



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3 December 2015
EMA/850509/2015
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: metformin

Procedure no.: PSUSA/00002001/201504



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
Dianben	FR/H/0181/002	55.211	Merck Santé S.A.S.	Spain
Dianben	FR/H/0181/005 FR/H/0181/006	70545 70546	Merck Santé S.A.S.	Spain
Glucophage		UP/I-530-09/11-02/233 UP/I-530-09/12-02/398 UP/I-530-09/12-02/399	Merck D.O.O	Croatia
Glucophage	FR/H/0181/001	H/98/00703/001-018	Merck D.O.O.	Slovenia
Glucophage	FR/H/0181/001 FR/H/0181/002 FR/H/0181/003	01-1628 5204 97-375	Merck Santé S.A.S.	Norway
Glucophage	FR/H/0181/001 FR/H/0181/002 FR/H/0181/003	1-24142 11.834 14.190	Merck Gesellschaft MbH	Austria
Glucophage	FR/H/0181/001 FR/H/0181/002 FR/H/0181/003	10799 17143 7690	Merck Santé S.A.S.	Sweden
Glucophage	FR/H/0181/001 FR/H/0181/002 FR/H/0181/003	1223/2008/01-19 2002/2009/01-29 2003/2009/01-24	Merck Santé S.A.S.	Romania
Glucophage	FR/H/0181/001 FR/H/0181/002 FR/H/0181/003	15716 16876 16877	Merck Santé S.A.S.	Poland
Glucophage	FR/H/0181/001 FR/H/0181/002 FR/H/0181/003	18/0561/09-S 18/0562/09-S 18/0589/08-S	Merck Santé S.A.S.	Slovakia
Glucophage	FR/H/0181/001 FR/H/0181/002 FR/H/0181/003	20469 20697 20698	Merck A.E.	Cyprus
Glucophage	FR/H/0181/001 FR/H/0181/002 FR/H/0181/003	20493/20-3-2012	Merck A.E.	Greece

Glucophage	FR/H/0181/001 FR/H/0181/002 FR/H/0181/003	34009 304 478 8 8 34009 304 480 2 1 34009 328 730 9 8 34009 329 827 6 9 34009 337 259 3 8 34009 337 260 1 0 34009 352 816 7 8 34009 372 048 5 9 34009 372 246 1 1 34009 551 036 1 5 34009 558 344 3 4 34009 558 346 6 3 34009 559 233 0 5 356 017-1 356 020-2 356 023-1 563 259-0	Merck Santé S.A.S.	France
Glucophage	FR/H/0181/001 FR/H/0181/002 FR/H/0181/003	51643.00.00 6207899.00.00 6373818.00.00	Merck Serono Gmbh	Germany
Glucophage	FR/H/0181/001 FR/H/0181/002 FR/H/0181/003	691229 853604 IS/1/01/019/01	Merck Santé S.A.S.	Iceland
Glucophage	FR/H/0181/001 FR/H/0181/002 FR/H/0181/003	PA 654/19/1 PA 654/19/2 PA 654/19/3	Merck Serono Ltd.	Ireland
Glucophage	FR/H/0181/001 FR/H/0181/003	08-0335 09-0344	Merck Santé S.A.S.	Latvia
Glucophage	FR/H/0181/001 FR/H/0181/003	16414 4566	Merck Santé S.A.S.	Finland
Glucophage	FR/H/0181/001/MR FR/H/0181/002/MR	017758018/M 017758020/M	Bruno Farmaceutici	Italy
Glucophage	FR/H/0181/002	BE058466 BE341467	Merck N.V.-S.A.	Belgium
Glucophage	FR/H/0181/002 FR/H/0181/003	194484 194498 286832	Merck N.V.-S.A.	Luxembourg
Glucophage	FR/H/0181/002 FR/H/0181/003	H/98/00703/019-064	Merck D.O.O.	Slovenia
Glucophage	FR/H/0181/002 FR/H/0181/003	BE058414 BE058466 BE341451 BE341467	Merck N.V.-S.A.	Belgium
Glucophage	FR/H/0181/002 FR/H/0181/003	PL 11648/0085 PL 11648/0086	Merck Serono Ltd.	United Kingdom

Glucophage	FR/H/0181/003	4485892 ; 4485991 4486197 ; 4486296 4486395 ; 4486593 4486692 ; 4486791 4486890 ; 4487096 4487195 ; 4487294 4487393 ; 4487492 4487591 ; 4487690 4487799 ; 4487898 4487997 ; 4488094 4488193 ; 4488292 4488391 ; 4488599 4488698 ; 8050807 8050815	Merck, S.A.	Portugal
Glucophage	FR/H/0181/003/MR	0177580107/M 0177580119/M 017758032/M 017758044/M 017758057/M 0177580671/M 0177580683/M 017758069/M 0177580695/M	Bruno Farmaceutici	Italy
Glucophage	FR/H/0181/004	5139167 5139175 5185061	Merck, S.A.	Portugal
Glucophage	FR/H/0181/004 FR/H/0181/005 FR/H/0181/006	34009 390 152 5 5 34009 390 153 1 6 34009 390 157 7 4 34009 390 158 3 5 34009 390 160 8 5 34009 390 161 4 6	Merck Santé S.A.S.	France
Glucophage	FR/H/0181/004 FR/H/0181/005 FR/H/0181/006	PA 654/19/4 PA 654/19/5 PA 654/19/6	Merck Serono Ltd.	Ireland
Glucophage	FR/H/0181/004 FR/H/0181/006	21096 21097 21098	Merck A.E.	Cyprus
Glucophage	FR/H/0181/004 FR/H/0181/006	27804/20-3-2014 27805/20-3- 2014 27806/20-3-2014	Merck A.E.	Greece
Glucophage	FR/H/0181/004 FR/H/0181/006	PL 11648/0088 PL 11648/0090	Merck Serono Ltd.	United Kingdom
Glucophage	FR/H/0181/004/DC	017758273	Bruno Farmaceutici	Italy
Glucophage	FR/H/0181/004/DC FR/H/0181/006/DC	017758210 017758222 017758297	Bruno Farmaceutici	Italy

Glucophage	FR/H/0181/005/DC	017758234 017758246	Bruno Farmaceutici	Italy
Glucophage	FR/H/0181/005/DC	017758285	Bruno Farmaceutici	Italy
Glucophage	FR/H/0181/006	18/0491/08-S	Merck Santé S.A.S.	Slovakia
Glucophage	FR/H/0181/006/DC	017758259 017758261	Bruno Farmaceutici	Italy
Glucophage Sr		PL 11648/0054 PL 11648/0066 PL 11648/0067	Merck Serono Ltd.	United Kingdom
Glucophage Xr		04-0289 10-0372	Merck Santé S.A.S.	Latvia
Glucophage Xr		12244 15192 18106	Merck Santé S.A.S.	Poland
Glucophage Xr		18/0150/10-S 18/0290/04-S 18/0515/06-S	Merck Santé S.A.S.	Slovakia
Glucophage Xr		6957/2006/01 6957/2006/02	Merck Santé S.A.S.	Romania
Glucophage Xr		UP/I-530-09/12-01/93 UP/I-530- 09/12-01/94 UP/I-530-09/12- 01/95	Merck D.O.O	Croatia
Glucostop		71732/13/04.02.2014	Ioulia And Irene Tseti Pharmaceutical Laboratories S.A.	Greece
Merckformin	FR/H/0181/001 FR/H/0181/002 FR/H/0181/003	OGYI-T-5157/01 OGYI-T-5157/02 OGYI-T-5157/03 OGYI-T-5157/07 OGYI-T-5157/10 OGYI-T-5157/11 OGYI-T-5157/12 OGYI-T-5157/17 OGYI-T-5157/18	Merck Kft.	Hungary

Merckformin Xr		OGYI-T-5157/04 OGYI-T-5157/05 OGYI-T-5157/06 OGYI-T-5157/13 OGYI-T-5157/14 OGYI-T-5157/15 OGYI-T-5157/16	Merck Kft.	Hungary
Metformin		018820011	Bayer Spa	Italy
Metforal		019449014	Laboratori Guidotti S.P.A.	Italy
Merformax		2004068285	S.A. Menarini Benelux N.V.	Luxembourg
Merformax		BE195264	S.A. Menarini Benelux N.V.	Belgium
Metformax		BE195264	S.A. Menarini Benelux N.V.	Belgium
Metformin Actavis	DK/H/2272/001-003	31251 31252	Actavis Group Ptc Ehf.	Finland
Metformin Actavis Ptc	DK/H/2272/001 DK/H/2272/002	51937 51938	Actavis Group Ptc Ehf.	Denmark
Metformin Actavis Uk Ltd.	PL 0142/0505 PL 0142/0506	PL 0142/0505 PL 0142/0506	Actavis Uk Ltd.	United Kingdom
Metformin Focus Pharmaceuticals Ltd		PL 20046/0255	Focus Pharmaceuticals Limited	United Kingdom
Metformin Actavis	FR/H/0387/001	IS/1/09/055/01 IS/1/09/055/03	Actavis Group Ptc Ehf.	Iceland
Metformin Wockhardt Uk Ltd		29831/0133 29831/0134	Wockhardt Uk Ltd	United Kingdom
Metformin Wockhardt Uk Ltd		29831/0133 29831/0134	Wockhardt Uk Ltd	United Kingdom
Metformin Zentiva		18/177/06-C	Zentiva, A.S.	Czech Republic
Metformina Aurobindo	NL/H/2086/003	040592014; 040592026; 040592038	Aurobindo Pharma (Italia) S.R.L.	Italy
Risidon	FR/H/0181/001 FR/H/0181/002	3638889 ; 3638988 3639085 ; 3639184 3639283 ; 3639382 3639481 ; 3639580 3639689 ; 4022786 4022885 ; 4022984 4023081 ; 4023180 4023289 ; 4023388 4023487 ; 4023586 8248922 ; 8248930	Merck, S.A.	Portugal

Risidon	FR/H/0181/005 FR/H/0181/006	5139209 ; 5139217 5139225 ; 5139233 5185053 ; 5194972	Merck, S.A.	Portugal
Siofor	DE/H/515/001	5363-I-2040/11 5363-I-2041/11	Laboratori Guidotti S.p.A.	Slovenia
Stagid		3400931927501 3400931927679	Merck Santé S.A.S.	France
Stagid		9546820 9546838	Merck, S.A.	Portugal
Glucophage	FR/H/0181/001 FR/H/0181/002 FR/H/0181/003	II-4493 II-9301 II-9302	Merck Santé S.A.S.	Bulgaria
Metformine Mylan		NL 33877	Mylan S.A.S.	France
Metformine HCl Disper Mylan		RVG 103134	Mylan B.V.	Netherlands
Metformina Solument		5213152; 5213137; 5213129; 5213145	Mylan Lda	Portugal
Metformin 500mg Tablets BP		PL 17907/0178	Bristol Laboratories Limited	United Kingdom
Metformin 850mg Tablets BP		PL 17907/0179	Bristol Laboratories Limited	United Kingdom
Glucophage	FR/H/0181/001	18/155/02-C	Merck Santé S.A.S.	Czech Republic
Glucophage	FR/H/0181/003	18/824/96-C	Merck Santé S.A.S.	Czech Republic
Glucophage	FR/H/0181/002	18/825/96-C	Merck Santé S.A.S.	Czech Republic
Glucophage	FR/H/0181/004	18/152/09-C	Merck Santé S.A.S.	Czech Republic
Glucophage	FR/H/0181/005	18/153/09-C	Merck Santé S.A.S.	Czech Republic
Glucophage	FR/H/0181/006	18/154/09-C	Merck Santé S.A.S.	Czech Republic
Glucophage Xr		18/166/04-C	Merck Santé S.A.S.	Czech Republic
Glucophage Xr		18/221/11-C	Merck Santé S.A.S.	Czech Republic
Glucophage Xr		18/222/11-C	Merck Santé S.A.S.	Czech Republic
Metformin Fourrts (Uk) Pharmacare Limited		PL39484-0032 PL39484-0033	Fourrts (Uk) Pharmacare Limited	United Kingdom

Metformin Special Concept Development (Uk) Ltd		PL 36722/0030 PL 36722/0031	Special Concept Development (Uk) Ltd	United Kingdom
Metformin Arcana	AT/H/0460/001	1-24143 1-19303	Arcana Arzneimittel GmbH	Austria
Metformin Tablets 500mg		PL 04416/0300	SANDOZ LTD.	United Kingdom
Metformin Tablets 500mg		PL 04416/0301	SANDOZ LTD.	United Kingdom