



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

20 July 2016  
EMA/587045/2016  
Procedure Management and Committees Support

## List of nationally authorised medicinal products

Active substance: minoxidil (topical formulation)

Procedure no.: PSUSA/00002067/201510



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
Alopexy		330 228-5	Pierre Fabre Dermatologie	France
Alopexy		BE286921	Pierre Fabre Benelux	Belgium
Alopexy	FR/H/0446/01/MR	1-30439	Pierre Fabre Dermatologie	Austria
Alopexy	FR/H/0446/01/MR	17842	Pierre Fabre Dermatologie	Poland
Alopexy	FR/H/0446/01/MR	34009 368 846 8 7	Pierre Fabre Dermatologie	France
Alopexy	FR/H/0446/01/MR	72923	Pierre Fabre Dermatologie	Spain
Alopexy	FR/H/0446/01/MR	81238.00.00	Pierre Fabre Dermokosmetik	Germany
Alopexy	FR/H/0446/01/MR	88474/27-12-2010	Pierre Fabre Hellas / Greece	Greece
Alopexy	FR/H/446/01/MR	BE376537	Pierre Fabre Benelux	Belgium
Alorexyl	FR/H/0446/01/MR	5316229	Pfdr / Portugal	Portugal
Regaine		1-20070 \$ 1-22451	Johnson & Johnson Gmbh	Austria
Regaine	SE/H/1173/01/DC	135574	Johnson & Johnson Gmbh	Austria
Aloxidil		027261015	Idi Farmaceutici Srl	Italy
Lacovin		58.331 \$ 66.881	Laboratorios Galderma, S.A.	Spain
Minovital		026796021	Laboratorio Terapeutico M.R. S.R.L.	Italy
Minoxidil Bio-H-Tin-Pharma	AT/H/0451/001 \$ AT/H/0451/002	1-31856 \$ 1-31857	Bio-H-Tin Pharma Gmbh & Co. Kg	Austria
Minoxidil Bio-H-Tin-Pharma	AT/H/0451/001 \$ AT/H/0451/002	87412.00.00 \$ 87413.00.00	Bio-H-Tin Pharma Gmbh & Co. Kg	Germany
Minoxidil Bailleul	NAT/H/5205	BE365504 \$ BE365513	Laboratoire Bailleul S.A.	Belgium
Minoxidil Sandoz Conseil	NL 20999	364 017-7 \$ 368 822-1 \$ 368 823-8 \$ 381 460-2	Sandoz	France
Minoximen		026729018 \$ 026729032	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Italy
Neoxidil		2007069351	Galderma Benelux B.V.	Luxembourg
Neoxidil		330 360-0	Galderma International	France
Neoxidil		BE137663	Galderma Benelux B.V.	Belgium
Regaine		BE 135965 \$ BE 165794	Johnson & Johnson Consumer N.V./S.A.	Belgium
Regaine		BE 150561	Johnson & Johnson Consumer N.V./S.A.	Belgium
Regaine	SE/H/1173/01/DC	BE435732	Johnson & Johnson Consumer N.V./S.A.	Belgium

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Regaine		19984 \$ 19985	Johnson & Johnson Hellas Consumer Ae	Cyprus
Regaine 5%		46/180/88-B/C	Mcneil Products Limited	Czech Republic
Regaine Forte		15280	Mcneil Denmark Aps	Denmark
Regaine Forte	SE/H/1173/01/DC	49353	Mcneil Denmark Aps	Denmark
Regaine		276599 \$ 276699	Mcneil Products Limited	Estonia
Rogaine		11442 \$ 9790	Mcneil, A Division Of Janssen-Cilag Oy	Finland
Rogaine	SE/H/1173/01/DC	30033	Mcneil, A Division Of Janssen-Cilag Oy	Finland
Regaine Frauen		42877.01.00 \$ 58036.00.00	Johnson & Johnson Gmbh	Germany
Regaine Männer Schaum		78203.00.00 \$ 90282.00.00	Johnson & Johnson Gmbh	Germany
Regaine Männer		42877.00.00	Johnson & Johnson Gmbh	Germany
Regaine		49988/16-7-2012 \$ 52074/16-07-2012	Johnson & Johnson Hellas Consumer Ae	Greece
Regaine Foam		90468/22-12-2011	Johnson & Johnson Hellas Consumer Ae	Greece
Regaine		OGYI-T-2065/01	Johnson & Johnson Kft.	Hungary
Regaine Forte	SE/H/1173/01/DC	IS/1/12/086/01	Mcneil Denmark Aps	Iceland
Regaine Extra Strength		PA 823/48/2	Mcneil Healthcare (Ireland) Limited	Ireland
Regaine Extra Strength Scalp Foam	SE/H/1173/01/DC	PA 823/48/3	Mcneil Healthcare (Ireland) Limited	Ireland
Regaine For Women Regular Strength		PA 823/48/1	Mcneil Healthcare (Ireland) Limited	Ireland
Regaine		026725010 \$ 026725034	Johnson & Johnson S.P.A.	Italy
Regaine		026725046 \$ 026725059	Johnson & Johnson S.P.A.	Italy
Regaine		00-0479 \$ 00-0480	Mcneil Products Limited	Latvia
Regaine		LT/1/96/2446/001 \$ LT/1/96/2446/002	Mcneil Products Limited	Lithuania
Regaine		2008099990	Johnson & Johnson Consumer N.V./S.A.	Luxembourg
Regaine		2008099991 \$ 2008099992	Johnson & Johnson Consumer N.V./S.A.	Luxembourg

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Regaine For Men Extra Strength		MA 100/00902	Mcneil Products Limited	Malta
Regaine For Men Extra Strength Scalp Foam		MA 100/00903	Mcneil Products Limited	Malta
Regaine For Women Regular Strength		MA 100/00901	Mcneil Products Limited	Malta
Regaine		RVG 12121	Johnson & Johnson Consumer B.V.	Netherlands
Regaine	SE/H/1173/01/DC	RVG110328	Johnson & Johnson Consumer B.V.	Netherlands
Rogaine	SE/H/1173/01/DC	11-8509	Mcneil Sweden Ab	Norway
Regaine		8672402 \$ 8672410	Johnson & Johnson Lda	Portugal
Regaine	SE/H/1173/01/DC	5562905 \$ 5562913	Johnson & Johnson Lda	Portugal
Regaine	SE/H/1173/01/DC	76.483	Johnson & Johnson S.A.	Spain
Rogaine		10981	Mcneil Sweden Ab	Sweden
Rogaine	SE/H/1173/01/DC	46526	Mcneil Sweden Ab	Sweden
Rogaine Forte		15343	Mcneil Sweden Ab	Sweden
Regaine for Women Once a Day Scalp Foam		15513/0135	Mcneil Products Limited	United Kingdom
Regaine For Men Extra Strength		PL 15513/0148	Mcneil Products Limited	United Kingdom
Regaine For Men Extra Strength Scalp Foam		PL 15513/0134 \$ 15513/0366	Mcneil Products Limited	United Kingdom
Regaine For Men Extra Strength Scalp Solution		PL 15513/0365	Mcneil Products Limited	United Kingdom
Trefostil	FR/H/0446/01/MR	040777017	Pierre Fabre Italia/Italy	Italy
Regaine For Women Regular Strength		15513/0149	Mcneil Products Limited	United Kingdom
Alopxy		BE286937	Pierre Fabre Benelux	Belgium
Alopxy	FR/H/446/01/MR	BE376546	Pierre Fabre Benelux	Belgium
Alopxy	FR/H/0446/01/MR	34009 368 847 4 8	Pierre Fabre Dermatologie	France
Alopxy	FR/H/0446/01/MR	34009 384 404 6 1	Pierre Fabre Dermatologie	France
Alopxy	FR/H/0446/01/MR	34009 384402 3 2	Pierre Fabre Dermatologie	France
Alopxy		330 924-1	Pierre Fabre Dermatologie	France

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Alopexy		332 175-6	Pierre Fabre Dermatologie	France
Alopexy		34009 362 991 6 0	Pierre Fabre Dermatologie	France
Alopexy		34009 364 307 5 4	Pierre Fabre Dermatologie	France
Alopexy		34009 335 273 9 6	Pierre Fabre Dermatologie	France
Alopexy		34009 330 925 8 0	Pierre Fabre Dermatologie	France
Trefostil	FR/H/0446/01/MR	040777029	Pierre Fabre Italia/Italy	Italy
Trefostil	FR/H/0446/01/MR	040777043	Pierre Fabre Italia/Italy	Italy
Trefostil	FR/H/0446/01/MR	040777031	Pierre Fabre Italia/Italy	Italy
Alopexy		651017-9	Pierre Fabre Iberica/Spain	Spain
Alopexy		665496-5	Pierre Fabre Iberica/Spain	Spain
Alopexy	FR/H/0446/01/MR	3116/2010/01	Pierre Fabre Dermatologie	Romania
Alopexy	FR/H/0446/01/MR	3116/2010/02	Pierre Fabre Dermatologie	Romania
Alopexy	FR/H/0446/01/MR	3116/2010/03	Pierre Fabre Dermatologie	Romania
Alopexy	FR/H/0446/01/MR	3116/2010/04	Pierre Fabre Dermatologie	Romania
Alopexy		5616/2005/01	Pierre Fabre Dermatologie	Romania
Alopexy		5616/2005/02	Pierre Fabre Dermatologie	Romania
Alopexy		5616/2005/03	Pierre Fabre Dermatologie	Romania
Alopexy		5616/2005/04	Pierre Fabre Dermatologie	Romania
Alopexy		5616/2005/05	Pierre Fabre Dermatologie	Romania
Alorexy	FR/H/0446/01/MR	5316211	Pfdc / Portugal	Portugal
Alopexy	2009010082		Pierre Fabre Dermatologie	Luxembourg
Alopexy	1128/09010038		Pierre Fabre Dermatologie	Luxembourg
Unipexil		NL 20198 - CIS 6 987 165 7	Gifrer Barbezat	France
Unipexil		NL 42721 - CIS 6 115 630 2	Gifrer Barbezat	France
Minoxidil Cooper		NL 14720	Cooperation Pharmaceutique Francaise	France
Alostil		NL 14560	Johnson & Johnson Santé Beauté France	France
Alostil	SE/H/1173/01/DC	NL 41453	Johnson & Johnson Santé Beauté France	France
Alostil		NL 19422 (339872-4) (339873-0)	Johnson & Johnson Santé Beauté France	France
Minoxidil Bailleul		NL27841	Laboratoire Bailleul S.A.	France
Minoxidil Bailleul		2006050019	Laboratoire Bailleul S.A.	Luxembourg

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Minoxidil Biorga	PT/H/0990/01/DC	78929	Laboratoire Bailleul S.A.	Spain
Minoxidil Biorga	PT/H/0990/02/DC	78930	Laboratoire Bailleul S.A.	Spain
Minoxidil Biorga	PT/H/0990/01/DC	5633979	Laboratoire Bailleul S.A.	Portugal
Minoxidil Biorga	PT/H/0990/02/DC	5634027 \$ 5634035	Laboratoire Bailleul S.A.	Portugal
Minoxidil Biorga	PT/H/0990/01/DC	42311035 \$ 042311047	Laboratoire Bailleul S.A.	Italy
Minoxidil Biorga	PT/H/0990/02/DC	042311011 \$ 042311023	Laboratoire Bailleul S.A.	Italy
Регин		20050511	Mcneil Products Limited	Bulgaria
Regaine	SE/H/1173/01/DC	6724/2014/01 \$ 6724/2014/02	Mcneil Products Limited	Romania
Regaine	SE/H/1173/01/DC	5363-I-2335/12	Mcneil Products Limited	Slovenia