



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 May 2020
EMA/276465/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: ambroxol / clenbuterol

Procedure no.: PSUSA/00000131/201909

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



| 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| CLEMBROXOL 30 mg + 0,02 mg COMPRIMIDOS | not available | 2266195 | PENTAFARMA - SOCIEDADE TECNICO-MEDICINAL S.A. | PT |
| CLEMBROXOL 30 mg + 0,02 mg COMPRIMIDOS | not available | 2266294 | PENTAFARMA - SOCIEDADE TECNICO-MEDICINAL S.A. | PT |
| Ventoliber 30 mg + 0,02 mg Granulado | not available | 2229193 | TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA | PT |
| Mucospas® - Saft | not available | 1-18236 | SANOFI-AVENTIS GMBH OSTERREICH | AT |
| SPASMO-MUCOSOLVAN SAFT | not available | 4661.00.00 | SANOFI-AVENTIS DEUTSCHLAND GMBH | DE |
| Mucospas 1,5 mg/ml + 0,001 mg/ml xarope | not available | 8670216 | SANOFI - PRODUTOS FARMACEUTICOS LDA | PT |
| Mucospas 3 mg/ml + 0,002 mg/ml xarope | not available | 8670208 | SANOFI - PRODUTOS FARMACEUTICOS LDA | PT |
| Mucospas® - Tabletten | not available | 1-18235 | SANOFI-AVENTIS GMBH OSTERREICH | AT |
| CLEMBROXOL 30 mg + 0,02 mg GRANULADO | not available | 2266393 | PENTAFARMA - SOCIEDADE TECNICO-MEDICINAL S.A. | PT |
| Ventoliber 30 mg + 0,02 mg Comprimido | not available | 2229490 | TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA | PT |
| Ventoliber 30 mg + 0,02 mg Comprimido | not available | 2229599 | TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA | PT |
| Spasmo-Mucosolvan® 0,02 mg/30 mg Tabletten | not available | 4661.01.01 | SANOFI-AVENTIS DEUTSCHLAND GMBH | DE |