

<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/1/22/1699/001	Qdenga	--1	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: vial (glass)	0.5 ml	1 vial + 1 vial
EU/1/22/1699/002	Qdenga	--1	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: vial (glass)	0.5 ml	10 vials + 10 vials
EU/1/22/1699/003	Qdenga	--1	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: pre-filled syringe (glass)	0.5 ml	1 vial + 1 pre-filled syringe
EU/1/22/1699/004	Qdenga	--1	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: pre-filled syringe (glass)	0.5 ml	5 vials + 5 pre-filled syringes
EU/1/22/1699/005	Qdenga	--1	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: pre-filled syringe (glass)	0.5 ml	1 vial + 1 pre-filled syringe + 2 needles
EU/1/22/1699/006	Qdenga	--1	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: pre-filled syringe (glass)	0.5 ml	5 vials + 5 pre-filled syringes + 10 needles

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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