



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

28 September 2017  
EMA/658449/2017  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: olodaterol

Procedure no.: PSUSA/00010245/201703



| 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 |
|----------------------------------------------------------------------------|------------------------------|-------------------------------|-----------------------------------------|------------------------------------------|
| Striverdi Respimat 2,5 mikrogram inhalationsvätska, lösning                | NL/H/2498/001                | 48116                         | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | SE                                       |
| Striverdi Respimat 2,5 mikrogramov, inhalačný roztok                       | NL/H/2498/001                | 14/0394/13-S                  | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | SK                                       |
| Striverdi Respimat, 2,5 mikrogrammi inhalatsioonilahus                     | NL/H/2498/001                | 825513                        | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | EE                                       |
| Striverdi Respimat 2,5 microgramos, solución para inhalación               | NL/H/2498/001                | 78253                         | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | ES                                       |
| Striverdi Respimat 2,5 mikrogramów/dawkę dostarczaną, roztwór do inhalacji | NL/H/2498/001                | 21718                         | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | PL                                       |
| Striverdi Respimat 2,5 microgramas, solução para inalação                  | NL/H/2498/001                | 5588223                       | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | PT                                       |
| Striverdi Respimat 2,5 mikrogramov/vdih raztopina za inhaliranje           | NL/H/2498/001                | 5363-I-369/14                 | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | SI                                       |
| Striverdi Respimat 2,5 Mikrogramm - Lösung zur Inhalation                  | NL/H/2498/001                | 1-35232                       | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | AT                                       |
| STRIVERDI RESPIMAT 2,5 microgrammi, soluzione per inalazione               | NL/H/2498/001                | 042432043                     | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | IT                                       |
| STRIVERDI RESPIMAT 2,5 microgrammi, soluzione per inalazione               | NL/H/2498/001                | 042432031                     | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | IT                                       |
| STRIVERDI RESPIMAT 2,5 microgrammi, soluzione per inalazione               | NL/H/2498/001                | 042432029                     | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | IT                                       |

| 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 |
|--------------------------------------------------------------------|------------------------------|-------------------------------|-----------------------------------------|------------------------------------------|
| STRIVERDI RESPIMAT 2,5 microgrammi, soluzione per inalazione       | NL/H/2498/001                | 042432017                     | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | IT                                       |
| Striverdi Respimat 2,5 mikrogram, inhalationsvätska, lösning       | NL/H/2498/001                | 30771                         | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | FI                                       |
| Striverdi Respimat 2,5 μικρογραμμάρια, εισπνεόμενο διάλυμα         | NL/H/2498/001                | 49642                         | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | GR                                       |
| Striverdi Respimat 2,5 mikrogramu roztok k inhalaci                | NL/H/2498/001                | 14/111/14-C                   | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | CZ                                       |
| STRIVERDI RESPIMAT 2,5 microgrammes/dose, solution pour inhalation | NL/H/2498/001                | 3400958626111                 | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | FR                                       |
| STRIVERDI RESPIMAT 2,5 microgrammes/dose, solution pour inhalation | NL/H/2498/001                | 3400958626050                 | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | FR                                       |
| STRIVERDI RESPIMAT 2,5 microgrammes/dose, solution pour inhalation | NL/H/2498/001                | 3400958625978                 | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | FR                                       |
| STRIVERDI RESPIMAT 2,5 microgrammes/dose, solution pour inhalation | NL/H/2498/001                | 3400927723278                 | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | FR                                       |
| Striverdi Respimat 2,5 micrograme soluție de inhalat               | NL/H/2498/001                | 6414/2014/04                  | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | RO                                       |
| Striverdi Respimat 2,5 micrograme soluție de inhalat               | NL/H/2498/001                | 6414/2014/03                  | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | RO                                       |
| Striverdi Respimat 2,5 micrograme soluție de inhalat               | NL/H/2498/001                | 6414/2014/02                  | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | RO                                       |

| 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 |
|--------------------------------------------------------------|------------------------------|-------------------------------|-----------------------------------------|------------------------------------------|
| Striverdi Respimat 2,5 micrograme soluție de inhalat         | NL/H/2498/001                | 6414/2014/01                  | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | RO                                       |
| Striverdi Respimat 2,5 μικρογραμμάρια, εισπνεόμενο διάλυμα   | NL/H/2498/001                | 022003                        | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | CY                                       |
| Striverdi Respimat 2,5 Mikrogramm - Lösung zur Inhalation    | NL/H/2498/001                | 2014040048                    | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | LU                                       |
| Striverdi Respimat 2,5 microgrammes/dose, solution à inhaler | NL/H/2498/001                | 2014040048                    | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | LU                                       |
| Striverdi Respimat 2,5 Mikrogramm - Lösung zur Inhalation    | NL/H/2498/001                | BE443791                      | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | BE                                       |
| Striverdi Respimat 2,5 microgram, inhalatieoplossing         | NL/H/2498/001                | BE443791                      | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | BE                                       |
| Striverdi Respimat 2,5 microgram, inhalatieoplossing         | NL/H/2498/001                | RVG 112058                    | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | NL                                       |
| Стриверди Респимат 2,5 микрограма, разтвор за инхалация      | NL/H/2498/001                | 20130417                      | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | BG                                       |
| Striverdi Respimat, inhalationsvæske, opløsning              | NL/H/2498/001                | 50975                         | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | DK                                       |
| Striverdi Respimat 2,5 mikrogramm inhalációs oldat           | NL/H/2498/001                | OGYI-T-22563/02               | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | HU                                       |
| Striverdi Respimat 2,5 mikrogramm inhalációs oldat           | NL/H/2498/001                | OGYI-T-22563/04               | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | HU                                       |

| 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 |
|---------------------------------------------------------------|------------------------------|-------------------------------|-----------------------------------------|------------------------------------------|
| Striverdi Respimat 2,5 Mikrogramm - Lösung zur Inhalation     | NL/H/2498/001                | 1-35232                       | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | LI                                       |
| Striverdi® Respimat® 2,5 Mikrogramm/Hub Lösung zur Inhalation | NL/H/2498/001                | 87146.00.00                   | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | DE                                       |
| Striverdi Respimat 2,5 mikrogrami šķīdums inhalācijām         | NL/H/2498/001                | 13-0232                       | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | LV                                       |
| Striverdi Respimat 2,5 mikrog, inhalaationeste, liuos         | NL/H/2498/001                | 30771                         | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | FI                                       |
| Striverdi Respimat 2,5 mikrogramm inhalációs oldat            | NL/H/2498/001                | OGYI-T-22563/01               | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | HU                                       |
| Striverdi Respimat 2,5 mikrogramm inhalációs oldat            | NL/H/2498/001                | OGYI-T-22563/03               | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | HU                                       |
| Striverdi Respimat 2,5 mikrógrömm, innöndunarlausn            | NL/H/2498/001                | IS/1/13/083/01                | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | IS                                       |
| Striverdi Respimat 2,5 microgrammes, solution à inhaler       | NL/H/2498/001                | BE443791                      | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | BE                                       |
| Striverdi 2,5 mikrogram, inhalasjonsvæske, oppløsning         | NL/H/2498/001                | 12-9096                       | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | NO                                       |
| Striverdi Respimat 2.5 microgram, inhalation solution         | NL/H/2498/001                | MA 211/00401                  | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | MT                                       |
| Striverdi Respimat 2.5 microgram, inhalation solution         | NL/H/2498/001                | PA 775/6/1                    | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | IE                                       |

| <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> |
|--------------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Striverdi Respimat 2.5 microgram, inhalation solution              | NL/H/2498/001                       | PL 14598/0093                        | BOEHRINGER INGELHEIM INTERNATIONAL GMBH   | UK                                              |
| Striverdi Respimat 2,5 mikrogramo/išpurškime įkvepiamasis tirpalas | NL/H/2498/001                       | LT/1/13/3429/001                     | BOEHRINGER INGELHEIM INTERNATIONAL GMBH   | LT                                              |
| Striverdi Respimat 2,5 mikrogramo/išpurškime įkvepiamasis tirpalas | NL/H/2498/001                       | LT/1/13/3429/002                     | BOEHRINGER INGELHEIM INTERNATIONAL GMBH   | LT                                              |
| Striverdi Respimat 2,5 mikrogramo/išpurškime įkvepiamasis tirpalas | NL/H/2498/001                       | LT/1/13/3429/003                     | BOEHRINGER INGELHEIM INTERNATIONAL GMBH   | LT                                              |
| Striverdi Respimat 2,5 mikrogramo/išpurškime įkvepiamasis tirpalas | NL/H/2498/001                       | LT/1/13/3429/004                     | BOEHRINGER INGELHEIM INTERNATIONAL GMBH   | LT                                              |