

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

--<sup>1</sup> One dose (0.5 ml) contains:

Diphtheria Toxoid<sup>1</sup>:

not less than 20 IU<sup>6</sup>

Tetanus Toxoid<sup>1</sup>:

not less than 40 IU<sup>6</sup>

*Bordetella pertussis* antigens<sup>1</sup>:

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<sup>2,3</sup>:

10 micrograms

Poliovirus (Inactivated)<sup>4</sup>:

Type 1 (Mahoney)

40 D antigen units<sup>5</sup>;

Type 2 (MEF-1)

8 D antigen units<sup>5</sup>

Type 3 (Saukett)

32 D antigen units<sup>5</sup>

*Haemophilus influenzae* type b polysaccharide

(Polyribosylribitol Phosphate)

3 micrograms

Conjugated to meningococcal protein<sup>2</sup>

50 micrograms

<sup>1</sup> adsorbed on aluminium phosphate (0.17 mg Al<sup>3+</sup>)

<sup>2</sup> adsorbed on amorphous aluminium hydroxyphosphate sulfate (0.15 mg Al<sup>3+</sup>)

<sup>3</sup> produced in yeast (*Saccharomyces cerevisiae*) cells by recombinant DNA technology

<sup>4</sup> produced in Vero cells

<sup>5</sup> or equivalent antigenic quantity determined by a suitable immunochemical method

<sup>6</sup> or equivalent activity determined by an immunogenicity evaluation.