



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

13 September 2017  
EMA/715760/2017  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: bacillus clausii multi-antibioresistant spores

Procedure no.: PSUSA/00000284/201611



| <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> |
|------------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| ENTEROGERMINA                                                    | not available                       | 013046026                            | SANOFI SPA                                | IT                                              |
| ENTEROGERMINA                                                    | not available                       | 013046014                            | SANOFI SPA                                | IT                                              |
| ENTEROGERMINA 2                                                  | not available                       | 013046040                            | SANOFI SPA                                | IT                                              |
| ENTEROGERMINA 2                                                  | not available                       | 013046038                            | SANOFI SPA                                | IT                                              |
| ENTEROGERMINA 2<br>MILIARDI CAPSULE<br>RIGIDE                    | not available                       | 013046053                            | SANOFI SPA                                | IT                                              |
| ENTEROGERMINA 2<br>MILIARDI CAPSULE<br>RIGIDE                    | not available                       | 013046065                            | SANOFI SPA                                | IT                                              |
| ENTEROGERMINA 4<br>MILIARDI / 5 ML<br>SOSPENSIONE ORALE          | not available                       | 013046077                            | SANOFI SPA                                | IT                                              |
| ENTEROGERMINA 4<br>MILIARDI / 5 ML<br>SOSPENSIONE ORALE          | not available                       | 013046089                            | SANOFI SPA                                | IT                                              |
| ENTEROGERMINA 6<br>miliardi/2 g polvere per<br>sospensione orale | not available                       | 013046091                            | SANOFI SPA                                | IT                                              |

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|------------------------------------------------------------|------------------------------|-------------------------------|------------------------------------|------------------------------------------|
| ENTEROGERMINA 6 miliardi/2 g polvere per sospensione orale | not available                | 013046103                     | SANOFI SPA                         | IT                                       |
| NORMAFLORE BELSOLEGES SZUSZPENZIO                          | not available                | OGYI-T-10357/02               | SANOFI-AVENTIS ZRT                 | HU                                       |
| Normaflore belsőleges szuszpenzió                          | not available                | OGYI-T-10357/05               | SANOFI-AVENTIS ZRT                 | HU                                       |
| Normaflore belsőleges szuszpenzió                          | not available                | OGYI-T-10357/01               | SANOFI-AVENTIS ZRT                 | HU                                       |
| Normaflore Extra 4 milliárd/5 ml belsőleges szuszpenzió    | not available                | OGYI-T-10357/08               | SANOFI-AVENTIS ZRT                 | HU                                       |
| Normaflore Extra 4 milliárd/5 ml belsőleges szuszpenzió    | not available                | OGYI-T-10357/06               | SANOFI-AVENTIS ZRT                 | HU                                       |
| Normaflore Extra 4 milliárd/5 ml belsőleges szuszpenzió    | not available                | OGYI-T-10357/07               | SANOFI-AVENTIS ZRT                 | HU                                       |
| NORMAFLORE KEMENY KAPSZULA                                 | not available                | OGYI-T-10357/04               | SANOFI-AVENTIS ZRT                 | HU                                       |
| NORMAFLORE KEMENY KAPSZULA                                 | not available                | OGYI-T-10357/03               | SANOFI-AVENTIS ZRT                 | HU                                       |

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|---------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Normaflore Max 6 milliárd por belsőleges szuszpenzióhoz | not available                       | OGYI-T-10357/09                      | SANOFI-AVENTIS ZRT                        | HU                                              |
| Normaflore Max 6 milliárd por belsőleges szuszpenzióhoz | not available                       | OGYI-T-10357/10                      | SANOFI-AVENTIS ZRT                        | HU                                              |
| Normaflore Max 6 milliárd por belsőleges szuszpenzióhoz | not available                       | OGYI-T-10357/11                      | SANOFI-AVENTIS ZRT                        | HU                                              |