



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

11 November 2021  
EMA/749047/2021  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: metamizole

Procedure no.: PSUSA/00001997/202103

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**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](http://www.ema.europa.eu/how-to-find-us)

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| <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> |
|---|-------------------------------------|--------------------------------------|---|---|
| ALGI-MABO 0,4 g/ml solución inyectable y para perfusión   | not available                       | 51.345                               | MABO-FARMA, S.A                           | ES  |
| ALGI-MABO 500 mg cápsulas duras                           | not available                       | 48.905                               | MABO-FARMA, S.A                           | ES  |
| ALGI-MABO ADULTOS 1 g supositorios                        | not available                       | 51.599                               | MABO-FARMA, S.A                           | ES  |
| Metalgial 500 mg/mL gotas orales en solución              | not available                       | 72.149                               | LABORATORIOS ERN, S.A.                    | ES  |
| Metamizol Zentiva 500 mg Filmtabletten                    | not available                       | 7000744.00.00                        | ZENTIVA PHARMA GMBH                       | DE  |
| Metamizol Zentiva 500 mg/ml Tropfen zum Einnehmen, Lösung | not available                       | 7000079.00.00                        | ZENTIVA PHARMA GMBH                       | DE  |
| Nolotil 2000 mg/5 ml solução inyectável                   | not available                       | 8512202                              | BOEHRINGER INGELHEIM, UNIPESSOAL, LDA.    | PT  |
| Nolotil 2000 mg/5 ml solução inyectável                   | not available                       | 8512210                              | BOEHRINGER INGELHEIM, UNIPESSOAL, LDA.    | PT  |
| Nolotil 0,4 g/ml solución inyectable y para perfusión     | not available                       | 42.304                               | BOEHRINGER INGELHEIM ESPANA S.A.          | ES  |

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|--|-------------------------------------|--------------------------------------|---|---|
| Nolotil 575 mg cápsulas                        | not available                       | 9512426                              | BOEHRINGER INGELHEIM, UNIPESSOAL, LDA.    | PT  |
| Nolotil 575 mg cápsulas                        | not available                       | 9512434                              | BOEHRINGER INGELHEIM, UNIPESSOAL, LDA.    | PT  |
| Nolotil 575 mg cápsulas                        | not available                       | 9512442                              | BOEHRINGER INGELHEIM, UNIPESSOAL, LDA.    | PT  |
| Nolotil 575 mg cápsulas duras                  | not available                       | 47.633                               | BOEHRINGER INGELHEIM ESPANA S.A.          | ES  |
| NOVALGIN 1,0 G AMPULLEN                        | not available                       | 3.191                                | SANOFI-AVENTIS GMBH OSTERREICH            | AT  |
| NOVALGIN 1,0 G AMPULLEN                        | not available                       | 3.191                                | SANOFI-AVENTIS GMBH OSTERREICH            | AT  |
| NOVALGIN 1,0 G AMPULLEN                        | not available                       | 3.191                                | SANOFI-AVENTIS GMBH OSTERREICH            | AT  |
| NOVALGIN 2,5 G AMPULLEN                        | not available                       | 5.139                                | SANOFI-AVENTIS GMBH OSTERREICH            | AT  |
| NOVALGIN 2,5 G AMPULLEN                        | not available                       | 5.139                                | SANOFI-AVENTIS GMBH OSTERREICH            | AT  |

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|--|-------------------------------------|--------------------------------------|---|---|
| NOVALGIN 2,5 G<br>AMPULLEN                     | not available                       | 5.139                                | SANOFI-AVENTIS GMBH<br>OSTERREICH         | AT  |
| NOVALGIN 2,5 G<br>AMPULLEN                     | not available                       | 5.139                                | SANOFI-AVENTIS GMBH<br>OSTERREICH         | AT  |
| NOVALGIN 500                                   | not available                       | 0080208                              | SANOFI BELGIUM                            | LU  |
| NOVALGIN 500 MG                                | not available                       | 07/0557/95-S                         | SANOFI-AVENTIS SLOVAKIA<br>SRO            | SK  |
| NOVALGIN 500 MG                                | not available                       | 07/0557/95-S                         | SANOFI-AVENTIS SLOVAKIA<br>SRO            | SK  |
| NOVALGIN 500 MG                                | not available                       | 07/0557/95-S                         | SANOFI-AVENTIS SLOVAKIA<br>SRO            | SK  |
| Novalgin 500 mg<br>potahované tablety          | not available                       | 07/447/00-C                          | SANOFI-AVENTIS SRO                        | CZ  |
| Novalgin 500 mg<br>potahované tablety          | not available                       | 07/447/00-C                          | SANOFI-AVENTIS SRO                        | CZ  |
| Novalgin 500 mg/1 ml<br>injekčný roztok        | not available                       | 07/0271/95-S                         | SANOFI-AVENTIS SLOVAKIA<br>SRO            | SK  |

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|--|-------------------------------------|--------------------------------------|---|---|
| Novalgin 500 mg/1 ml injekčný roztok           | not available                       | 07/0271/95-S                         | SANOFI-AVENTIS SLOVAKIA SRO               | SK  |
| Novalgin 500 mg/ml injekční roztok             | not available                       | 07/448/00-C                          | SANOFI-AVENTIS SRO                        | CZ  |
| Novalgin 500 mg/ml injekční roztok             | not available                       | 07/448/00-C                          | SANOFI-AVENTIS SRO                        | CZ  |
| NOVALGIN FILMTABLETTEN                         | not available                       | 3.192                                | SANOFI-AVENTIS GMBH OSTERREICH            | AT  |
| NOVALGIN FILMTABLETTEN                         | not available                       | 3.192                                | SANOFI-AVENTIS GMBH OSTERREICH            | AT  |
| NOVALGIN FILMTABLETTEN                         | not available                       | 3.192                                | SANOFI-AVENTIS GMBH OSTERREICH            | AT  |
| NOVALGIN FILMTABLETTEN                         | not available                       | 3.192                                | SANOFI-AVENTIS GMBH OSTERREICH            | AT  |
| NOVALGIN FILMTABLETTEN                         | not available                       | 3.192                                | SANOFI-AVENTIS GMBH OSTERREICH            | AT  |
| Novalgin Tropfen                               | not available                       | 6.704                                | SANOFI-AVENTIS GMBH OSTERREICH            | AT  |

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|--|-------------------------------------|--------------------------------------|---|---|
| Novalgin Tropfen                               | not available                       | 6.704                                | SANOFI-AVENTIS GMBH<br>OSTERREICH         | AT  |
| Novalgin Tropfen                               | not available                       | 6.704                                | SANOFI-AVENTIS GMBH<br>OSTERREICH         | AT  |
| Novalgin Tropfen                               | not available                       | 6.704                                | SANOFI-AVENTIS GMBH<br>OSTERREICH         | AT  |
| NOVALGINA 1g/2 ml<br>soluzione iniettabile     | not available                       | 008679021                            | SANOFI S.R.L.                             | IT  |
| NOVALGINA 500 mg/ml<br>gocce orali, soluzione  | not available                       | 008679033                            | SANOFI S.R.L.                             | IT  |
| NOVALGINE 1000 mg/2<br>ml Injektionslösung     | not available                       | BE067986                             | SANOFI BELGIUM                            | BE  |
| NOVALGINE 1000 mg/2<br>ml Injektionslösung     | not available                       | BE067986                             | SANOFI BELGIUM                            | BE  |
| NOVALGINE 1000 mg/2<br>ml Injektionslösung     | not available                       | BE067986                             | SANOFI BELGIUM                            | BE  |
| NOVALGINE 500 mg<br>comprimés pelliculés       | not available                       | BE067977                             | SANOFI BELGIUM                            | BE  |

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| NOVALGINE 500 mg filmomhulde tabletten                     | not available                       | BE067977                             | SANOFI BELGIUM                            | BE  |
| NOVALGINE 500 mg Filmtabletten                             | not available                       | BE067977                             | SANOFI BELGIUM                            | BE  |
| NOVALGINE 500 mg/ml druppels voor oraal gebruik, oplossing | not available                       | BE067995                             | SANOFI BELGIUM                            | BE  |
| NOVALGINE 500 mg/ml solution buvable en gouttes            | not available                       | BE067995                             | SANOFI BELGIUM                            | BE  |
| NOVALGINE 500 mg/ml solution buvable en gouttes            | not available                       | 0235847                              | SANOFI BELGIUM                            | LU  |
| NOVALGINE 500 mg/ml Tropfen zum Einnehmen, Lösung          | not available                       | BE067995                             | SANOFI BELGIUM                            | BE  |
| NOVALGINE I.M./I.V. 1 000 mg/2 ml oplossing voor injectie  | not available                       | BE067986                             | SANOFI BELGIUM                            | BE  |
| NOVALGINE I.M./I.V. 1 000 mg/2 ml oplossing voor injectie  | not available                       | BE067986                             | SANOFI BELGIUM                            | BE  |
| NOVALGINE I.M./I.V. 1 000 mg/2 ml oplossing voor injectie  | not available                       | BE067986                             | SANOFI BELGIUM                            | BE  |

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|--|-------------------------------------|--------------------------------------|---|---|
| NOVALGINE I.M./I.V.<br>1000 mg/2 ml solution<br>injectable | not available                       | BE067986                             | SANOFI BELGIUM                            | BE  |
| NOVALGINE I.M./I.V.<br>1000 mg/2 ml solution<br>injectable | not available                       | BE067986                             | SANOFI BELGIUM                            | BE  |
| NOVALGINE I.M./I.V.<br>1000 mg/2 ml solution<br>injectable | not available                       | BE067986                             | SANOFI BELGIUM                            | BE  |
| NOVALGINE I.M./I.V.<br>1000 mg/2 ml solution<br>injectable | not available                       | 0743491                              | SANOFI BELGIUM                            | LU  |
| NOVALGINE I.M./I.V.<br>1000 mg/2 ml solution<br>injectable | not available                       | 0080239                              | SANOFI BELGIUM                            | LU  |