



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3 December 2015
EMA/98477/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: acarbose

Procedure no.: PSUSA/00000017/201503



| 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 |
|------------------------------------------------|--------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Acarbosa Apotex | | 75115 | Apotex Europe B.V. | Spain |
| Acarbosa Apotex | | 75116 | Apotex Europe B.V. | Spain |
| Acarbosa Mylan | DE/H/0869/001 \$ DE/H/0869/002/DC | 71442 \$ 71443 | Mylan Pharmaceuticals S.L. | Spain |
| Acarbosa Qualigen | | 75315 \$ 75316 | Qualigen, S.L. | Spain |
| Acarbosa Tarbis | | 70536 \$ 70537 | Tarbis Farma, S.L. | Spain |
| Acarbosa Tecnigen | | 70451 \$ 70452 | Tecnimede España Ind. Fca., S.A. | Spain |
| Acarbose | PT/H/0662/02/DC | PL 25258/0092 | Glenmark Pharmaceuticals Europe Limited | United Kingdom |
| Acarbose | 30306/0567 \$ 30306/0568 | 30306/0567 \$ 30306/0568 | Actavis Group Ptc Ehf. | United Kingdom |
| Acarbose | UK/H/5049/001 \$ UK/H/5049/002/DC | PL 04569/1619 \$ PL 04569/1620 | Generics [uk] Limited | United Kingdom |

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| Acarbose | PT/H/0662/01/DC | PL 25258/0091 | Glenmark Pharmaceuticals Europe Limited | United Kingdom |
| Acarbose | UK/H/5049/001 \$ UK/H/5049/002/DC | PA 0577/171/001 \$ PA 0577/171/002 | Mcdermott Laboratories Ltd | Ireland |
| Acarbose | | 5110168 \$ 5110176 \$ 5110200 \$ 5110218 \$ 5110226 \$ 5110234 \$ 5110242 \$ 5110259 | Pentafarma - Sociedade Tecnico-Medicinal S.A. | Portugal |
| Acarbose | | NL 19888, NL 19889 | Bayer HealthCare | France |
| Acarbose 1 A Pharma | | 88416.00.00 \$ 88417.00.00 | 1 A Pharma Gmbh | Germany |
| Acarbose Abz | | 79563.00.00 \$ 79564.00.00 | Abz-Pharma Gmbh, Graf- Arco-Str. 3 | Germany |
| Acarbose Al | | 69772.00.00 \$ 69773.00.00 | Aliud Pharma Gmbh | Germany |
| Acarbose Arrow | | 31982 \$ 31983 | Laboratoires Gerda | France |
| Acarbose Biogaran | | 36088, 36089 | Biogaran | France |

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| Acarbose Bluepharma | 07/H/0199/001 | 5107172 | Bluepharma Genéricos - Comércio De Medicamentos, S.A. | Portugal |
| Acarbose Bluepharma | 07/H/0199/001 | 5107206 | Bluepharma Genéricos - Comércio De Medicamentos, S.A. | Portugal |
| Acarbose Bluepharma | 07/H/0199/002 | 5107214 | Bluepharma Genéricos - Comércio De Medicamentos, S.A. | Portugal |
| Acarbose Bluesar | PT/H/0662/01/DC \$ PT/H/0662/02/DC | 5462775 \$ 5462809 \$ 5462817 | Bluepharma Indústria Farmacêutica S.A. | Portugal |
| Acarbose Dna Pharma | | 07/H/0198/001 \$ 07/H/0198/002 | Dna Pharma, Lda | Portugal |
| Acarbose Dura | DE/H/0869/002/DC | 66757.00.00 | Mylan Dura Gmbh | Germany |
| Acarbose Dura | DE/H/0869/001/DC | 66756.00.00 | Mylan Dura Gmbh | Germany |
| Acarbose Farnoz | | 5110069 \$ 5110077 \$ 5110101 \$ 5110119 \$ 5110127 \$ 5110135 \$ 5110143 \$ 5110150 | Farnoz - Sociedade Técnico Medicinal, S.A. | Portugal |
| Acarbose Friulchem | | 5228903 \$ 5228911 \$ 5228929 \$ 5228937 \$ 5228945 \$ 5228952 | Friulchem Spa | Portugal |

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| Acarbose Generis | | 5111471 \$ 5111505 \$ 5111513 | Generis Farmacêutica, S.A. | Portugal |
| Acarbose Hexal | | 69770.00.00 \$ 69771.00.00 | Hexal Ag | Germany |
| Acarbose Labesfal | | 5111521 \$ 5111539 \$ 5111547 | Labesfal Genéricos, S.A. | Portugal |
| Acarbose Mylan | | NL 50719 \$ NL 50720 | Mylan S.A.S | France |
| Acarbose Mylan | DE/H/0869/001 \$ DE/H/0869/002/DC | 5168067 \$ 5168075 \$ 5168109 \$ 5168117 | Mylan, Lda | Portugal |
| Acarbose Mylan | DE/H/0869/001 \$ DE/H/0869/002/DC | OGYI-T-20981/01 \$ OGYI-T-20981/02 \$ OGYI-T-20981/03 \$ OGYI-T-20981/04 \$ OGYI-T-20981/05 \$ OGYI-T-20981/06 \$ OGYI-T-20981/07 \$ OGYI-T-20981/08 \$ OGYI-T-20981/09 \$ OGYI-T-20981/10 \$ OGYI-T-20981/11 \$ OGYI-T-20981/12 \$ OGYI-T-20981/13 \$ OGYI-T-20981/14 \$ OGYI-T-20981/15 \$ OGYI-T-20981/16 \$ OGYI-T-20981/17 \$ OGYI-T-20981/18 \$ OGYI-T-20981/19 \$ OGYI-T-20981/20 | Generics [uk] Limited | Hungary |
| Acarbose Sandoz | NL 42774 \$ NL 42775 | 269 827-5 \$ 269 828-1 \$ 269 829-8 \$ 269 830-6 \$ 269 831-2 \$ 273 838-8 | Sandoz | France |

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| Acarbose Stada | | 79059.00.00 \$ 79060.00.00 | Stadapharm Gmbh | Germany |
| Acarbose | UK/H/1218/01 \$ UK/H/1218/02 | PL 20117/0178 \$ PL 20117/0179 | Morningside Healthcare Ltd | United Kingdom |
| Acarbose Zentiva | | 34009 305 782 2 3 \$ 34009 305 819 3 3 \$ 34009 305 835 9 3 \$ 34009 305 836 5 4 \$ 34009 305 837 1 5 \$ 34009 305 866 1 7 | Sanofi-Aventis France | France |
| Acarbose-CT | | 79565.00.00 \$ 79566.00.00 | Abz-Pharma Gmbh, Graf- Arco-Str. 3 | Germany |
| Acarbose-Ratiopharm | | 69768.00.00 | Ratiopharm Gmbh | Germany |
| Acarbose-Ratiopharm | | 69769.00.00 | Ratiopharm Gmbh | Germany |
| Acarbosio TecniGen | UK/H/1218/01 \$ UK/H/1218/02 | 039716016/M \$ 039716028/M \$ 039716030/M \$ 039716170/M \$ 039716042/M \$ 039716055/M \$ 039716056/M \$ 039716067/M \$ 039716079/M \$ 039716081/M \$ 039716093/M \$ 039716105/M \$ 039716182/M \$ 039716117/M \$ 039716129/M \$ 039716168/M \$ 039716131/M \$ 039716143 /M | Tecnimede - Sociedade Técnico-Medicinal, Sa | Italy |
| Acarphage | DE/H/0869/001 \$ DE/H/0869/002/DC | 038835082 \$ 038835094 \$ 038835106 \$ 038835118 \$ 038835120 \$ 038835132 \$ 038835144 \$ 038835157 \$ | Merck Serono S.P.A. | Italy |

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| | | 038835169 \$ 038835171 \$ 038835183 \$ 038835195 \$ 038835207 | | |
| Adeksa | | 18537 \$ 18538 | Polfarmex S.A. | Poland |
| Akarboza Mylan | DE/H/0869/002/DC | 18/613/08-C | Generics [uk] Limited | Czech Republic |
| Glicobase | | 029532013 \$ 029532025 | Bayer Spa | Italy |
| Glucarb | PT/H/0662/01-02/DC | 21602 \$ 21603 | Tarchominskie Zakłady Farmaceutyczne "polfa" Spółka Akcyjna | Poland |
| Glucobay | | 026851016 \$ 026851028 | Bayer Spa | Italy |
| Glucobay | | 1-19232 \$ 1-19233 | Bayer Austria Gmbh | Austria |
| Glucobay | | 11011 \$ 11024 | Bayer Pharma Ag | Denmark |
| Glucobay | | 12125 \$ 12126 | Bayer Pharma Ag | Finland |

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| Glucobay | | 12193 \$ 12194 | Bayer Pharma Ag | Sweden |
| Glucobay | | 14977 | Bayer Hellas Sa | Cyprus |
| Glucobay | | 18/061/87-A/C \$ 18/061/87-B/C | Bayer Pharma Ag | Czech Republic |
| Glucobay | | 1995065250 \$ 1995065251 | Bayer Sa Nv | Luxembourg |
| Glucobay | | 20727/1-4-2008 \$ 20728/1-4-2008 | Bayer Hellas Sa | Greece |
| Glucobay | | 5363-I-966/12 \$ 5363-I-967/12 | Bayer D.O.O | Slovenia |
| Glucobay | 12/H0063/001 | 5486600, 5486576, 54886618 | Centrofarma Lda | Portugal |
| Glucobay | | 5553/2005/01-02 \$ 5554/2005/01-02 | Bayer Pharma Ag | Romania |
| Glucobay | 13/H0097/001 | 5620026 \$ 5620034 \$ 5620042 | Centrofarma Lda | Portugal |

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| Glucobay | | 59.419 \$ 59.420 | Bayer Hispania SI | Spain |
| Glucobay | | 8113 \$ 8114 | Bayer Pharma Ag | Norway |
| Glucobay | | 960097 | Bayer Pharma Ag | Iceland |
| Glucobay | | 960098 | Bayer Pharma Ag | Iceland |
| Glucobay | 1/55/87 | 8775007 \$ 8775015 \$ 8775023 \$ 9775007 \$ 9775015 \$ 9775023 | Centrofarma Lda | Portugal |
| Glucobay | | 9835.00.00 \$ 9835.01.00 | Bayer Vital Gmbh | Germany |
| Glucobay | | BE 143972 \$ BE 144313 | Bayer Sa Nv | Belgium |
| Glucobay | | MA513/00901 \$ MA513/00902 | Bayer Plc | Malta |
| Glucobay | | OGYI-T-1657/01 \$ OGYI-T-1657/02 \$ OGYI-T-1657/03 \$ OGYI-T-1657/04 \$ OGYI-T-1657/05 \$ OGYI-T-1657/06 \$ OGYI-T-1657/07 \$ OGYI-T-1657/08 \$ OGYI-T-1657/09 \$ OGYI-T-1657/10 \$ OGYI-T- | Bayer Pharma Ag | Hungary |

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| | | 1657/11 \$ OGYI-T-1657/12 | | |
| Glucobay | | PA 1410/29/1 \$ PA 1410/29/2 | Bayer Ltd | Ireland |
| Glucobay | | PL 00010/0171 \$ PL 00010/0172 | Bayer Plc | United Kingdom |
| Glucobay | | R/2854 \$ R/2855 | Bayer Pharma Ag | Poland |
| Glucobay | | RVG 12604 \$ RVG 12605 | Bayer Bv | Netherlands |
| Glucobay | | UP/I-530-09/09-02/554 \$ UP/I-530-09/09-02/555 | Bayer Doo | Croatia |
| Glucor | | NL 19834, NL 19835 | Bayer HealthCare | France |
| Symrose | UK/H/1218/01-02 | 18571 \$ 18572 | Symphar Sp. Z O.O. | Poland |
| глюкобай | | 20010298 | Bayer Pharma Ag | Bulgaria |