



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

29 September 2022  
EMA/806061/2022  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: moxonidine

Procedure no.: PSUSA/00002095/202201



| <b>Product Name (in authorisation country)</b> | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
|------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| MOXON 0,2 mg comprimés pelliculés              | not available                       | BE168822                             | MYLAN EPD BVBA/SPRL                       | BE                                              |
| MOXON 0,3 mg comprimés pelliculés              | not available                       | BE199613                             | MYLAN EPD BVBA/SPRL                       | BE                                              |
| MOXON 0,4 mg comprimés pelliculés              | not available                       | BE199622                             | MYLAN EPD BVBA/SPRL                       | BE                                              |
| MOXON 0,3 mg filmomhulde tabletten             | not available                       | BE199613                             | MYLAN EPD BVBA/SPRL                       | BE                                              |
| MOXON 0,3 mg Filmtabletten                     | not available                       | BE199613                             | MYLAN EPD BVBA/SPRL                       | BE                                              |
| MOXON 0,2 mg filmomhulde tabletten             | not available                       | BE168822                             | MYLAN EPD BVBA/SPRL                       | BE                                              |
| MOXON 0,2 mg Filmtabletten                     | not available                       | BE168822                             | MYLAN EPD BVBA/SPRL                       | BE                                              |
| MOXON 0,4 mg filmomhulde tabletten             | not available                       | BE199622                             | MYLAN EPD BVBA/SPRL                       | BE                                              |
| MOXON 0,4 mg Filmtabletten                     | not available                       | BE199622                             | MYLAN EPD BVBA/SPRL                       | BE                                              |

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|------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Физиотенс 0,2 mg филмирани таблетки                  | not available                       | 9900124                              | MYLAN EOOD                                | BG                                              |
| Физиотенс 0,4 mg филмирани таблетки                  | not available                       | 9900126                              | MYLAN EOOD                                | BG                                              |
| Physiotens 0,2 mg apvalkotās tabletes                | not available                       | 00-0562                              | MYLAN HEALTHCARE SIA                      | LV                                              |
| Physiotens 0,4 mg apvalkotās tabletes                | not available                       | 00-0564                              | MYLAN HEALTHCARE SIA                      | LV                                              |
| FISIOTENS® 0,3 mg, επικαλυμμένα με υμένιο δισκία     | not available                       | 45593/15-09-2009                     | BGP PRODUCTS S.LTD                        | GR                                              |
| FISIOTENS® 0,4 mg, επικαλυμμένα με υμένιο δισκία     | not available                       | 45594/15-09-2009                     | BGP PRODUCTS S.LTD                        | GR                                              |
| FISIOTENS® 0,2 mg, επικαλυμμένα με υμένιο δισκία     | not available                       | 45589/15-09-2009                     | BGP PRODUCTS S.LTD                        | GR                                              |
| Physiotens 0,2 mg, õhukese polümeerikattega tabletid | not available                       | 394902                               | MYLAN HEALTHCARE SIA                      | EE                                              |
| Physiotens 0,4 mg, õhukese polümeerikattega tabletid | not available                       | 395102                               | MYLAN HEALTHCARE SIA                      | EE                                              |

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|------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| CYNT® 0,4 mg, επικαλυμμένα με υμένιο δισκία    | not available                       | 42527/10/21-06-2011                  | BGP PRODUCTS S.LTD                        | GR                                              |
| CYNT® 0,2 mg, επικαλυμμένα με υμένιο δισκία    | not available                       | 42523/10/21-06-2011                  | BGP PRODUCTS S.LTD                        | GR                                              |
| CYNT® 0,3 mg, επικαλυμμένα με υμένιο δισκία    | not available                       | 42524/10/21-06-2011                  | BGP PRODUCTS S.LTD                        | GR                                              |
| Cynt 0,2 mg potahované tablety                 | not available                       | 58/385/96-A/C                        | MYLAN IRE HEALTHCARE LIMITED              | CZ                                              |
| Cynt 0,4 mg potahované tablety                 | not available                       | 58/385/96-C/C                        | MYLAN IRE HEALTHCARE LIMITED              | CZ                                              |
| Cynt 0,3 mg potahované tablety                 | not available                       | 58/385/96-B/C                        | MYLAN IRE HEALTHCARE LIMITED              | CZ                                              |
| Physiotens 0,2 mg kalvopäällysteinen tabletti  | not available                       | 12352                                | VIATRIS OY                                | FI                                              |
| Physiotens 0,4 mg kalvopäällysteinen tabletti  | not available                       | 12354                                | VIATRIS OY                                | FI                                              |
| Physiotens 0,2 mg filmdragerad tablett         | not available                       | 12352                                | VIATRIS OY                                | FI                                              |

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|------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Physiotens 0,4 mg filmdragerad tablett         | not available                       | 12354                                | VIATRIS OY                                | FI                                              |
| Cynt 0,2 mg filmom obložene tablete            | not available                       | HR-H-057111823                       | MYLAN HRVATSKA D.O.O.                     | HR                                              |
| Cynt 0,4 mg filmom obložene tablete            | not available                       | HR-H-013551625                       | MYLAN HRVATSKA D.O.O.                     | HR                                              |
| MoxonidinHEXAL 0,3 mg plêvele dengtos tabletês | /                                   | LT/1/04/3092/026                     | HEXAL AG                                  | LT                                              |
| MoxonidinHEXAL 0,3 mg plêvele dengtos tabletês | /                                   | LT/1/04/3092/009                     | HEXAL AG                                  | LT                                              |
| MoxonidinHEXAL 0,3 mg plêvele dengtos tabletês | /                                   | LT/1/04/3092/010                     | HEXAL AG                                  | LT                                              |
| MoxonidinHEXAL 0,3 mg plêvele dengtos tabletês | /                                   | LT/1/04/3092/013                     | HEXAL AG                                  | LT                                              |
| MoxonidinHEXAL 0,3 mg plêvele dengtos tabletês | /                                   | LT/1/04/3092/014                     | HEXAL AG                                  | LT                                              |
| MoxonidinHEXAL 0,3 mg plêvele dengtos tabletês | /                                   | LT/1/04/3092/016                     | HEXAL AG                                  | LT                                              |

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| MoxonidinHEXAL 0,3 mg plêvele dengtos tabletės | /                                   | LT/1/04/3092/015                     | HEXAL AG                                  | LT                                              |
| MoxonidinHEXAL 0,3 mg plêvele dengtos tabletės | /                                   | LT/1/04/3092/011                     | HEXAL AG                                  | LT                                              |
| MoxonidinHEXAL 0,3 mg plêvele dengtos tabletės | /                                   | LT/1/04/3092/012                     | HEXAL AG                                  | LT                                              |
| Physiotens Tablets 200 micrograms              | not available                       | MA 1187/01501                        | MYLAN IRE HEALTHCARE LIMITED              | MT                                              |
| Physiotens® Tablets 400 micrograms             | not available                       | MA 1187/01502                        | MYLAN IRE HEALTHCARE LIMITED              | MT                                              |
| PHYSIOTENS 0,2 mg, comprimé pelliculé          | not available                       | 34009 337 782 8 6                    | MYLAN MEDICAL SAS                         | FR                                              |
| PHYSIOTENS 0,2 mg, comprimé pelliculé          | not available                       | 34009 337 783 4 7                    | MYLAN MEDICAL SAS                         | FR                                              |
| PHYSIOTENS 0,2 mg, comprimé pelliculé          | not available                       | 34009 371 485 2 8                    | MYLAN MEDICAL SAS                         | FR                                              |
| PHYSIOTENS 0,2 mg, comprimé pelliculé          | not available                       | 34009 337 784 0 8                    | MYLAN MEDICAL SAS                         | FR                                              |

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| PHYSIOTENS 0,2 mg, comprimé pelliculé          | not available                       | 34009 558 526 4 3                    | MYLAN MEDICAL SAS                         | FR                                              |
| PHYSIOTENS 0,2 mg, comprimé pelliculé          | not available                       | 34009 338 313 1 8                    | MYLAN MEDICAL SAS                         | FR                                              |
| PHYSIOTENS 0,4 mg, comprimé pelliculé          | not available                       | 34009 337 789 2 7                    | MYLAN MEDICAL SAS                         | FR                                              |
| PHYSIOTENS 0,4 mg, comprimé pelliculé          | not available                       | 34009 337 790 0 9                    | MYLAN MEDICAL SAS                         | FR                                              |
| PHYSIOTENS 0,4 mg, comprimé pelliculé          | not available                       | 34009 371 486 9 6                    | MYLAN MEDICAL SAS                         | FR                                              |
| PHYSIOTENS 0,4 mg, comprimé pelliculé          | not available                       | 34009 337 791 7 7                    | MYLAN MEDICAL SAS                         | FR                                              |
| PHYSIOTENS 0,4 mg, comprimé pelliculé          | not available                       | 34009 558 528 7 2                    | MYLAN MEDICAL SAS                         | FR                                              |
| PHYSIOTENS 0,4 mg, comprimé pelliculé          | not available                       | 34009 338 483 4 7                    | MYLAN MEDICAL SAS                         | FR                                              |
| FISIOTENS 0,2 mg compresse rivestite con film  | not available                       | 034063026                            | MYLAN ITALIA S.R.L.                       | IT                                              |

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| FISIOTENS 0,2 mg compresse rivestite con film  | not available                       | 034063014                            | MYLAN ITALIA S.R.L.                       | IT                                              |
| FISIOTENS 0,3 mg compresse rivestite con film  | not available                       | 034063040                            | MYLAN ITALIA S.R.L.                       | IT                                              |
| FISIOTENS 0,3 mg compresse rivestite con film  | not available                       | 034063038                            | MYLAN ITALIA S.R.L.                       | IT                                              |
| FISIOTENS 0,4 mg compresse rivestite con film  | not available                       | 034063065                            | MYLAN ITALIA S.R.L.                       | IT                                              |
| FISIOTENS 0,4 mg compresse rivestite con film  | not available                       | 034063053                            | MYLAN ITALIA S.R.L.                       | IT                                              |
| CYNT 0,3                                       | not available                       | 58/0373/03-S                         | BIOMIN, A.S.                              | SK                                              |
| CYNT 0,4                                       | not available                       | 58/0374/03-S                         | BIOMIN, A.S.                              | SK                                              |
| CYNT 0,2                                       | not available                       | 58/0372/03-S                         | BIOMIN, A.S.                              | SK                                              |
| MOXON 0,2 mg comprimés pelliculés              | not available                       | 2005098212                           | MYLAN EPD BVBA/SPRL                       | LU                                              |

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| MOXON 0,3 mg comprimés pelliculés              | not available                       | 2005098213                           | MYLAN EPD BVBA/SPRL                       | LU                                              |
| MOXON 0,4 mg comprimés pelliculés              | not available                       | 2005098214                           | MYLAN EPD BVBA/SPRL                       | LU                                              |
| MOXON 0,2 mg Filmtabletten                     | not available                       | 2005098212                           | MYLAN EPD BVBA/SPRL                       | LU                                              |
| MOXON 0,3 mg Filmtabletten                     | not available                       | 2005098213                           | MYLAN EPD BVBA/SPRL                       | LU                                              |
| MOXON 0,4 mg Filmtabletten                     | not available                       | 2005098214                           | MYLAN EPD BVBA/SPRL                       | LU                                              |
| Moxonibene 0,2 mg-Filmtabletten                | not available                       | 1-19606                              | TEVA B.V                                  | AT                                              |
| Moxonibene 0,4 mg-Filmtabletten                | not available                       | 1-19608                              | TEVA B.V                                  | AT                                              |
| physiotens 0,2 mg plêvele dengtos tabletès     | not available                       | LT/1/97/1627/002                     | MYLAN HEALTHCARE SIA                      | LT                                              |
| physiotens 0,2 mg plêvele dengtos tabletès     | not available                       | LT/1/97/1627/001                     | MYLAN HEALTHCARE SIA                      | LT                                              |

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| physiotens 0,4 mg plêvele dengtos tabletės     | not available                       | LT/1/97/1627/004                     | MYLAN HEALTHCARE SIA                      | LT                                              |
| physiotens 0,4 mg plêvele dengtos tabletės     | not available                       | LT/1/97/1627/003                     | MYLAN HEALTHCARE SIA                      | LT                                              |
| Physiotens 0,2 mg filmom obložene tablete      | not available                       | HR-H-790867387                       | MYLAN HRVATSKA D.O.O.                     | HR                                              |
| Physiotens 0,4 mg filmom obložene tablete      | not available                       | HR-H-577589830                       | MYLAN HRVATSKA D.O.O.                     | HR                                              |
| Moxon 0,2 mg comprimidos revestidos            | not available                       | 4895785                              | BGP PRODUCTS UNIPESOAL, LDA.              | PT                                              |
| Moxon 0,2 mg comprimidos revestidos            | not available                       | 3497682                              | BGP PRODUCTS UNIPESOAL, LDA.              | PT                                              |
| Moxon 0,2 mg comprimidos revestidos            | not available                       | 3497583                              | BGP PRODUCTS UNIPESOAL, LDA.              | PT                                              |
| Moxon 0,4 mg comprimidos revestidos            | not available                       | 3498284                              | BGP PRODUCTS UNIPESOAL, LDA.              | PT                                              |
| Moxon 0,4 mg comprimidos revestidos            | not available                       | 5800388                              | BGP PRODUCTS UNIPESOAL, LDA.              | PT                                              |

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| Moxon 0,4 mg comprimidos revestidos            | not available                       | 3497989                              | BGP PRODUCTS UNIPESOAAL, LDA.             | PT                                              |
| Moxon 0,3 mg comprimidos revestidos            | not available                       | 3498482                              | BGP PRODUCTS UNIPESOAAL, LDA.             | PT                                              |
| Moxon 0,3 mg comprimidos revestidos            | not available                       | 3498383                              | BGP PRODUCTS UNIPESOAAL, LDA.             | PT                                              |
| Physiotens Tablets 200 micrograms              | not available                       | PL 46302/0045                        | MYLAN PRODUCTS LIMITED                    | XI                                              |
| Physiotens® Tablets 300 micrograms             | not available                       | PL 46302/0046                        | MYLAN PRODUCTS LIMITED                    | XI                                              |
| Physiotens® Tablets 400 micrograms             | not available                       | PL 46302/0047                        | MYLAN PRODUCTS LIMITED                    | XI                                              |
| Physiotens 0,2 mg comprimate filmate           | not available                       | 5991/2013/01                         | MYLAN HEALTHCARE GMBH                     | RO                                              |
| Physiotens 0,2 mg comprimate filmate           | not available                       | 5991/2013/02                         | MYLAN HEALTHCARE GMBH                     | RO                                              |
| Physiotens 0,2 mg comprimate filmate           | not available                       | 5991/2013/03                         | MYLAN HEALTHCARE GMBH                     | RO                                              |

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| Physiotens 0,4 mg comprimate filmate              | not available                       | 5992/2013/02                         | MYLAN HEALTHCARE GMBH                     | RO                                              |
| Physiotens 0,4 mg comprimate filmate              | not available                       | 5992/2013/03                         | MYLAN HEALTHCARE GMBH                     | RO                                              |
| Physiotens 0,4 mg comprimate filmate              | not available                       | 5992/2013/01                         | MYLAN HEALTHCARE GMBH                     | RO                                              |
| Physiotens® 0,2 mg Filmtabletten                  | not available                       | 9958.00.00                           | MYLAN HEALTHCARE GMBH                     | DE                                              |
| Physiotens® 0,3 mg Filmtabletten                  | not available                       | 9958.01.00                           | MYLAN HEALTHCARE GMBH                     | DE                                              |
| Physiotens® 0,4 mg Filmtabletten                  | not available                       | 9958.02.00                           | MYLAN HEALTHCARE GMBH                     | DE                                              |
| Physiotens 0,2 mg tabletter, filmdrasjerte        | not available                       | 96-142                               | VIATRIS AS                                | NO                                              |
| Physiotens 0,4 mg tabletter, filmdrasjerte        | not available                       | 96-144                               | VIATRIS AS                                | NO                                              |
| Moxon 0,2 mg comprimidos recubiertos con película | not available                       | 61.156                               | MYLAN IRE HEALTHCARE LIMITED              | ES                                              |

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| Moxon 0,3 mg comprimidos recubiertos con película | not available                       | 61.157                               | MYLAN IRE HEALTHCARE LIMITED              | ES                                              |
| Moxon 0,4 mg comprimidos recubiertos con película | not available                       | 61.158                               | MYLAN IRE HEALTHCARE LIMITED              | ES                                              |
| Physiotens® 0.2 mg, film-coated tablets           | not available                       | 19127                                | MYLAN IRE HEALTHCARE LIMITED              | CY                                              |
| Physiotens® 0.3 mg, film-coated tablets           | not available                       | 19128                                | MYLAN IRE HEALTHCARE LIMITED              | CY                                              |
| Physiotens® 0.4 mg, film-coated tablets           | not available                       | 19129                                | MYLAN IRE HEALTHCARE LIMITED              | CY                                              |
| Physiotens 0,2 mg filmdragerad tablett            | not available                       | 13110                                | BGP PRODUCTS AB                           | SE                                              |
| Physiotens 0,4 mg filmdragerad tablett            | not available                       | 13112                                | BGP PRODUCTS AB                           | SE                                              |
| Physiotens 0,2, 0,2 mg, tabletki powlekane        | not available                       | 4008                                 | MYLAN HEALTHCARE SP. Z.O.O.               | PL                                              |
| Physiotens 0,4, 0,4 mg, tabletki powlekane        | not available                       | 4010                                 | MYLAN HEALTHCARE SP. Z.O.O.               | PL                                              |

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| Physiotens 0,2 mg filmdabletta                 | not available                       | OGYI-T-6365/01                       | MYLAN EPD KFT.                            | HU                                              |
| Physiotens 0,3 mg filmdabletta                 | not available                       | OGYI-T-6365/04                       | MYLAN EPD KFT.                            | HU                                              |
| Physiotens 0,4 mg filmdabletta                 | not available                       | OGYI-T-6365/06                       | MYLAN EPD KFT.                            | HU                                              |