

<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/1/15/1079/001	Vaxelis	-- ¹	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe
EU/1/15/1079/002	Vaxelis	-- ¹	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes
EU/1/15/1079/003	Vaxelis	-- ¹	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe + 1 needle
EU/1/15/1079/004	Vaxelis	-- ¹	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe + 2 needles
EU/1/15/1079/005	Vaxelis	-- ¹	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes + 10 needles
EU/1/15/1079/006	Vaxelis	-- ¹	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes + 20 needles
EU/1/15/1079/007	Vaxelis	-- ¹	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	50 (5x10) pre-filled syringes (multipack)

--¹ One dose (0.5 ml) contains:

Diphtheria Toxoid¹:

not less than 20 IU⁶

Tetanus Toxoid¹:

not less than 40 IU⁶

Bordetella pertussis antigens¹:

Pertussis Toxoid (PT)

20 micrograms

Filamentous Haemagglutinin (FHA)

20 micrograms

Pertactin (PRN)

3 micrograms

Fimbriae Types 2 and 3 (FIM)

5 micrograms

Hepatitis B surface antigen^{2,3}:

10 micrograms

Poliovirus (Inactivated)⁴:

Type 1 (Mahoney)

29 D antigen units⁵;

Type 2 (MEF-1)

7 D antigen units⁵

Type 3 (Saukett)

26 D antigen units⁵

Haemophilus influenzae type b polysaccharide

(Polyribosylribitol Phosphate)

3 micrograms

Conjugated to meningococcal protein²

50 micrograms

¹ adsorbed on aluminium phosphate (0.17 mg Al³⁺)

² adsorbed on amorphous aluminium hydroxyphosphate sulfate (0.15 mg Al³⁺)

³ produced in yeast (*Saccharomyces cerevisiae*) cells by recombinant DNA technology

⁴ produced in Vero cells

⁵ These antigen quantities are strictly the same as those previously expressed as 40-8-32 D-antigen units, for virus type 1, 2 and 3 respectively, when measured by another suitable immunochemical method

⁶ or equivalent activity determined by an immunogenicity evaluation.