

Anness I

Lista ta' prodotti medicinali u prezentazzjonijet

Member State EU/EEA	Marketing authorisation holder company name, address	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Austria	GlaxoSmithKline Pharma GmbH Euro Plaza, Gebäude I, 4. Stock Wagenseilgasse 3 1120 Vienna Austria	VARILRIX	Varicella virus (OKA strain): ≥ 10 ^{3.3} plaque forming unit(s)	Powder and solvent for solution for injection	Subcutaneous use
Belgium	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	VARILRIX	Live attenuated Varicella virus (OKA strain): ≥ 10 ^{3.3} plaque forming unit(s)	Powder and solvent for solution for injection	Subcutaneous use
Cyprus	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	VARILRIX	Varicella virus (OKA strain): ≥ 10 ^{3.3} plaque forming unit(s)	Powder and solvent for solution for injection	Subcutaneous use
Czech Republic	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	VARILRIX	Varicella virus (OKA strain): ≥ 10 ^{3.3} plaque forming unit(s)	Powder and solvent for solution for injection	Subcutaneous use
Denmark	GlaxoSmithKline Pharma A/S Nykaer 68 DK-2605 Broendby Denmark	VARILRIX	Varicella zoster-virus ≥2000 plaque forming unit(s) per dose	Powder and solvent for solution for injection	Subcutaneous use

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Estonia	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	VARILRIX	Varicella virus (OKA strain): ≥ 10 ^{3.3} plaque forming unit(s)	Powder and solvent for solution for injection	Subcutaneous use
Finland	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	VARILRIX	Varicella virus (OKA strain): ≥ 10 ^{3.3} plaque forming unit(s)	Powder and solvent for solution for injection	Subcutaneous use
France	LABORATOIRE GLAXOSMITHKLINE 23, RUE FRANCOIS JACOB 92500 RUEIL MALMAISON France	VARILRIX	Live attenuated Varicella virus (OKA strain): not less than 10 ^{3.3} plaque forming unit(s)	Powder and solvent for solution for injection	Subcutaneous use
Germany	GlaxoSmithKline GmbH & Co. KG Prinzregentenplatz 9 Bogenhausen Bayern 81675 München Germany	VARILRIX	Varicella virus (OKA strain): ≥ 10 ^{3.3} plaque forming unit(s)	Powder and solvent for solution for injection	Subcutaneous use Intramuscular use

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Greece	GlaxoSmithKline Single Member A.E.B.E. Kifissias avenue 266 152 32 Halandri, Athens Greece	VARILRIX	Varicella virus (OKA strain): ≥ 10 ^{3.3} plaque forming unit(s)	Powder and solvent for solution for injection	Subcutaneous use
Hungary	GlaxoSmithKline Kft. 43. Csörsz Street 1124 Budapest Hungary	VARILRIX	Varicella virus (OKA strain): ≥ 10 ^{3.3} plaque forming unit(s)	Powder and solvent for solution for injection	Subcutaneous use
Iceland	GlaxoSmithKline Pharma A/S Nykaer 68 DK-2605 Broendby Denmark	VARILRIX	Varicella virus (OKA strain): ≥ 10 ^{3.3} plaque forming unit(s)	Powder and solvent for solution for injection	Subcutaneous use
Italy	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	VARILRIX	Varicella virus (OKA strain): not less than 2000 plaque forming unit(s)	Powder and solvent for solution for injection	Subcutaneous use
Latvia	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	VARILRIX pulveris un šķīdinātājs injekciju šķīduma pagatavošanai	Varicella virus (OKA strain): ≥ 10 ^{3.3} plaque forming unit(s)	Powder and solvent for solution for injection	Subcutaneous use

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Lithuania	GlaxoSmithKline Lietuva UAB Ukmergės st. 120 LT-08105 Vilnius Lithuania	Varilrix milteliai ir tirpiklis injekciniam tirpalui	Varicella virus (OKA strain): ≥ 10 ^{3.3} plaque forming unit(s)	Powder and solvent for solution for injection	Subcutaneous use
Luxembourg	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	VARILRIX	Live attenuated Varicella virus (OKA strain): ≥ 10 ^{3.3} plaque forming unit(s)	Powder and solvent for solution for injection	Subcutaneous use
Malta	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	VARILRIX	Varicella virus (OKA strain): ≥ 10 ^{3.3} plaque forming unit(s)	Powder and solvent for solution for injection	Subcutaneous use
Norway	GlaxoSmithKline AS Postboks 180, Vinderen 0319 Oslo Norway	VARILRIX	Varicella virus (OKA strain): ≥ 10 ^{3.3} plaque forming unit(s)	Powder and solvent for solution for injection	Subcutaneous use
Poland	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	VARILRIX	Not less than 2000 plaque forming unit(s) of Varicella zoster virus, OKA strain/0,5 ml	Powder and solvent for solution for injection	Subcutaneous use

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Portugal	Smith Kline & French Portuguesa-Produtos Farmaceuticos LDA Rua Dr. António Loureiro Borges, 3 Arquiparque, Miraflores Algés 1495-131 Algés Portugal	VARILRIX	Varicella virus (OKA strain): ≥ 10 ^{3.3} plaque forming unit(s)	Powder and solvent for solution for injection	Subcutaneous use
Romania	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 B-1330 Rixensart Belgium	Varilrix vaccin varicelic viu atenuat, pulbere și solvent pentru solutie injectabila	Varicella virus (OKA strain): ≥ 10 ^{3.3} plaque forming unit(s)/0.5 ml	Powder and solvent for solution for injection	Subcutaneous use
Spain	GlaxoSmithKline S.A. Severo Ochoa, 2 Parque Tecnologico de Madrid Tres Cantos 28760 Madrid Spain	VARILRIX 103,3 UFP/0,5 ml polvo y disolvente para solución inyectable	Varicella virus (OKA strain): ≥ 10 ^{3.3} plaque forming unit(s)	Powder and solvent for solution for injection	Subcutaneous use
Sweden	GlaxoSmithKline AB P.O. Box 516 169 29 Solna Sweden	Varilrix	Varicella virus (OKA strain): ≥ 10 ^{3.3} plaque forming unit(s)	Powder and solvent for solution for injection	Subcutaneous use

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United Kingdom (Northern Ireland)	SmithKline Beecham Ltd trading as GlaxoSmithKline UK 980, Great West Road Brentford Middlesex TW8 9GS United Kingdom	Varilrix 10 ^{3.3} PFU/0.5ml, powder and solvent for solution for injection	One dose (0.5 ml) contains: Live attenuated varicella- zoster (Oka strain) virus* $10^{3.3}$ plaque forming units (PFU) *propagated in MRC5 human diploid cells	Powder and solvent for solution for injection	Subcutaneous use