



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 April 2016
EMA/394142/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: nifedipine

Procedure no.: PSUSA/00002156/201508



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
Adalat		1-19035	Bayer Austria Gmbh	Austria
Adalat		11457 \$ 12286	Bayer Pharma Ag	Denmark
Adalat		8624 \$ 9347	Bayer Pharma Ag	Finland
Adalat		12430.00.00	Bayer Vital Gmbh	Germany
Adalat		12430.01.00	Bayer Vital Gmbh	Germany
Adalat		32669.00.00	Bayer Pharma Ag	Germany
Adalat		808.00.01	Bayer Vital Gmbh	Germany
Adalat		808.01.02	Bayer Vital Gmbh	Germany
Adalat		39973/9-9-2009 \$ 39975/9-9-2009	Bayer Hellas Sa	Greece
Adalat		39976/9-9-2009	Bayer Hellas Sa	Greece
Adalat		39979/9-9-2009	Bayer Hellas Sa	Greece
Adalat		OGYI-T-6196/03	Bayer Pharma Ag	Hungary
Adalat		833264 \$ 890161	Bayer Pharma Ag	Iceland
Adalat		PA1410/025/001 \$ PA1410/025/002	Bayer Ltd	Ireland
Adalat		023316021	Bayer Spa	Italy
Adalat		023316033	Bayer Spa	Italy
Adalat		MA513/00501	Bayer Plc	Malta
Adalat		7206	Bayer Pharma Ag	Norway
Adalat		4659389 \$ 4659488 \$ 8419010 \$ 8419036 \$ 8419002	Centrofarma Lda	Portugal
Adalat		52.661	Bayer Hispania Sl	Spain
Adalat		09959 \$ 10266	Bayer Pharma Ag	Sweden
Adalat		PL 00010/0021	Bayer Plc	United Kingdom
Adalat 2-Phasen		1-18561	Bayer Austria Gmbh	Austria
Adalat 5		PL 00010/0079	Bayer Plc	United Kingdom
Adalat A.P		4659595 \$ 9563304 \$ 9563320	Centrofarma Lda	Portugal

Adalat Cr		19152	Bayer Hellas Sa	Cyprus
Adalat Cr		19153	Bayer Hellas Sa	Cyprus
Adalat Cr		8563353 \$ 8563361 \$ 8563379	Centrofarma Lda	Portugal
Adalat Cr		8111/2006/01	Bayer Pharma Ag	Romania
Adalat Crono		027980010 \$ 027980022 \$ 027980034 \$ 027980046 \$ 027980059 \$ 027980061	Bayer Spa	Italy
Adalat Eins		1-20858 \$ 1-20859	Bayer Austria Gmbh	Austria
Adalat Eins		31221.00.00 \$ 31221.01.00	Bayer Vital Gmbh	Germany
Adalat Gits		OGYI-T-6196/01 \$ OGYI- T-6196/02	Bayer Pharma Ag	Hungary
Adalat La		37545.00.00 \$ 37545.01.00	Bayer Pharma Ag	Germany
Adalat La		PA 1410/25/5 \$ PA 1410/25/6 \$ PA 1410/25/7	Bayer Ltd	Ireland
Adalat La		MA513/00502	Bayer Plc	Malta
Adalat La		PL 00010/0174 \$ PL 00010/0175 \$ PL 00010/0222	Bayer Plc	United Kingdom
Adalat Oros		BE159144 \$ BE208643	Bayer Sa Nv	Belgium
Adalat Oros		13973 \$ 13974	Bayer Pharma Ag	Denmark
Adalat Oros		30112	Bayer Pharma Ag	Denmark
Adalat Oros		112795 \$ 287199 \$ 287299	Bayer Pharma Ag	Estonia
Adalat Oros		10754 \$ 10755	Bayer Pharma Ag	Finland
Adalat Oros		13817	Bayer Pharma Ag	Finland
Adalat Oros		920178 \$ 920179	Bayer Pharma Ag	Iceland
Adalat Oros		980235	Bayer Pharma Ag	Iceland
Adalat Oros		0442/04090034 \$ 1997094168	Bayer Sa Nv	Luxembourg

Adalat Oros		RVG 14794 \$ RVG 14795	Bayer Bv	Netherlands
Adalat Oros		7755 \$ 7756 \$ 98-2503	Bayer Pharma Ag	Norway
Adalat Oros		5363-I-488/12 \$ 5363-I-489/12	Bayer D.O.O	Slovenia
Adalat Oros		59.537 \$ 59.538	Bayer Hispania Sl	Spain
Adalat Oros		11805 \$ 11806 \$ 13170	Bayer Pharma Ag	Sweden
Adalat Retard		1-17404	Bayer Austria Gmbh	Austria
Adalat Retard		BE140795	Bayer Sa Nv	Belgium
Adalat Retard		PA 1410/025/003 \$ PA1410/025/004	Bayer Ltd	Ireland
Adalat Retard		0442/99/03/5235	Bayer Sa Nv	Luxembourg
Adalat Retard		MA 513/00504	Bayer Plc	Malta
Adalat Retard		56.920	Bayer Hispania Sl	Spain
Adalat Retard		PL 00010/0078 \$ PL 00010/0151	Bayer Plc	United Kingdom
Adalat Sl		6220.00.00	Bayer Vital Gmbh	Germany
Adalate		322 347-9 \$ 322 348-5	Bayer Healthcare	France
Adalate Lp		327 401-1 \$ 327 402-8 \$ 372 387-4 \$ 557 492-9	Bayer Healthcare	France
Amakor		035067014 \$ 035067026	S.F. Group Srl	Italy
Aprical		5868.00.00	Amdipharm Limited	Germany
Cardilate MR 10mg/Angiopine MR		PL 00530/0517	Norton Healthcare Limited T/A Ivax Pharmaceuticals Uk Ridings Point, Whistler Drive	United Kingdom
Cardilate MR 20		PL 00530/0488	Norton Healthcare Limited T/A Ivax Pharmaceuticals Uk Ridings Point, Whistler Drive	United Kingdom
Chronadate Lp		357 803-0 \$ 357 804-7 \$ 357 805-3 \$ 357 807-6 \$ 371 968-3 \$ 380 482-2 \$	Bayer Healthcare	France

		380 483-9 \$ 571 175-7 \$ 571 176-3 \$ 571 178-6		
Coracten		10199/86	Vianex, S.A.	Greece
Coracten Sr		PL 00039/0365 \$ PL 00039/0367	Ucb Pharma Ltd (Slough Gb)	United Kingdom
Coracten XI		PL 00039/0506 \$ PL 00039/0507	Ucb Pharma Ltd (Slough Gb)	United Kingdom
Fortipine LA 40mg Modified Release Tablets		PL 12762/0014	Mercury Pharmaceuticals Limited	United Kingdom
Hypan	BE/H/0127/001 \$ BE/H/127/01	BE198143	Takeda Belgium Sca/Cva	Belgium
Hypan	BE/H/0127/001	0430/05/08/8290	Takeda Belgium Sca/Cva	Luxembourg
Hypolar Retard		PL 04416/0245 \$ PL 04416/0283	Sandoz Ltd	United Kingdom
Nifedidor		024608046	Meda Pharma S.P.A.	Italy
Nifedipin Basics		31220.00.00 \$ 31220.01.00	Bayer Pharma Ag	Germany
Nifedipine Mr Tablets		PL 00530/0517	Norton Healthcare Limited T/A Ivax Pharmaceuticals Uk Ridings Point, Whistler Drive	United Kingdom
Nifehexal Uno		28391.00.00 \$ 28391.01.00	Hexal Ag	Germany
Nifendipin Retard		RVG 17073	Amdipharm Limited	Netherlands
Nife-Par		78233	Laboratorio Reig Jofre, S.A.	Spain
adalat Cr		39967/9-9-2009	Bayer Hellas Sa	Greece
adalat Cr		39969/9-9-2009 \$ 39972/9-9-2009	Bayer Hellas Sa	Greece
адалат айнс		9900383	Bayer Pharma Ag	Bulgaria