



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 September 2019
EMA/497439/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: bezafibrate

Procedure no.: PSUSA/00000405/201901

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An agency of the European Union



| 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| Eulitop Retard 400 mg comprimidos de liberación prolongada. | not available | 57.150 | AUROVITAS SPAIN,S.A.U. | ES |
| Eulitop 200 mg comprimidos recubiertos con película | not available | 55.728 | AUROVITAS SPAIN,S.A.U. | ES |
| Cedur retard 400 mg Retardtabletten | not available | 52.00.01 | PUREN PHARMA GMBH & CO. KG | DE |
| Difaterol Retard 400 mg comprimidos de liberación prolongada | not available | 57184 | LABORATORIOS BIAL, S.A. | ES |
| Bezalip 200 mg compresse rivestite con film | not available | 024732012 | AUROBINDO PHARMA (ITALIA) S.R.L. | IT |
| Bezalip 400 mg compresse a rilascio prolungato | not available | 024732024 | AUROBINDO PHARMA (ITALIA) S.R.L. | IT |
| Bezalip Retard 400 mg depottabletter | not available | 12224 | ACTAVIS GROUP PTC EHF. | SE |
| BEFIZAL L.P. 400 mg, comprimé enrobé à libération prolongée | not available | NL 14385 | ARROW GENERIQUES | FR |
| Bezalip 200 mg filmdragerade tabletter | not available | 11237 | ACTAVIS GROUP PTC EHF. | SE |
| Cedur 200 mg comprimés pelliculés | not available | BE124406 | AUROBINDO PHARMA B.V. | BE |
| Cedur 200 mg filmomhulde tabletten | not available | BE124406 | AUROBINDO PHARMA B.V. | BE |
| Cedur 200 mg Filmtabletten | not available | BE124406 | AUROBINDO PHARMA B.V. | BE |
| Eulitop 400 mg comprimés à libération prolongée | not available | BE167517 | AUROBINDO PHARMA B.V. | BE |

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|--|-------------------------------------|--------------------------------------|---|---|
| Eulitop 400 mg tabletten met verlengde afgifte | not available | BE167517 | AUROBINDO PHARMA B.V. | BE |
| Eulitop 400 mg Retardtabletten | not available | BE167517 | AUROBINDO PHARMA B.V. | BE |
| Cedur 200 mg comprimés pelliculés | not available | 0268591 | AUROBINDO PHARMA B.V. | LU |
| Cedur 200 mg Filmtabletten | not available | 0268591 | AUROBINDO PHARMA B.V. | LU |
| Eulitop 400 mg comprimés à libération prolongée | not available | 1786/04078339 | AUROBINDO PHARMA B.V. | LU |
| Eulitop 400 mg Retardtabletten | not available | 1786/04078339 | AUROBINDO PHARMA B.V. | LU |
| Bezalip Retard 400 mg, tabletten met gereguleerde afgifte | not available | RVG 18388 | AUROBINDO PHARMA B.V. | NL |
| Bezalip 200 mg, tabletten | not available | RVG 15982 | AUROBINDO PHARMA B.V. | NL |
| BEFIZAL 200 mg, comprimé pelliculé | not available | 12804 | ARROW GENERIQUES | FR |
| Bezalip Retard 400 mg comprimidos de libertação prolongada | not available | 8641902 | GENERIS FARMACÊUTICA, S.A. | PT |
| Bezafibrat 1A Pharma retard 400 mg - Filmtabletten | not available | 1-23777 | 1A PHARMA GMBH | AT |
| Bezalip 400 mg módosított hatóanyagleadású filmtabletta | not available | OGYI-T-2028/01 | ACTAVIS GROUP PTC EHF. | HU |
| Bezalip® | not available | 20920/4-6-2009 | ACTAVIS GROUP PTC EHF. | GR |
| BEZALIP® retard 400 mg - Filmtabletten | not available | 17.805 | ACTAVIS GROUP PTC EHF. | AT |

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|---|-------------------------------------|--------------------------------------|---|---|
| BEZALIP 400 mg depottabletti | not available | 10935 | ACTAVIS GROUP PTC EHF. | FI |
| Bezalip 200 mg comprimidos revestidos por película | not available | 8508424 | GENERIS FARMACÉUTICA, S.A. | PT |
| Bezalip 200 mg comprimidos revestidos por película | not available | 8508432 | GENERIS FARMACÉUTICA, S.A. | PT |
| Cedur 200 mg Filmtabletten | not available | 52.00.00 | PUREN PHARMA GMBH & CO. KG | DE |
| Eulitop Retard 400 mg comprimidos de liberación prolongada. | not available | 57.150 | AUROVITAS SPAIN,S.A.U. | ES |
| Eulitop 200 mg comprimidos recubiertos con película | not available | 55.728 | AUROVITAS SPAIN,S.A.U. | ES |
| Calberzol XL 400mg Prolonged-Release Tablets | not available | PL 30306/0126 | ACTAVIS GROUP PTC EHF. | UK |
| Bezalip Mono | not available | PL 30306/0126 | ACTAVIS GROUP PTC EHF. | UK |