

<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)
EU/1/15/1079/008	Vaxelis	--1	Suspension for injection	Intramuscular use	vial (glass)	0.5 ml	10 vials

- 1 One dose (0.5 ml) contains:
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| Diphtheria Toxoid ¹ : | not less than 20 IU ⁶ |
| Tetanus Toxoid ¹ : | not less than 40 IU ⁶ |
| <i>Bordetella pertussis</i> antigens ¹ : | |
| 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) | 40 D antigen units ⁵ ; |
| Type 2 (MEF-1) | 8 D antigen units ⁵ |
| Type 3 (Saukett) | 32 D antigen units ⁵ |
| <i>Haemophilus influenzae</i> type b polysaccharide (Polyribosylribitol Phosphate) | |
| Conjugated to meningococcal protein ² | 3 micrograms |
| Conjugated to aluminium phosphate (0.17 mg Al ³⁺) | 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 or equivalent antigenic quantity determined by a suitable immunochemical method
- ⁶ or equivalent activity determined by an immunogenicity evaluation.