



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

15 January 2026  
EMADOC-1700519818-2850276  
Human Medicines Division

## List of nationally authorised medicinal products

Active substance(s): hyoscine butylbromide / paracetamol

EURD list No. PSUSA/00002303/202505



| Product full name                                      | MRP/DCP or CP Authorisation number | National Authorisation Number of product in the member state | MAH of product in the member state                       | Member State where product is authorised |
|--------------------------------------------------------|------------------------------------|--------------------------------------------------------------|----------------------------------------------------------|------------------------------------------|
| Buscopan® plus Paracetamol 10 mg/ 500 mg Filmtabletten | not available                      | 1-19251                                                      | OPELLA HEALTHCARE AUSTRIA GMBH                           | AT                                       |
| Buscopan Plus®                                         | not available                      | 14583                                                        | OPELLA Ε.Π.Ε.                                            | CY                                       |
| Buscopan Plus®                                         | not available                      | 14583                                                        | OPELLA Ε.Π.Ε.                                            | CY                                       |
| Buscopan® plus 10 mg/800 mg, Zäpfchen                  | not available                      | 2476.00.01                                                   | A. NATTERMANN & CIE. GMBH                                | DE                                       |
| Buscopan® plus 10 mg/800 mg, Zäpfchen                  | not available                      | 2476.00.01                                                   | A. NATTERMANN & CIE. GMBH                                | DE                                       |
| Buscopan® plus 10 mg/500 mg, Filmtabletten             | not available                      | 2476.00.00                                                   | A. NATTERMANN & CIE. GMBH                                | DE                                       |
| Buscopan Plus®                                         | not available                      | 37246/10/18.04.2011                                          | OPELLA Ε.Π.Ε.                                            | GR                                       |
| Buscopan Plus®                                         | not available                      | 37246/10/18.04.2011                                          | OPELLA Ε.Π.Ε.                                            | GR                                       |
| SPASMO-APOTEL (600+20) mg/4mL, Ενέσιμο διάλυμα         | not available                      | 40810/05-05-2021                                             | UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A. | GR                                       |
| Buscopan compositum 10 mg + 500 mg compresse rivestite | not available                      | 029454016                                                    | OPELLA HEALTHCARE ITALY S.R.L.                           | IT                                       |
| Buscopan compositum 10 mg + 500 mg compresse rivestite | not available                      | 029454042                                                    | OPELLA HEALTHCARE ITALY S.R.L.                           | IT                                       |
| Buscopan Compositum N 10 mg + 800 mg supositórios      | not available                      | 9767103                                                      | OPELLA HEALTHCARE PORTUGAL UNIPESSOAL LDA.               | PT                                       |