C/2024/5668

30.9.2024

Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 August 2024 to 31 August 2024

(Decisions taken pursuant to Article 34 of Directive 2001/83/EC [1], Article 38 of Directive 2001/82/EC [2] or Article 5 of Regulation (EU) 2019/6 of the European Parliament and of the Council [3])

(C/2024/5668)

— **Issuing, maintenance or modification of a national marketing authorisation**

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorisation	Member State concerned	Date of notification
26.8.2024	Havrix and associated names	inactivated hepatitis A virus	See Annex I	See Annex I	26.8.2024
29.8.2024	Lorazepam Macure	lorazepam	See Annex II	See Annex II	29.8.2024

[1] OJ L 311, 28.11.2001, p. 67, ELI: https://data.europa.eu/eli/dir/2001/83/oj.
[2] OJ L 311, 28.11.2001, p. 1, ELI: https://data.europa.eu/eli/dir/2001/82/oj.
[3] OJ L 4, 7.1.2019, p. 43, ELI: https://data.europa.eu/eli/reg/2019/6/oj.

ANNEX I

List of medicinal products and presentations

Member State EU/EEA	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Austria	GlaxoSmithKline Pharma GmbH Wienerbergstraße 7, 5. Stock 1100 Vienna Austria	HAVRIX 1440	One dose (1,0 ml) contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml
Austria	GlaxoSmithKline Pharma GmbH Wienerbergstraße 7, 5. Stock 1100 Vienna Austria	HAVRIX JUNIOR 720	One dose (0,5 ml) contains: Hepatitis A virus (inactivated) 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml
Belgium	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	HAVRIX 1440	One dose (1,0 ml) contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml
Belgium	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	HAVRIX JUNIOR 720	One dose (0,5 ml) contains: Hepatitis A virus (inactivated) 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml

Member State EU/EEA	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Bulgaria	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 1330 Rixensart Belgium	ХАВРИКС 1440 инжекционна суспензия (доза за възрастни)	One dose (1,0 ml) contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml
Bulgaria	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 1330 Rixensart Belgium	ХАВРИКС 720 инжекционна суспензия (доза за деца)	One dose (0,5 ml) contains: Hepatitis A virus (inactivated) 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml
Cyprus	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	HAVRIX 1440 IU	One dose (1,0 ml) contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml
Cyprus	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	HAVRIX JUNIOR	One dose (0,5 ml) contains: Hepatitis A virus (inactivated) 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml

Member State EU/EEA	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Czech Republic	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	HAVRIX	One dose (1,0 ml) of Havrix 1440 Adult contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml
Czech Republic	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	HAVRIX JUNIOR MONODOSE	One dose (0,5 ml) contains: Hepatitis A virus (inactivated) 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml
Denmark	GlaxoSmithKline Pharma A/S Delta Park 37 2665 Vallensbæk Strand Denmark	HAVRIX	One dose (1,0 ml) of Havrix 1440 Adult contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml
Denmark	GlaxoSmithKline Pharma A/S Delta Park 37 2665 Vallensbæk Strand Denmark	HAVRIX	One dose (0,5 ml) of Havrix for Children contains: Hepatitis A virus (inactivated) 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml

ELI: http://data.europa.eu/eli/C/2024/5668/oj

Member State EU/EEA	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Estonia	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	HAVRIX	One dose (1,0 ml) of Havrix 1440 Adult contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml
Estonia	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	HAVRIX	One dose (0,5 ml) of Havrix 720 Junior contains: Hepatitis A virus (inactivated) 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml
Finland	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	HAVRIX	One dose (1,0 ml) of Havrix 1440 Adult contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml
Finland	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	HAVRIX	One dose (0,5 ml) of Havrix 720 Junior contains: Hepatitis A virus (inactivated) 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml

Member State EU/EEA	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
France	LABORATOIRE GLAXOSMITHKLINE 23, RUE FRANCOIS JACOB 92500 RUEIL MALMAISON France	HAVRIX 1440 U/1ml ADULTES	One dose (1,0 ml) contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml
France	LABORATOIRE GLAXOSMITHKLINE 23, RUE FRANCOIS JACOB 92500 RUEIL MALMAISON France	HAVRIX NOURRISSONS ET ENFANTS 720 U/0,5 ml	One dose (0,5 ml) contains: Hepatitis A virus (inactivated) 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml
Germany	GlaxoSmithKline GmbH & Co. KG Prinzregentenplatz 9 Bogenhausen Bayern 81675 München Germany	Havrix 1440	One dose (1,0 ml) contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml
Germany	GlaxoSmithKline GmbH & Co. KG Prinzregentenplatz 9 Bogenhausen Bayern 81675 München Germany	Havrix 720 Kinder	One dose (0,5 ml) contains: Hepatitis A virus (inactivated) 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml

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Member State EU/EEA	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Greece	GlaxoSmithKline Single Member A.E.B.E. Kifissias avenue 266 152 32 Halandri, Athens Greece	HAVRIX	One dose (1,0 ml) of Havrix 1440 Adult contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml
Greece	GlaxoSmithKline Single Member A.E.B.E. Kifissias avenue 266 152 32 Halandri, Athens Greece	HAVRIX	One dose (0,5 ml) of Havrix 720 Junior contains: Hepatitis A virus (inactivated) 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml
Hungary	GlaxoSmithKline Biologicals SA Rue de l'Institut 89, B-1330 Rixensart, Belgium	HAVRIX 1440	One dose (1,0 ml) contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml
Hungary	GlaxoSmithKline Biologicals SA Rue de l'Institut 89, B-1330 Rixensart, Belgium	HAVRIX 720 JUNIOR	One dose (0,5 ml) contains: Hepatitis A virus (inactivated) 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml

Member State EU/EEA	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Iceland	GlaxoSmithKline Pharma A/S Delta Park 37 2665 Vallensbæk Strand Denmark	HAVRIX	One dose (1,0 ml) of Havrix 1440 Adult contains: Hepatitis A virus (inactivated) ≥ 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml
Iceland	GlaxoSmithKline Pharma A/S Delta Park 37 2665 Vallensbæk Strand Denmark	HAVRIX	One dose (0,5 ml) of Havrix 720 Junior contains: Hepatitis A virus (inactivated) ≥ 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml
Ireland	GLAXOSMITHKLINE (IRELAND) LIMITED 12 Riverwalk, Citywest Business Campus, Ireland	HAVRIX MONODOSE	One dose (1,0 ml) contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml
Ireland	GLAXOSMITHKLINE (IRELAND) LIMITED 12 Riverwalk, Citywest Business Campus, Ireland	HAVRIX JUNIOR MONODOSE	One dose (0,5 ml) contains: Hepatitis A virus (inactivated) 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml

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Member State EU/EEA	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Italy	GlaxoSmithKline S.p.A. Viale dell'Agricoltura, 7 37135 Verona VR Italy	HAVRIX	One dose (1,0 ml) contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml
Italy	GlaxoSmithKline S.p.A. Viale dell'Agricoltura, 7 37135 Verona VR Italy	HAVRIX	One dose (0,5 ml) contains: Hepatitis A virus (inactivated) 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml
Latvia	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	HAVRIX 1440 ELISA units/ml vienības/ml suspensija injekcijām	One dose (1,0 ml) contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml
Latvia	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	HAVRIX 720 ELISA units/0,5 ml vienības/0,5 ml suspensija injekcijām	One dose (0,5 ml) contains: Hepatitis A virus (inactivated) 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml

Member State EU/EEA	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Lithuania	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	Havrix 1440 ELISA vienetų/ml injekcinė suspensija	One dose (1,0 ml) contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0m50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml
Lithuania	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	Havrix 720 ELISA vienetų/0,5 ml injekcinė suspensija	One dose (0m5 ml) contains: Hepatitis A virus (inactivated) 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0m25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml
Luxembourg	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	HAVRIX 1440	One dose (1,0 ml) contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml
Luxembourg	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	HAVRIX JUNIOR 720	One dose (0,5 ml) contains: Hepatitis A virus (inactivated) 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml
Malta	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24 Ireland	HAVRIX MONO-DOSE	One dose (1,0 ml) contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml

Member State EU/EEA	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Malta	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24 Ireland	HAVRIX JUNIOR	One dose (0,5 ml) contains: Hepatitis A virus (inactivated) 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total : 0,25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml
Netherlands	GlaxoSmithKline BV Van Asch van Wijckstraat 55H 3811 LP Amersfoort Netherlands	HAVRIX 1440	One dose (1,0 ml) contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml
Netherlands	GlaxoSmithKline BV Van Asch van Wijckstraat 55H 3811 LP Amersfoort Netherlands	HAVRIX JUNIOR	One dose (0,5 ml) contains: Hepatitis A virus (inactivated) 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml
Norway	GlaxoSmithKline AS Postboks 180, Vinderen 0319 Oslo Norway	Havrix	1,0 ml of Havrix 1440 contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml

Member State EU/EEA	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Norway	GlaxoSmithKline AS Postboks 180, Vinderen 0319 Oslo Norway	Havrix	1,0 ml of Havrix 1440 contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml
Poland	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	HAVRIX ADULT	One dose (1,0 ml) contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml
Poland	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	HAVRIX 720 JUNIOR	One dose (0,5 ml) contains: Hepatitis A virus (inactivated) 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml
Portugal	Smith Kline & French Portuguesa-Produtos Farmaceuticos LDA Rua Dr. António Loureiro Borges, 3 Arquiparque, Miraflores Algés 1495-131 Algés Portugal	HAVRIX 1440 ADULTO	One dose (1,0 ml) contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml

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Member State EU/EEA	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Portugal	Smith Kline & French Portuguesa-Produtos Farmaceuticos LDA Rua Dr. António Loureiro Borges, 3 Arquiparque, Miraflores Algés 1495-131 Algés Portugal	HAVRIX 720 Júnior	One dose (0,5 ml) contains: Hepatitis A virus (inactivated) 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml
Romania	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	HAVRIX ADULT 1440 suspensie injectabilă	One dose (1,0 ml) contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml
Romania	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	HAVRIX JUNIOR 720 suspensie injectabilă	One dose (0,5 ml) contains: Hepatitis A virus (inactivated) 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml
Slovak Republic	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	HAVRIX 1440 Dosis adulta	One dose (1,0 ml) contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml
Slovak Republic	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	HAVRIX 720 Junior monodose	One dose (0,5 ml) contains: Hepatitis A virus (inactivated) 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml

Member State EU/EEA	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Slovenia	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	HAVRIX 1440 ELISA enot suspenzija za injiciranje za odrasle	One dose (1,0 ml) contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml
Slovenia	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	HAVRIX 720 ELISA enot suspenzija za injiciranje za otroke	One dose (0,5 ml) contains: Hepatitis A virus (inactivated) 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml
Spain	GlaxoSmithKline S.A. Severo Ochoa, 2 Parque Tecnologico de Madrid Tres Cantos 28760 Madrid Spain	HAVRIX 1440 suspensión inyectable en jeringa precargada	One dose (1,0 ml) contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml
Spain	GlaxoSmithKline S.A. Severo Ochoa, 2 Parque Tecnologico de Madrid Tres Cantos 28760 Madrid Spain	HAVRIX 720 suspensión inyectable en jeringa precargada	One dose (0,5 ml) contains: Hepatitis A virus (inactivated) 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml

Member State EU/EEA	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Sweden	GlaxoSmithKline AB P.O. Box 516 169 29 Solna Sweden	Havrix	One dose (1,0 ml) of Havrix contains: Hepatitis A virus (inactivated) 1440 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,50 milligrams Al^{3+}	Suspension for injection	Intramuscular use	1 ml
Sweden	GlaxoSmithKline AB P.O. Box 516 169 29 Solna Sweden	Havrix	One dose (0,5 ml) of Havrix contains: Hepatitis A virus (inactivated) 720 ELISA Units Produced on human diploid (MRC-5) cells Adsorbed on aluminium hydroxide, hydrated Total: 0,25 milligrams Al^{3+}	Suspension for injection	Intramuscular use	0,5 ml

ANNEX II

List of medicinal products and presentations

Member State EU/EEA	Marketing authorisation holder company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Austria	Macure Pharma ApS, Hejrevej 39, 2400 Copenhagen NV, Denmark	Lorazepam Macure 4 mg/ml Injektionslösung	4 mg/ml	Solution for injection	Intravenous use, Intramuscular use	4 mg
Belgium	Macure Pharma ApS, Hejrevej 39, 2400 Copenhagen NV, Denmark	Lorazepam Macure 4 mg/ml solution injectable / oplossing voor injectie	4 mg/ml	Solution for injection	Intravenous use, Intramuscular use	4 mg
Denmark	Macure Pharma ApS, Hejrevej 39, 2400 Copenhagen NV, Denmark	Lorazepam Macure	4 mg/ml	Solution for injection	Intravenous use, Intramuscular use	4 mg
Finland	Macure Pharma ApS, Hejrevej 39, 2400 Copenhagen NV, Denmark	Lorazepam Macure 4 mg/ml injektioneste, liuos / injektionsvätska, lösning	4 mg/ml	Solution for injection	Intravenous use, Intramuscular use	4 mg
Germany	Macure Pharma ApS, Hejrevej 39, 2400 Copenhagen NV, Denmark	Lorazepam Macure	4 mg/ml	Solution for injection	Intravenous use, Intramuscular use	4 mg
Ireland	Macure Pharma ApS, Hejrevej 39, 2400 Copenhagen NV, Denmark	Lorazepam Macure 4 mg/ml solution for injection	4 mg/ml	Solution for injection	Intravenous use, Intramuscular use	4 mg
Italy	Macure Pharma ApS, Hejrevej 39, 2400 Copenhagen NV, Denmark	Lorazepam Macure	4 mg/ml	Solution for injection	Intravenous use, Intramuscular use	4 mg
The Netherlands	Macure Pharma ApS, Hejrevej 39, 2400 Copenhagen NV, Denmark	Lorazepam Macure 4 mg/ml oplossing voor injectie	4 mg/ml	Solution for injection	Intravenous use, Intramuscular use	4 mg
Norway	Macure Pharma ApS, Hejrevej 39, 2400 Copenhagen NV, Denmark	Lorazepam Macure	4 mg/ml	Solution for injection	Intravenous use, Intramuscular use	4 mg

ELI: http://data.europa.eu/eli/C/2024/5668/oj

Member State EU/EEA	Marketing authorisation holder company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Slovenia	Macure Pharma ApS, Hejrevej 39, 2400 Copenhagen NV, Denmark	Lorazepam Macure 4 mg/ml raztopina za injiciranje	4 mg/ml	Solution for injection	Intravenous use, Intramuscular use	4 mg
Sweden	Macure Pharma ApS, Hejrevej 39, 2400 Copenhagen NV, Denmark	Lorazepam Macure	4 mg/ml	Solution for injection	Intravenous use, Intramuscular use	4 mg