

<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/1/13/828/001	Hexacima	--1	Suspension for injection	Intramuscular use	vial (glass)	0.5 ml	10 vials
EU/1/13/828/002	Hexacima	--1	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe
EU/1/13/828/003	Hexacima	--1	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes
EU/1/13/828/004	Hexacima	--1	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe + 1 needle
EU/1/13/828/005	Hexacima	--1	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes + 10 needle
EU/1/13/828/006	Hexacima	--1	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe + 2 needles
EU/1/13/828/007	Hexacima	--1	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes + 20 needles

--1	One dose <sup>1</sup> (0.5 ml) contains:	
	Diphtheria Toxoid	not less than 20 IU <sup>2</sup>
	Tetanus Toxoid	not less than 40 IU <sup>2</sup>
	Bordetella pertussis antigens	
	Pertussis Toxoid	25 micrograms
	Filamentous Haemagglutinin	25 micrograms
	Poliovirus (Inactivated) <sup>3</sup>	
	Type 1 (Mahoney)	40 D antigen units <sup>4</sup>
	Type 2 (MEF-1)	8 D antigen units <sup>4</sup>
	Type 3 (Saukett)	32 D antigen units <sup>4</sup>
	Hepatitis B surface antigen <sup>5</sup>	10 micrograms
	Haemophilus influenzae type b polysaccharide (Polyribosylribitol Phosphate) conjugated to Tetanus protein	12 micrograms
		22-36 micrograms

<sup>1</sup> Adsorbed on aluminium hydroxide, hydrated (0.6 mg Al<sub>3</sub>+)

<sup>2</sup> As lower confidence limit (p= 0.95)

<sup>3</sup> Produced on Vero cells

<sup>4</sup> Or equivalent antigenic quantity determined by a suitable immunochemical method

<sup>5</sup> Produced in yeast Hansenula polymorpha cells by recombinant DNA technology