



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

14 September 2016  
EMA/731767/2016  
Procedure Management and Committees Support

## List of nationally authorised medicinal products

Active substance: testosterone undecanoate (injection)

Procedure no.: PSUSA/00010161/201512



| <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> |
|------------------------------------------------|---------------------------------------|--------------------------------------------|-------------------------------------------|-------------------------------------------------|
| Nebid                                          | FI/H/0313/001                         | 037051012                                  | Bayer Spa                                 | Italy                                           |
| Nebid                                          | FI/H/0313/001                         | 037051024                                  | Bayer Spa                                 | Italy                                           |
| Nebido                                         |                                       | 7615/2015/01-02                            | Bayer Pharma Ag                           | Romania                                         |
| Nebido                                         | FI/H/0313/001                         | 05-0141                                    | Bayer Pharma Ag                           | Latvia                                          |
| Nebido                                         | FI/H/0313/001                         | 1-25516                                    | Bayer Austria Gmbh                        | Austria                                         |
| Nebido                                         | FI/H/0313/001                         | 11740                                      | Bayer Pharma Ag                           | Poland                                          |
| Nebido                                         | FI/H/0313/001                         | 19681                                      | Bayer Hellas Sa                           | Cyprus                                          |
| Nebido                                         | FI/H/0313/001                         | 2007060006                                 | Bayer Sa Nv                               | Luxembourg                                      |
| Nebido                                         | FI/H/0313/001                         | 2007060006                                 | Bayer Sa Nv                               | Luxembourg                                      |
| Nebido                                         | FI/H/0313/001                         | 5159587 \$<br>5490057                      | Bayer Portugal Sa                         | Portugal                                        |
| Nebido                                         | FI/H/0313/001                         | 56/0144/05-S                               | Bayer Pharma Ag                           | Slovakia                                        |
| Nebido                                         | FI/H/0313/001                         | 5917/26-1-2011                             | Bayer Hellas Sa                           | Greece                                          |
| Nebido                                         | FI/H/0313/001                         | BE266384 \$<br>BE437132                    | Bayer Sa Nv                               | Belgium                                         |
| Nebido                                         | FI/H/0313/001                         | BE437132                                   | Bayer Sa Nv                               | Belgium                                         |
| Nebido                                         | FI/H/0313/001                         | H/05/01097/001 \$<br>H/05/01097/002        | Bayer Pharma Ag                           | Slovenia                                        |
| Nebido                                         | FI/H/0313/001                         | LT/1/05/0222/001<br>\$<br>LT/1/05/0222/002 | Bayer Pharma Ag                           | Lithuania                                       |
| Nebido                                         | FI/H/0313/001                         | MA185/02701                                | Bayer Plc                                 | Malta                                           |
| Nebido                                         | FI/H/0313/001                         | PL 00010/0549                              | Bayer Plc                                 | United Kingdom                                  |
| Nebido                                         | FI/H/0313/001                         | RVG 30794                                  | Bayer Bv                                  | Netherlands                                     |
| Nebido                                         | FI/H/313/01                           | 04- 2635                                   | Bayer Pharma Ag                           | Norway                                          |
| Nebido                                         | FI/H/313/01                           | 17857                                      | Bayer Oy                                  | Finland                                         |
| Nebido                                         | FI/H/313/01                           | 20890                                      | Bayer Pharma Ag                           | Sweden                                          |
| Nebido                                         | FI/H/313/01                           | NL30240                                    | Bayer Healthcare                          | France                                          |
| Nebido                                         | FI/H/313/01                           | 36481                                      | Bayer Pharma Ag                           | Denmark                                         |

|          |             |                                        |                        |                |
|----------|-------------|----------------------------------------|------------------------|----------------|
| Nebido   | FI/H/313/01 | 472505                                 | Bayer Pharma Ag        | Estonia        |
| Nebido   | FI/H/313/01 | 56/176/05-C                            | Bayer Pharma Ag        | Czech Republic |
| Nebido   | FI/H/313/01 | 60074.00.00                            | Jenapharm Gmbh & Co Kg | Germany        |
| Nebido   | FI/H/313/01 | HR-H-728666888-01 \$ HR-H-728666888-02 | Bayer Doo              | Croatia        |
| Nebido   | FI/H/313/01 | IS/1/04/026/01                         | Bayer Pharma Ag        | Iceland        |
| Nebido   | FI/H/313/01 | OGYI-T-10175/01 \$ OGYI-T-10175/02     | Bayer Pharma Ag        | Hungary        |
| Nebido   | FI/H/313/01 | PA 1410/20/1                           | Bayer Ltd              | Ireland        |
| Reandron | FI/H/313/01 | 66.470                                 | Bayer Hispania Sl      | Spain          |
| небидо   |             | II-14422/12.08.2011                    | Bayer Pharma Ag        | Bulgaria       |