



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

22 July 2015  
EMA/586234/2015  
Procedure Management and Committees Support

## List of nationally authorised medicinal products

Active substance: amiodarone

Procedure no.: PSUSA/00000166/201412



| 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 |
|-----------------------------------------|------------------------------|-------------------------------|------------------------------------|------------------------------------------|
| Amiodaron Ratiopharm                    |                              | 38165.00.00                   | Ratiopharm Gmbh                    | DE                                       |
| Amiodaron Winthrop                      |                              | 37702.00.01                   | Winthrop Arzneimittel Gmbh         | DE                                       |
| Amiodarone                              |                              | UK: PL 03265                  | International Medication Systems   | UK                                       |
| Amiodarone - ratiopharm                 |                              | 46221.00.00                   | Ratiopharm Gmbh                    | DE                                       |
| Amiodarone Hydrochloride Tablets        | PL 11311/0170                | Tillomed Laboratories Ltd     | UK                                 |                                          |
| Amiodarone Hydrochloride Tablets        | PL 11311/0171                | Tillomed Laboratories Ltd     | UK                                 |                                          |
| Amiodarone Tablets                      |                              | PL 21880/0095                 | Medreich Plc                       | UK                                       |
| Amiodarone Tablets                      |                              | PL 21880/0096                 | Medreich Plc                       | UK                                       |
| Amiodarone Zentiva                      |                              | NL 12687                      | Sanofi-Aventis France              | FR                                       |
| Amiodarone Zentiva                      |                              | 32801019                      | Zentiva Italia SRL                 | IT                                       |
| Amiodarone-ratiopharm                   |                              | 38165.01.00                   | Ratiopharm Gmbh                    | DE                                       |
| Angoron                                 |                              | Γ9A 5895/6045                 | Sanofi-Aventis Aebe                | GR                                       |
| Angoron                                 |                              | A6a/3174/6045                 | Sanofi-Aventis Aebe                | GR                                       |
| Cordarex                                |                              | 1617.00.00                    | Sanofi-Aventis Deutschland Gmbh    | DE                                       |
| Cordarex                                |                              | 41452.00.01                   | Sanofi-Aventis                     | DE                                       |

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|                                         |                              |                               | Deutschland Gmbh                   |                                          |
| Cordarone                               |                              | BE048885                      | Sanofi Belgium                     | BE                                       |
| Cordarone                               |                              | BE110634                      | Sanofi Belgium                     | BE                                       |
| Cordarone                               |                              | 20000427                      | Sanofi-Aventis Bulgaria Eood       | BG                                       |
| Cordarone                               |                              | 980 002 8                     | Sanofi-Aventis Bulgaria Eood       | BG                                       |
| Cordarone                               |                              | 019165                        | Sanofi-Aventis Cyprus Ltd          | CY                                       |
| Cordarone                               |                              | 019178                        | Sanofi-Aventis Cyprus Ltd          | CY                                       |
| Cordarone                               |                              | 13/134/82-C                   | Sanofi-Aventis Sro                 | CZ                                       |
| Cordarone                               |                              | 13/135/82-C                   | Sanofi-Aventis Sro                 | CZ                                       |
| Cordarone                               |                              | 11775                         | Sanofi-Aventis Denmark A/S         | DK                                       |
| Cordarone                               |                              | 11776                         | Sanofi-Aventis Denmark A/S         | DK                                       |
| Cordarone                               |                              | 13084                         | Sanofi-Aventis Denmark A/S         | DK                                       |
| Cordarone                               |                              | 311300                        | Sanofi-Aventis Estonia Oü          | EE                                       |

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| Cordarone                               |                              | 311400                        | Sanofi-Aventis Estonia OÜ          | EE                                       |
| Cordarone                               |                              | 10522                         | Sanofi Oy                          | FI                                       |
| Cordarone                               |                              | 9367                          | Sanofi Oy                          | FI                                       |
| Cordarone                               |                              | 9368                          | Sanofi Oy                          | FI                                       |
| Cordarone                               |                              | VNL 07878                     | Sanofi-Aventis France              | FR                                       |
| Cordarone                               |                              | VNL 10526                     | Sanofi-Aventis France              | FR                                       |
| Cordarone                               |                              | UP/I-530-09/12-02/356         | Sanofi-Aventis Croatia D.O.O.      | HR                                       |
| Cordarone                               |                              | UP/I-530-09/12-02/357         | Sanofi-Aventis Croatia D.O.O.      | HR                                       |
| Cordarone                               | National authorisation       | OGYI-T-1166/01-02             | Sanofi-Aventis Private Co Ltd      | HU                                       |
| Cordarone                               | National authorisation       | 1166/03-04                    | Sanofi-Aventis Private Co Ltd      | HU                                       |
| Cordarone                               |                              | PA 540/142/1                  | Sanofi-Aventis Ireland Ltd         | IE                                       |
| Cordarone                               |                              | PA 540/142/2                  | Sanofi-Aventis Ireland Ltd         | IE                                       |

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| Cordarone                               |                              | PA 540/142/3                  | Sanofi-Aventis Ireland Ltd         | IE                                       |
| Cordarone                               |                              | 853696                        | Sanofi-Aventis Norge As            | IS                                       |
| Cordarone                               |                              | 11349 853697                  | Sanofi-Aventis Norge As            | IS                                       |
| Cordarone                               |                              | 890017                        | Sanofi-Aventis Norge As            | IS                                       |
| Cordarone                               |                              | 025035015                     | Sanofi Spa                         | IT                                       |
| Cordarone                               |                              | 025035027                     | Sanofi Spa                         | IT                                       |
| Cordarone                               |                              | 025035039                     | Sanofi Spa                         | IT                                       |
| Cordarone                               |                              | 12963<br>LT/1/96/1502/001     | Uab Sanofi-Aventis Lietuva         | LT                                       |
| Cordarone                               |                              | LT/1/96/1502/002              | Uab Sanofi-Aventis Lietuva         | LT                                       |
| Cordarone                               |                              | 0005/03/10/7960               | Sanofi Belgium                     | LU                                       |
| Cordarone                               |                              | 0006/03/10/7888               | Sanofi Belgium                     | LU                                       |
| Cordarone                               |                              | 96-0386-01                    | Sanofi-Aventis Latvia Sia          | LV                                       |
| Cordarone                               |                              | 97-0599-01                    | Sanofi-Aventis Latvia              | LV                                       |

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|                                         |                              |                               | Sia                                 |                                          |
| Cordarone                               |                              | MA082/04701                   | Sanofi Malta Ltd                    | MT                                       |
| Cordarone                               |                              | MA082/04702                   | Sanofi Malta Ltd                    | MT                                       |
| Cordarone                               |                              | RVG 05443                     | Sanofi-Aventis Netherlands B.V.     | NL                                       |
| Cordarone                               |                              | RVG 10937                     | Sanofi-Aventis Netherlands B.V.     | NL                                       |
| Cordarone                               |                              | 7415                          | Sanofi-Aventis Norge As             | NO                                       |
| Cordarone                               |                              | 7416                          | Sanofi-Aventis Norge As             | NO                                       |
| Cordarone                               |                              | 7617                          | Sanofi-Aventis Norge As             | NO                                       |
| Cordarone                               |                              | R/1636                        | Sanofi-Aventis France               | PL                                       |
| Cordarone                               |                              | R/1637                        | Sanofi-Aventis France               | PL                                       |
| Cordarone                               |                              | 4590584                       | Sanofi - Produtos Farmaceuticos Lda | PT                                       |
| Cordarone                               |                              | 8287607                       | Sanofi - Produtos Farmaceuticos Lda | PT                                       |

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| Cordarone                               |                              | 8287623                       | Sanofi - Produtos Farmaceuticos Lda | PT                                       |
| Cordarone                               |                              | 8468009                       | Sanofi - Produtos Farmaceuticos Lda | PT                                       |
| Cordarone                               |                              | 5713/2005                     | Sanofi-Aventis France               | RO                                       |
| Cordarone                               |                              | 10572                         | Sanofi Ab                           | SE                                       |
| Cordarone                               |                              | 10656                         | Sanofi Ab                           | SE                                       |
| Cordarone                               |                              | 11032                         | Sanofi Ab                           | SE                                       |
| Cordarone                               |                              | 5363-I-1553/12                | Sanofi-Aventis D.O.O.               | SI                                       |
| Cordarone                               |                              | 5363-I-87/14                  | Sanofi-Aventis D.O.O.               | SI                                       |
| Cordarone                               |                              | 5363-I-88/14                  | Sanofi-Aventis D.O.O.               | SI                                       |
| Cordarone                               |                              | 13/134/82-C/S                 | Sanofi-Aventis Slovakia Sro         | SK                                       |
| Cordarone                               |                              | 13/135/82-C/S                 | Sanofi-Aventis Slovakia Sro         | SK                                       |
| Cordarone                               |                              | PL 17780/0586                 | Winthrop Pharmaceuticals Uk Ltd     | UK                                       |

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| Cordarone                               |                              | PL 17780/0587                 | Winthrop Pharmaceuticals Uk Ltd    | UK                                       |
| Cordarone X Intravenous                 |                              | PL 04425/0643                 | Aventis Pharma Ltd Uk              | UK                                       |
| Trangorex                               |                              | 48048                         | Sanofi-Aventis Sa                  | ES                                       |
| Trangorex                               |                              | 54723                         | Sanofi-Aventis Sa                  | ES                                       |