



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

17 March 2016  
EMA/268896/2016  
Procedure Management and Committees Support

## List of nationally authorised medicinal products

Active substance: ribavirin (aerosol application)

Procedure no.: PSUSA/00010003/201508



| 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 |
|-----------------------------------------------------------------------------------------------------|--------------------------------|-------------------------------|------------------------------------|------------------------------------------|
| Virazole®-<br>Trockensubstanz 6 g,<br>Pulver zur Herstellung<br>einer Lösung für einen<br>Vernebler | not available                  | 13580.00.00                   | MEDA PHARMA GMBH & CO.<br>KG       | DE                                       |
| VIRAZOLE 6 g                                                                                        | not available                  | 57750                         | MEDA PHARMA S.A.U.                 | ES                                       |
| VIRAZOLE 6 g polvere<br>per soluzione per<br>nebulizzatore                                          | not available                  | 026875017                     | MEDA PHARMA S.P.A.                 | IT                                       |
| Virazole 6 g poudre pour<br>solution pour inhalation<br>par nébuliseur                              | not available                  | 1993/010033                   | S.A. MEDA PHARMA N.V.              | LU                                       |
| Virazole 6 g poudre pour<br>solution pour inhalation<br>par nébuliseur                              | not available                  | BE 143893                     | S.A. MEDA PHARMA N.V.              | BE                                       |

| 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 |
|--------------------------------------------------|--------------------------------|-------------------------------|------------------------------------|------------------------------------------|
| Virazole 6g, poeder voor verneveloplossing       | not available                  | BE 143893                     | S.A. MEDA PHARMA N.V.              | BE                                       |
| Virazole 6 g pulver till lösning för nebulisator | not available                  | 10914                         | MEDA AB                            | SE                                       |
| Virazole, poeder voor verneveloplossing          | not available                  | RVG 12588                     | MEDA PHARMA B.V.                   | NL                                       |