

<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/1/13/887/001	Fluenz Tetra	-- <sup>1</sup>	Nasal spray, suspension	Nasal use	sprayer (glass) in trays	0.2 ml	10 sprayers
EU/1/13/887/002	Fluenz Tetra	-- <sup>1</sup>	Nasal spray, suspension	Nasal use	sprayer (glass)	0.2 ml	1 sprayer
EU/1/13/887/003	Fluenz Tetra	-- <sup>1</sup>	Nasal spray, suspension	Nasal use	sprayer (glass) in a tri-fold carton	0.2 ml	1 sprayer
EU/1/13/887/004	Fluenz Tetra	-- <sup>1</sup>	Nasal spray, suspension	Nasal use	sprayer (glass)	0.2 ml	10 sprayers

--<sup>1</sup> After reconstitution, 1 dose (0.2 ml) contains:

Reassortant influenza virus<sup>1</sup> (live attenuated) of the following four strains<sup>2</sup>:

A/Michigan/45/2015 (H1N1)pdm09-like strain (A/Slovenia/2903/2015, MEDI 279432)	10 <sup>7.0±0.5</sup> FFU <sup>3</sup>
A/Singapore/INFIMH-16-0019/2016 (H3N2) - like strain (A/Singapore/INFIMH-16-0019/2016, MEDI 291690)	10 <sup>7.0±0.5</sup> FFU <sup>3</sup>
B/Colorado/06/2017 - like strain (B/Colorado/06/2017, MEDI 293454)	10 <sup>7.0±0.5</sup> FFU <sup>3</sup>
B/Phuket/3073/2013 - like strain (B/Phuket/3073/2013, MEDI 254977)	10 <sup>7.0±0.5</sup> FFU <sup>3</sup>

<sup>1</sup> propagated in fertilised hens' eggs from healthy chicken flocks.

<sup>2</sup> produced in VERO cells by reverse genetic technology. This product contains genetically modified organisms (GMOs).

<sup>3</sup> fluorescent focus units