

Annex A

<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/1/20/1503/001	HEPLISAV B	-- ¹	Solution for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml (40 µg/ml)	5 syringes
EU/1/20/1503/002	HEPLISAV B	-- ¹	Solution for injection	Intramuscular use	Pre-filled syringe (glass)	0.5 ml (40 µg/ml)	1 syringe

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One dose (0.5 ml) contains:

Hepatitis B surface antigen^{1,2} 20 µg

¹Adjuvanted with 3000 micrograms cytidine phosphoguanosine (CpG) 1018 adjuvant, a 22-mer phosphothioate oligonucleotide (PS-ODN) comprising microbial DNA-like unmethylated CpG motifs

²Produced in Hansenula polymorpha yeast cells by recombinant DNA technology