

<u>EMA procedure 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/1/97/029/001	Twinrix Paediatric	- <sup>1</sup> -	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe without needle
EU/1/97/029/002	Twinrix Paediatric	- <sup>1</sup> -	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes without needles
EU/1/97/029/006	Twinrix Paediatric	- <sup>1</sup> -	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe + 1 needle
EU/1/97/029/007	Twinrix Paediatric	- <sup>1</sup> -	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes + 10 needles
EU/1/97/029/008	Twinrix Paediatric	- <sup>1</sup> -	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	50 pre-filled syringes without needles
EU/1/97/029/009	Twinrix Paediatric	- <sup>1</sup> -	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe + 2 needles
EU/1/97/029/010	Twinrix Paediatric	- <sup>1</sup> -	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes + 20 needles

<sup>1</sup>

1 dose (0.5 ml):  
Hepatitis A virus (inactivated)<sup>1,2</sup>  
Hepatitis B surface antigen<sup>3,4</sup>

360 ELISA Units  
10 micrograms

<sup>1</sup>Produced on human diploid (MRC-5) cells

<sup>2</sup>Adsorbed on aluminium hydroxide, hydrated

0.025 milligrams Al<sup>3+</sup>

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

<sup>4</sup>Adsorbed on aluminium phosphate

0.2 milligrams Al<sup>3+</sup>