

<u>EMA 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>
EMA/H/W/005362/001	Dengue Tetravalent Vaccine (Live, Attenuated) Takeda	-- ¹	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass) ; solution: vial (glass)	0.5 ml	1 vial + 1 vial
EMA/H/W/005362/002	Dengue Tetravalent Vaccine (Live, Attenuated) Takeda	-- ¹	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass) ; solution: vial (glass)	0.5 ml	10 vials + 10 vials
EMA/H/W/005362/003	Dengue Tetravalent Vaccine (Live, Attenuated) Takeda	-- ¹	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass) ; solution: pre-filled syringe (glass)	0.5 ml	1 vial + 1 pre-filled syringe
EMA/H/W/005362/004	Dengue Tetravalent Vaccine (Live, Attenuated) Takeda	-- ¹	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass) ; solution: pre-filled syringe (glass)	0.5 ml	5 vials + 5 pre-filled syringes
EMA/H/W/005362/005	Dengue Tetravalent Vaccine (Live, Attenuated) Takeda	-- ¹	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass) ; solution: pre-filled syringe (glass)	0.5 ml	1 vial + 1 pre-filled syringe + 2 needles
EMA/H/W/005362/006	Dengue Tetravalent Vaccine (Live, Attenuated) Takeda	-- ¹	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass) ; solution: pre-filled syringe (glass)	0.5 ml	5 vials + 5 pre-filled syringes + 10 needles

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

Dengue virus serotype 1 (live, attenuated)*: $\geq 3.3 \log_{10}$ PFU**/dose

Dengue virus serotype 2 (live, attenuated)#: $\geq 2.7 \log_{10}$ PFU**/dose

Dengue virus serotype 3 (live, attenuated)*: $\geq 4.0 \log_{10}$ PFU**/dose

Dengue virus serotype 4 (live, attenuated)*: $\geq 4.5 \log_{10}$ PFU**/dose

*Produced in Vero cells by recombinant DNA technology. Genes of serotype-specific surface proteins engineered into dengue type 2 backbone

#Produced in Vero cells by recombinant DNA technology

**PFU = Plaque-forming units