedure. Cervarix is currently approved in the United States, all European Economic Area countries, the United Kingdom, Japan and in 67 other countries.
   Cervarix is indicated for use in Europe from the age of 9 years for the prevention of premalignant anogenital lesions (cervical, vulvar, vaginal and anal) and cervical and anal cancers causally related to certain oncogenic Human Papillomavirus (HPV) types.
2. **Quality aspects:**
   - **General information**
     Cervarix is a recombinant C-terminally truncated HPV-16 L1 and HPV-18 L1 proteins, assembled into virus-like particles (VLPs) adjuvanted with the GSK proprietary adjuvant AS04.

   - **Manufacture, process controls and characterization:**
     Name and address of the manufacturers of the biological active substance:
     GlaxoSmithKline Biologicals SA Parc de la Noire Epine rue Flemming 20-1300 Wavre Belgium.
     Name and address of the manufacturer responsible for batch release:
     GlaxoSmithKline Biologicals S.A. 89, rue de l'Institut BE-1330 Rixensart Belgium.
   - **List of excipients:**
   - Sodium chloride (NaCl)
   - Sodium dihydrogen phosphate dihydrate (NaH2PO4.2 H2O)
   - Water for injections.

   - **Stability of the drug product.**
     - Based on available stability data,
     approved Shelf Life: 5 years

approved Storage Conditions: 2-8°C.
Do not freeze. Store in the original package in order to protect from light.

3. General Conclusion and Recommendations if any:

Based on the review of CTD modules and other supplementary documents, the product is approved.

For more information, please visit EMA published assessment report link:

https://www.ema.europa.eu/en/documents/product-information/cervarix-epar-product-information_en.pdf