

<u>EU Number</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of Administration</u>	<u>Packaging</u>	<u>Content (concentration)</u>	<u>Package size</u>
EU/1/10/624/001	Arepanrix	-- ¹	Suspension and emulsion for emulsion for injection	Intramuscular use	suspension (H1N1): vial (glass); emulsion (adjuvant): vial (glass)	suspension: 2.5 ml; emulsion: 2.5 ml	50 vials (suspension) + 2 x 25 vials (emulsion)

--¹

3.75 µg HA

After mixing, 1 dose (0.5 ml) contains:

Split influenza virus inactivated, containing antigen* equivalent to:

A/California/7/2009 (H1N1)v like strain (X-179A) 3.75 micrograms**

* propagated in eggs

** haemagglutinin

AS03 adjuvant composed of squalene (10.69 milligrams), DL- α -tocopherol (11.86 milligrams) and polysorbate 80 (4.86 milligrams)