

<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/1/00/152/001	Infanrix hexa	-- ¹	Powder and suspension for injection	Intramuscular use	powder: vial (glass); suspension: pre-filled syringe (glass)	suspension: 0.5 ml	1 vial + 1 pre-filled syringe without needle
EU/1/00/152/002	Infanrix hexa	-- ¹	Powder and suspension for injection	Intramuscular use	powder: vial (glass); suspension: pre-filled syringe (glass)	suspension: 0.5 ml	10 vials + 10 prefilled syringes without needles
EU/1/00/152/005	Infanrix hexa	-- ¹	Powder and suspension for injection	Intramuscular use	powder: vial (glass); suspension: pre-filled syringe (glass)	suspension: 0.5 ml	1 vial + 1 pre-filled syringe + 2 needles
EU/1/00/152/006	Infanrix hexa	-- ¹	Powder and suspension for injection	Intramuscular use	powder: vial (glass); suspension: pre-filled syringe (glass)	suspension: 0.5 ml	10 vials + 10 pre-filled syringes + 20 needles
EU/1/00/152/021	Infanrix hexa	-- ¹	Powder and suspension for injection	Intramuscular use	powder: vial (glass); suspension: pre-filled syringe (glass)	suspension: 0.5 ml	50 (5 X 10) vials + 50 (5 X 10) pre-filled syringes without needles (multipack)

--¹ After reconstitution, 1 dose (0.5 ml) contains:

Diphtheria toxoid, adsorbed	≥ 30 IU
Tetanus toxoid, adsorbed	≥ 40 IU
Pertussis toxoid, adsorbed	25 µg
Filamentous haemagglutinin, adsorbed	25 µg
Pertactin, adsorbed	8 µg
Recombinant hepatitis B surface antigen (S protein), adsorbed	10 µg
Inactivated type 1 poliovirus	40 DU
Inactivated type 2 poliovirus	8 DU
Inactivated type 3 poliovirus	32 DU

Conjugate of *Haemophilus influenzae*
type b capsular polysaccharide (PRP)
and tetanus toxoid (T), adsorbed
(PRP-T)

10 µg

Approximately 25 µg