

<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/1/18/1338/001	Dengvaxia	-- ¹	Powder and solvent for suspension for injection	Subcutaneous use	powder: vial (glass); solvent: pre-filled syringe (glass)	Powder: 1 dose; solvent: 0.5 ml	1 vial + 1 pre-filled syringe + 2 needles
EU/1/18/1338/002	Dengvaxia	-- ¹	Powder and solvent for suspension for injection	Subcutaneous use	powder: vial (glass); solvent: pre-filled syringe (glass)	Powder: 1 dose; solvent: 0.5 ml	10 vials + 10 pre-filled syringes + 20 needles
EU/1/18/1338/003	Dengvaxia	-- ¹	Powder and solvent for suspension for injection	Subcutaneous use	powder: vial (glass); solvent: pre-filled syringe (glass)	Powder: 1 dose; solvent: 0.5 ml	1 vial + 1 pre-filled syringe
EU/1/18/1338/004	Dengvaxia	-- ¹	Powder and solvent for suspension for injection	Subcutaneous use	powder: vial (glass); solvent: pre-filled syringe (glass)	Powder: 1 dose; solvent: 0.5 ml	10 vials + 10 pre-filled syringes
EU/1/18/1338/005	Dengvaxia	-- ¹	Powder and solvent for suspension for injection	Subcutaneous use	powder: vial (glass); solvent: vial (glass)	Powder: 5 doses; solvent: 2.5 ml	5 sets of 2 vials (1 with powder + 1 with solvent, 5 doses each)

--¹ After reconstitution, one dose (0.5 mL) contains:

Chimeric yellow fever dengue virus serotype 1* (live, attenuated).....4.5 - 6.0 log₁₀ CCID₅₀/dose**
Chimeric yellow fever dengue virus serotype 2* (live, attenuated).....4.5 - 6.0 log₁₀ CCID₅₀/dose**
Chimeric yellow fever dengue virus serotype 3* (live, attenuated).....4.5 - 6.0 log₁₀ CCID₅₀/dose**
Chimeric yellow fever dengue virus serotype 4* (live, attenuated).....4.5 - 6.0 log₁₀ CCID₅₀/dose**

* Produced in Vero cells by recombinant DNA technology. This product contains genetically modified organisms (GMOs).

** CCID₅₀: 50% Cell Culture Infectious Dose.