

| <u>MA (EU) number</u> | <u>(Invented)<br/>name</u> | <u>Strength</u> | <u>Pharmaceutical<br/>form</u> | <u>Route of<br/>administration</u> | <u>Immediate<br/>Packaging</u> | <u>Content<br/>(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 |
| EU/1/15/1007/004      | Gardasil 9                 | --1             | Suspension for injection       | Intramuscular use                  | pre-filled syringe (glass)     | 0.5 ml                             | 10 syringes              |

--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)