

<u>MA (EU) number</u>	<u>(Invented name)</u>	<u>Strength</u>	<u>Pharmaceutical form</u>	<u>Route of administration</u>	<u>Immediate Packaging</u>	<u>Content (concentration)</u>	<u>Pack size</u>
EU/1/07/419/001	Cervarix	-- <sup>1</sup>	Suspension for injection	Intramuscular use	vial (glass)	0.5 ml	1 vial
EU/1/07/419/002	Cervarix	-- <sup>1</sup>	Suspension for injection	Intramuscular use	vial (glass)	0.5 ml	10 vials
EU/1/07/419/003	Cervarix	-- <sup>1</sup>	Suspension for injection	Intramuscular use	vial (glass)	0.5 ml	100 vials
EU/1/07/419/004	Cervarix	-- <sup>1</sup>	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe + 1 needle
EU/1/07/419/005	Cervarix	-- <sup>1</sup>	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe + 2 needles
EU/1/07/419/006	Cervarix	-- <sup>1</sup>	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes + 10 needles
EU/1/07/419/007	Cervarix	-- <sup>1</sup>	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes + 20 needles
EU/1/07/419/008	Cervarix	-- <sup>1</sup>	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe
EU/1/07/419/009	Cervarix	-- <sup>1</sup>	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes
EU/1/07/419/010	Cervarix	-- <sup>1</sup>	Suspension for injection	Intramuscular use	vial (glass)	1 ml	1 vial (multidose)
EU/1/07/419/011	Cervarix	-- <sup>1</sup>	Suspension for injection	Intramuscular use	vial (glass)	1 ml	10 vials (multidose)
EU/1/07/419/012	Cervarix	-- <sup>1</sup>	Suspension for injection	Intramuscular use	vial (glass)	1 ml	100 vials (multidose)

--1 1 dose (0.5 ml) contains:

Human Papillomavirus<sup>1</sup> type 16 L1 protein<sup>2,3,4</sup> 20 micrograms  
Human Papillomavirus<sup>1</sup> type 18 L1 protein<sup>2,3,4</sup> 20 micrograms

<sup>1</sup>Human Papillomavirus = HPV

<sup>2</sup>adjuvanted by AS04 containing:

3-O-desacyl-4'- monophosphoryl lipid A (MPL)<sup>3</sup> 50 micrograms

<sup>3</sup>adsorbed on aluminium hydroxide, hydrated (Al(OH)<sub>3</sub>) 0.5 milligrams Al<sup>3+</sup> in total

<sup>4</sup>L1 protein in the form of non-infectious virus-like particles (VLPs) produced by recombinant DNA technology using a Baculovirus expression system which uses Hi-5 Rix4446 cells derived from *Trichoplusia ni*.