

<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/1/15/1007/001	Gardasil 9	--1	Suspension for injection	Intramuscular use	vial (glass)	0.5 ml	1 vial
EU/1/15/1007/002	Gardasil 9	--1	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 syringe + 2 needles
EU/1/15/1007/003	Gardasil 9	--1	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 syringes + 20 needles

--1 1 dose (0.5 ml) contains approximately:

Human Papillomavirus1 Type 6 L1 protein<sup>2,3</sup> 30 micrograms

Human Papillomavirus1 Type 11 L1 protein<sup>2,3</sup> 40 micrograms

Human Papillomavirus1 Type 16 L1 protein<sup>2,3</sup> 60 micrograms

Human Papillomavirus1 Type 18 L1 protein<sup>2,3</sup> 40 micrograms

Human Papillomavirus1 Type 31 L1 protein<sup>2,3</sup> 20 micrograms

Human Papillomavirus1 Type 33 L1 protein<sup>2,3</sup> 20 micrograms

Human Papillomavirus1 Type 45 L1 protein<sup>2,3</sup> 20 micrograms

Human Papillomavirus1 Type 52 L1 protein<sup>2,3</sup> 20 micrograms

Human Papillomavirus1 Type 58 L1 protein<sup>2,3</sup> 20 micrograms

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

<sup>2</sup> L1 protein in the form of virus-like particles produced in yeast cells (*Saccharomyces cerevisiae* CANADE 3C-5 (Strain 1895)) by recombinant DNA technology

<sup>3</sup> adsorbed on amorphous aluminium hydroxyphosphate sulphate adjuvant (0.5 milligrams Al)