



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 June 2015
EMA/449226/2015
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: Sumatriptan

Procedure no.: PSUSA/00002832/201409



Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Imigra	NL/H/115/02	027975135/M 027975147/M	GlaxoSmithKline SpA	Italy
Imigran	NL/H/115/01	18362	GlaxoSmithKline Pharma A/S	Denmark
Imigran	NL/H/115/01	027975123/M	GlaxoSmithKline SpA	Italy
Imigran	NL/H/115/01	13219	GlaxoSmithKline AB	Sweden
Imigran	NL/H/115/01	PL 10949/0260	Glaxo Wellcome UK Ltd	United Kingdom
Imigran		IS/1/05/102/01	GlaxoSmithKline ehf	Iceland
Imigran		PA 1077/008/003	GlaxoSmithKline (Ireland) Limited	Ireland
IMIGRAN		5363-I-1223/13	GlaxoSmithKline d.o.o	Slovenia
Imigran	NL/H/115/02	18363	GlaxoSmithKline Pharma A/S	Denmark
Imigran	NL/H/115/02	13220	GlaxoSmithKline AB	Sweden
Imigran	NL/H/115/02	PL 10949/0261	Glaxo Wellcome UK Ltd	United Kingdom
Imigran		UP/I-530-09/09-02/422	GlaxoSmithKline d.o.o.	Croatia
Imigran		167997	Glaxo Wellcome UK Ltd	Estonia
Imigran		OGYI-T-5410/04	GlaxoSmithKline Kft	Hungary
Imigran		980420	GlaxoSmithKline ehf.	Iceland
Imigran		PA 1077/008/004	GlaxoSmithKline (Ireland) Limited	Ireland
Imigran		LT/1/94/0344/003	GlaxoSmithKline	Lithuania

			Lietuva UAB	
Imigran		95-2920	GlaxoSmithKline AS	Norway
Imigran		4916	GlaxoSmithKline Export Ltd	Poland
Imigran		33/0244/99-S	GlaxoSmithKline s.r.o.	Slovakia
Imigran		5363-I-1224/13	GlaxoSmithKline d.o.o	Slovenia
Imigran	NL/H/119/001	1845	GlaxoSmithKline Pharma A/S	Denmark
Imigran	NL/H/119/001	027975097 027975109 027975111	GlaxoSmithKline SpA	Italy
Imigran	NL/H/119/001	13277	GlaxoSmithKline AB	Sweden
Imigran		96-1007	GlaxoSmithKline AS	Norway
Imigran		9654	GlaxoSmithKline Export Ltd	Poland
Imigran		1-21119	GlaxoSmithKline Pharma GmbH	Austria
IMIGRAN		9600076	GlaxoSmithKline EOOD	Bulgaria
Imigran		UP/I-530-09/10-02/130	GlaxoSmithKline d.o.o	Croatia
IMIGRAN		19508	Glaxo Group Ltd	Cyprus
IMIGRAN		31483.01.00 31485.01.00	GlaxoSmithKline GmbH & Co. KG	Germany
Imigran		29284/15-12-11	GlaxoSmithKline AEBE	Greece
Imigran		OGYI-T 5410/01	GlaxoSmithKline Kft	Hungary
Imigran		98-0612	GlaxoSmithKline Latvia SIA	Latvia
Imigran		LT/1/94/0344/002	GlaxoSmithKline Lietuva UAB	Lithuania
Imigran		167/00901	Glaxo Wellcome UK	Malta

			Ltd	
Imigran		7991	GlaxoSmithKline AS	Norway
Imigran		7381	GlaxoSmithKline Export Ltd	Poland
Imigran		5363-I-1225/13	GlaxoSmithKline d.o.o	Slovenia
Imigran		10949/0222	Glaxo Wellcome UK Ltd	United Kingdom
Imigran		1-19777	GlaxoSmithKline Pharma GmbH	Austria
IMIGRAN		25621.00.01 25623.00.01	GlaxoSmithKline GmbH & Co. KG	Germany
Imigran		29283/15-12-11	GlaxoSmithKline AEBE	Greece
Imigran		OGYI-T-5410/02 OGYI-T-5410/03	GlaxoSmithKline Kft	Hungary
Imigran		LT/1/94/0344/001	GlaxoSmithKline Lietuva UAB	Lithuania
Imigran		7896	GlaxoSmithKline AS	Norway
Imigran		R/1516	GlaxoSmithKline Export Ltd	Poland
Imigran		33/0265/93-S	GlaxoSmithKline s.r.o.	Slovakia
Imigran		5363-I-1226/13	GlaxoSmithKline d.o.o	Slovenia
Imigran		10949/0231	Glaxo Wellcome UK Ltd	United Kingdom
Imigran		437504	GlaxoSmithKline Export Ltd	Estonia
IMIGRAN		PA 1077/008/006	GlaxoSmithKline (Ireland) Limited	Ireland
Imigran		027975073	GlaxoSmithKline SpA	Italy
IMIGRAN		RVG 29413	GlaxoSmithKline	Netherlands

			BV	
Imigran		437604	GlaxoSmithKline Export Ltd	Estonia
IMIGRAN		PA 1077/008/007	GlaxoSmithKline (Ireland) Limited	Ireland
Imigran		027975059	GlaxoSmithKline SpA	Italy
IMIGRAN		RVG 29414	GlaxoSmithKline BV	Netherlands
Imigran		1-19773	GlaxoSmithKline Pharma GmbH	Austria
Imigran		33/701/93-C	Glaxo Group Ltd	Czech Republic
IMIGRAN		14113	GlaxoSmithKline Pharma A/S	Denmark
IMIGRAN		10737	Glaxo Operations UK Ltd	Finland
IMIGRAN		25623.00.00	GlaxoSmithKline GmbH & Co. KG	Germany
Imigran		29281/15-12-11	GlaxoSmithKline AEBE	Greece
Imigran		OGYI-T-5410/05	GlaxoSmithKline Kft	Hungary
Imigran		900125	GlaxoSmithKline ehf.	Iceland
Imigran		027975061	GlaxoSmithKline SpA	Italy
IMIGRAN		RVG 15009	GlaxoSmithKline BV	Netherlands
Imigran		7895	GlaxoSmithKline AS	Norway
Imigran		R/1515	GlaxoSmithKline Export Ltd	Poland
Imigran		8788604 8788612	Glaxo Wellcome Farmaceutica Lda	Portugal
Imigran		33/266/93-S	Glaxo Group Ltd	Slovakia

Imigran		5363-I-1227/13	GlaxoSmithKline d.o.o	Slovenia
IMIGRAN		59.973	GlaxoSmithKline S.A.	Spain
Imigran		11435	GlaxoSmithKline AB	Sweden
Imigran		10949/0113	Glaxo Wellcome UK Ltd	United Kingdom
Imigran - Suppositories	NL/H/119/001	1-2185	GlaxoSmithKline Pharma GmbH	Austria
Imigran 10 Neusspray	NL/H/115/01	RVG 19469	GlaxoSmithKline BV	Netherlands
Imigran 10 mg nenäsumute	NL/H/115/01	12426	GlaxoSmithKline Oy	Finland
Imigran 10 mg solución para pulverización nasal	NL/H/115/01	61.629	GlaxoSmithKline S.A.	Spain
Imigran 20 Neusspra	NL/H/115/02	RVG 19470	GlaxoSmithKline BV	Netherlands
Imigran 20 mg nenäsumut	NL/H/115/02	12427	GlaxoSmithKline Oy	Finland
Imigran 20 mg solución para pulverización nasa	NL/H/115/02	61.630	GlaxoSmithKline S.A.	Spain
Imigran 25 mg peräpuikko	NL/H/119/001	1247	GlaxoSmithKline Oy	Finland
Imigran 25 Zetpil	NL/H/119/001	RVG 19853	GlaxoSmithKline BV	Netherlands
IMIGRAN DR		2922/2010/01-05	Glaxo Wellcome UK Ltd	Romania
IMIGRAN DR		2921/2010/01-05	Glaxo Wellcome UK Ltd	Romaina
Imigran FDT		04-0358	GlaxoSmithKline Latvia SIA	Latvia
Imigran FDT		12497	GlaxoSmithKline Export Ltd	Poland

Imigran FDT		12498	GlaxoSmithKline Export Ltd	Poland
Imigran Inalador Nasal	NL/H/115/01	2539583, 2539682, 2711786, 2711885, 2711984, 2712081	Glaxo Wellcome Farmacêutica Lda	Portugal
Imigran Inalador Nasa	NL/H/115/02	2539781, 2539880, 2712180, 2539989, 2712289, 2712388	Glaxo Wellcome Farmacêutica Lda	Portugal
Imigran Juvenil		95-2919	GlaxoSmithKline AS	Norway
Imigran Migraine Relief		PA 0678/110/01	GlaxoSmithKline Consumer Healthcare (Ireland) Ltd	Ireland
Imigran Nasal 20 m	NL/H/115/02	31483.01.01	GlaxoSmithKline GmbH & Co. KG	Germany
Imigran Nasal mite 10 mg	NL/H/115/01	31483.00.01	GlaxoSmithKline GmbH & Co. KG	Germany
Imigran Neo		66.406	GlaxoSmithKline S.A.	Spain
Imigran Novum		19492	GlaxoSmithKline AB	Sweden
Imigran Novum		19493	GlaxoSmithKline AB	Sweden
Imigran Radis		18197	GlaxoSmithKline Oy	Finland
Imigran Radis		IS/1/04/190/01	GlaxoSmithKline ehf.	Iceland
Imigran Radis		03-1915	GlaxoSmithKline AS	Norway
Imigran Radis		19494/0013	GlaxoSmithKline UK Ltd	United Kingdom
Imigran Radis		18198	GlaxoSmithKline Oy	Finland

Imigran Radis		IS/1/04/190/02	GlaxoSmithKline ehf.	Iceland
Imigran Radis		03-1916	GlaxoSmithKline AS	Norway
Imigran Radis		19494/0014	Glaxo Wellcome UK Ltd	United Kingdom
Imigran Sprint		34997	GlaxoSmithKline Pharma A/S	Denmark
Imigran Sprint		OGYI-T-10096/01 OGYI-T-10096/02 OGYI-T-10096/03 OGYI-T-10096/04 OGYI-T-10096/05	GlaxoSmithKline Kft	Hungary
Imigran Sprint		33/0292/05-S	Glaxo Group Ltd	Slovakia
Imigran Sprint		5363-I-845/14 5363-I-846/14 5363-I-847/14	GlaxoSmithKline d.o.o	Slovenia
Imigran Sprint		34998	GlaxoSmithKline Pharma A/S	Denmark
Imigran Sprint		OGYI-T-10096/06 OGYI-T-10096/07 OGYI-T-10096/08 OGYI-T-10096/09 OGYI-T-10096/10	GlaxoSmithKline Kft	Hungary
Imigran Sprint		33/0290/05-S	Glaxo Group Ltd	Slovakia
Imigran Sprint		5363-I-848/14 5363-I-849/14	GlaxoSmithKline d.o.o	Slovenia
Imigran T		LT/1/06/0531/001	GlaxoSmithKline Lietuva UAB	Lithuania
Imigran T		LT/1/06/0531/002	GlaxoSmithKline Lietuva UAB	Lithuania
Imigran Zäpfchen	NL/H/119/001	31483.00.0	GlaxoSmithKline GmbH & Co. KG	Germany
IMIGRANE		NL22468	Laboratoire GlaxoSmithKline	France
IMIGRANE		NL22469	Laboratoire GlaxoSmithKline	France

IMIGRANE		NL22916	Laboratoire GlaxoSmithKline	France
IMIGRANE		NL17324	Laboratoire GlaxoSmithKline	France
IMIJECT		NL20439	Laboratoires Paucourt	France
Imitre	NL/H/115/02	260/07/11/9552	GlaxoSmithKline Pharmaceuticals s.a./n.v.	Luxemburg
Imitrex	NL/H/115/01	BE182716	GlaxoSmithKline Pharmaceuticals s.a./n.v.	Belgium
Imitrex	NL/H/115/01	260/07/11/9551	GlaxoSmithKline Pharmaceuticals s.a./n.v.	Luxemburg
Imitrex	NL/H/115/02	BE182707	GlaxoSmithKline Pharmaceuticals s.a./n.v.	Belgium
Imitrex		BE157473	GlaxoSmithKline Pharmaceuticals s.a.	Belgium
Imitrex		0260/01/11/6611	GlaxoSmithKline Pharmaceuticals s.a.	Luxemburg
Imitrex Instant		BE279465	GlaxoSmithKline Pharmaceuticals s.a.	Belgium
Imitrex Instant		0260/06030004	GlaxoSmithKline Pharmaceuticals s.a.	Luxemburg
Imitrex Instant		BE279474	GlaxoSmithKline Pharmaceuticals s.a.	Belgium
Imitrex Instant		260/06 03 0005	GlaxoSmithKline Pharmaceuticals s.a.	Luxemburg
Migrave		155513/0353	McNeill Products Limited	United Kingdom
NOMIGRANE		NL22920	GlaxoSmithKline	France

50mg, comprimé pelliculé			Santé Grand Public	
Rosemig		33/148/99-C	Montrose Fine Chemical Company Ltd	Czech Republic
Rosemig		33/149/99-C	Montrose Fine Chemical Company Ltd	Czech Republic
Rosemig		33/025/04-C	Montrose Fine Chemical Company Ltd	Czech Republic
Rosemig		33/026/04-C	Montrose Fine Chemical Company Ltd	Czech Republic
Rosemig		33/195/04-C	Montrose Fine Chemical Company Ltd	Czech Republic
Rosemig		33/196/04-C	Montrose Fine Chemical Company Ltd	Czech Republic
SUMA GSK		57494.00.00 57920.00.00	GlaxoSmithKline GmbH & Co. KG	Germany
SUMA GSK		57494.01.00 57920.01.00	GlaxoSmithKline GmbH & Co. KG	Germany
Sumatriptan 100mg tablets		PL 11311/0440	Tillomed Laboratoris Limited	United Kingdom
Sumatriptan 50 mg tablets		PL 11311/0439	Tillomed Laboratories Limited	United Kingdom
Sumatriptan GSK 20 mg/0,1 ml Nasenspray, Lösung im		87686.00.00	GlaxoSmithKline Consumer Healthcare GmbH &	Germany

Einzel dosisbehältnis			Co. Kg	
Sumatriptan GSK		38279	GlaxoSmithKline Pharma A/S	Denmark
Sumatriptan GSK		38280	GlaxoSmithKline Pharma A/S	Denmark
Sumatriptan ratiopharm T 100 mg Filmdabletten	57918.01.00	918.01.00	ratiopharm GmbH; Graf-Arco-Str. 3, 89079 Ulm, German	Germany
Sumatriptan ratiopharm T 50 mg Filmdabletten	57918.00.00	57918.00.00	ratiopharm GmbH; Graf-Arco-Str. 3, 89079 Ulm, German	Germany
Sumatriptan ratiopharm 100 mg Filmdabletten	58693.01.01	58693.01.01	ratiopharm GmbH; Graf-Arco-Str. 3, 89079 Ulm, German	Germany
Sumatriptan ratiopharm 50 mg Filmdabletten	58693.00.01	58693.01.01	ratiopharm GmbH; Graf-Arco-Str. 3, 89079 Ulm, German	Germany
Sumavel DosePro	DE/H/2603/001/DC	2179680	Endo Ventures Limited	Germany
Sumavel DosePro	DE/H/2603/001/DC	45913	Endo Ventures Limited	Denmark
Suvalan		PA 0678/108/01	GlaxoSmithKline Consumer Healthcare (Ireland) Ltd	Ireland
Suvalan		PA 0678/108/02	GlaxoSmithKline	Ireland

			Consumer Healthcare (Ireland) Ltd	
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