

<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>
EU/1/23/1740/001	AREXVY	-- ¹	Powder and suspension for injection	Intramuscular use	powder: vial (glass); suspension: vial (glass)	powder: 120 µg; suspension: 0.5 ml	1 powder vial + 1 suspension vial
EU/1/23/1740/002	AREXVY	-- ¹	Powder and suspension for injection	Intramuscular use	powder: vial (glass); suspension: vial (glass)	powder: 120 µg; suspension: 0.5 ml	10 powder vials + 10 suspension vials

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After reconstitution, one dose (0.5 mL) contains:

RSVPreF3¹ antigen^{2,3} 120 micrograms

¹ Respiratory Syncytial Virus recombinant glycoprotein F stabilised in the pre-fusion conformation = RSVPreF3

² RSVPreF3 produced in Chinese Hamster Ovary (CHO) cells by recombinant DNA technology

³ adjuvanted with AS01E containing:

plant extract Quillaja saponaria Molina, fraction 21 (QS-21) 25 micrograms

3-O-desacyl-4'-monophosphoryl lipid A (MPL) from Salmonella minnesota 25 micrograms