



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 February 2016
EMA/284356/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: glibenclamide / metformin hydrochloride

Procedure no.: PSUSA/00002002/201506



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
Diaglimet		034693010	Abiogen Pharma S.P.A.	Italy
Glibomet		026129015 \$ 026129027 \$ 026129039 \$ 026129041	Laboratori Guidotti S.P.A.	Italy
Glibomet		1412/2009/01 \$ 1412/2009/02 \$ 1412/2009/03 \$ 1412/2009/04	Laboratori Guidotti S.P.A.	Romania
Glibomet		18/0011/99-S	Laboratori Guidotti S.P.A.	Slovakia
Glibomet		18/264/00-C	Laboratori Guidotti S.P.A.	Czech Republic
Glibomet		MA203/00101	Laboratori Guidotti S.P.A.	Malta
Gliconorm		031995018	Abiogen Pharma S.P.A.	Italy
Glicorest		034576013	BGP Products S.r.l. Mylan EPD	Italy
Glucovance		18/0139/02-S \$ 18/0140/02-S	Merck Santé S.A.S.	Slovakia
Glucovance		19574 \$ 19575	Merck A.E.	Cyprus
Glucovance		6741/2014/01 \$ 6741/2014/02 \$ 6741/2014/03 \$ 6741/2014/04	Merck Santé S.A.S.	Romania

		\$ 6741/2014/05		
Glucovance		5363-I-1502/11 \$ 5363-I-1503/11 \$ 5363-I-222/12	Merck D.O.O.	Slovenia
Glucovance		UP/I-530-09/12-01/105	Merck D.O.O	Croatia
Glucovance	FR/H/0200/001 \$ FR/H/0200/001 \$ FR/H/0200/002 \$ FR/H/0200/002 \$ FR/H/0200/003 \$ FR/H/0200/002	34009 350 265 3 8 \$ 34009 350 267 6 7 \$ 34009 350 268 2 8 \$ 3400935801333 \$ 3400935801562 \$ 3400935801623 \$ 3400935801852 \$ 3400935801913 \$ 3400935802163 \$ 3400935802224 \$ 3400935802453 \$ 3400935802514 \$ 3400935802682 \$ 3400935802743 \$ 3400935802804 \$ 3400935803054 \$ 3400935803115 \$ 3400935803283 \$ 3400935803344 \$ 3400935803573 \$ 3400935803634 \$ 3400956355365 \$ 3400956355426 \$ 3400956355594 \$ 3400956355655	Merck Santé S.A.S.	France
Glucovance	FR/H/0200-01 \$ FR/H/0200-02	RVG 27245 \$ RVG 27246	Merck B.V.	Netherlands
Glucovance	FR/H/0200/001 \$ FR/H/0200/002 \$ FR/H/0200/003	3950789 \$ 3950888 \$ 3950987 \$ 3951084 \$ 3951183 \$ 3951282 \$ 3951381 \$ 3951480 \$ 3951589 \$ 3951688 \$ 3951787 \$ 3951886	Merck, S.A.	Portugal

		\$ 3951985 \$ 3952082 \$ 3952181 \$ 3952280 \$ 3952389 \$ 3952488 \$ 3952587 \$ 3952686 \$ 3952785 \$ 3952884 \$ 3952983 \$ 3953080 \$ 5273362 \$ 5273370		
Normell		5975/95/04-11-1996	Sanofi-Aventis Aebe	Greece
Suguan M		027174010	Sanofi Spa	Italy
Glucovance		6742/2014-01-02-03-04-05	Merck Santé S.A.S.	Romania
Glucovance		HR-H-479494195 \$ HR-H-253928915	Merck D.O.O	Croatia
Glucovance	FR/H/0200-01 \$ FR/H/0200-02 \$ FR/H/0200/003/DC	25 742 \$25 743 \$ 37 195	Merck Santé S.A.S.	France
Glucovance	FR/H/0200-01	3951282, 3950987, 3951084, 3951183, 3951381, 3951589, 3951688, 3951787, 3951886, 3950789, 3950888, 3951480	Merck, S.A.	Portugal
Glucovance	FR/H/020002	3952082, 3952280, 3952389, 3952587, 3952785, 3952884, 3952983, 3952686, 3952181, 3951985, 3952488, 3953080	Merck, S.A.	Portugal
Glucovance	FR/H/200/03/DC	5273362, 5273370	Merck, S.A.	Portugal