

APPENDIX A

**Extracted from GP Magazine dated 26th September 2008. Double sided advert
between pages 6 and 7**

**Cervarix[®] helps you give women cervical
cancer protection, with a strong and
sustained immune response^{1,2}**



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ABBREVIATED PRESCRIBING INFORMATION: (Refer to Summary of Product Characteristics for full product information).

CERVARIX[®] Human Papillomavirus Vaccine [Types 16, 18] (Recombinant, adjuvanted, adsorbed). Suspension for injection. **Uses:** Prevention of high-grade cervical intraepithelial neoplasia (CIN 2/3) and cervical cancer causally related to Human Papillomavirus (HPV) types 16 and 18. Indication is based on clinical efficacy in women aged 15-25 years, and inferred efficacy in adolescent girls aged 10-14 years on the basis of non-inferior immunogenicity. **Data in women aged 26-55 years:** Cervarix[®] is immunogenic in women aged 26-55 years, but antibody levels were lower than those in women aged 15-25 years. **Dosage and administration:** It is recommended that a 3-dose vaccination course with Cervarix[®] is completed. The recommended vaccination schedule is one 0.5ml dose at 0, 1 and 6 months. Cervarix[®] should be administered by intramuscular injection (IM) in the deltoid region. Need for booster dose has not been established. *Girls under 10 years:* not recommended.

Active ingredients: Each 0.5 ml dose contains: HPV 16 L1 protein (20 micrograms), HPV 18 L1 protein (20 micrograms), adjuvanted by AS04 containing monophosphoryl lipid A (50 micrograms), adsorbed on aluminium hydroxide (0.5 milligrams AP[®] in total). **Contraindications:** Hypersensitivity to any component of the vaccine. Acute severe febrile illness. **Precautions and warnings:**

Appropriate treatment should be available in case of rare anaphylactic reactions. Cervarix[®] must not be administered intravascularly or intradermally. Caution in thrombocytopenia or any coagulation disorder, as bleeding may occur following an IM injection. As with any vaccine, a protective immune response may not be elicited in all vaccinees. Cervarix[®] protects against disease caused by HPV 16 and 18. Other oncogenic HPV types can also cause cervical cancer. Vaccination is not therefore a substitute for regular cervical screening, or for precautions against exposure to HPV and sexually transmitted diseases. Cervarix[®] does not prevent HPV-related lesions in women infected with HPV-16 or HPV-18 at the time of vaccination and has not been shown to have a therapeutic effect. There are no data on the use of Cervarix[®] in subjects with impaired immune responsiveness. Duration of protection has not been fully established. Timing and need of booster has not been investigated. **Interactions:** Data not generated on the concomitant administration of Cervarix[®] and other vaccines. As with other vaccines it may be expected that, in patients receiving immunosuppressive treatment, an adequate response may not be elicited. **Pregnancy/lactation:** Vaccination should be postponed until after pregnancy. Cervarix[®] should only be used during breast-feeding if possible advantages outweigh possible risks. **Undesirable effects:** See SPC for full details. *Very common:* headache, myalgia and injection site reactions (including pain, redness, swelling), and fatigue. *Common:* gastrointestinal symptoms (including nausea, vomiting, diarrhoea and abdominal pain), itching/pruritus, rash, urticaria, arthralgia and fever ($\geq 38^{\circ}\text{C}$). *Uncommon:* dizziness, upper respiratory tract infection and other injection site reactions such



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