



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 November 2020
EMA/270645/2015
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: metamizole

Procedure no.: PSUSA/00001997/202003

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 |
|---|-------------------------------------|--------------------------------------|---|---|
| ALGI-MABO Ampollas | not available | 51345 | MABO-FARMA, S.A | ES |
| ALGI-MABO Cápsulas | not available | 48905 | MABO-FARMA, S.A | ES |
| ALGI-MABO Supositorios adultos | not available | 51599 | MABO-FARMA, S.A | ES |
| Nolotil 0,4 g/ml solución inyectable y para perfusión | not available | 42.304 | BOEHRINGER INGELHEIM ESPANA S.A. | ES |
| Nolotil 2000 mg/5 ml solução injetável | not available | 8512202 | BOEHRINGER INGELHEIM, UNIPessoal, LDA. | PT |
| Nolotil 2000 mg/5 ml solução injetável | not available | 8512210 | BOEHRINGER INGELHEIM, UNIPessoal, LDA. | PT |
| 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 |

| 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| 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 |
| 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 |
| NOVALGIN 500 | not available | 0080208 | SANOFI BELGIUM | LU |

| 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| NOVALGIN 500 DROPS | not available | 0235847 | SANOFI BELGIUM | LU |
| NOVALGIN 500 MG | not available | 07/0557/95-S | SANOFI-AVENTIS SLOVAKIA SRO | SK |
| NOVALGIN 500 MG | not available | 07/0557/95-S | SANOFI-AVENTIS SLOVAKIA SRO | SK |
| NOVALGIN 500 MG | not available | 07/0557/95-S | SANOFI-AVENTIS SLOVAKIA SRO | SK |
| Novalgin 500 mg potahované tablety | not available | 07/447/00-C | SANOFI-AVENTIS SRO | CZ |
| Novalgin 500 mg potahované tablety | not available | 07/447/00-C | SANOFI-AVENTIS SRO | CZ |
| NOVALGIN 500 MG/1 ML | not available | 07/0271/95-S | SANOFI-AVENTIS SLOVAKIA SRO | SK |
| 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 |

| 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| 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 |
| NOVALGINA | not available | 008679021 | SANOFI S.P.A | IT |
| NOVALGINA 500 mg/ml gocce orali, soluzione | not available | 008679033 | SANOFI S.P.A | IT |

| 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| NOVALGINE 1000 mg/2 ml Injektionslösung | not available | BE067986 | SANOFI BELGIUM | BE |
| NOVALGINE 1000 mg/2 ml Injektionslösung | not available | BE067986 | SANOFI BELGIUM | BE |
| NOVALGINE 1000 mg/2 ml Injektionslösung | not available | BE067986 | SANOFI BELGIUM | BE |
| NOVALGINE 500 mg comprimés pelliculés | not available | BE067977 | SANOFI BELGIUM | BE |
| 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 Tropfen zum Einnehmen, Lösung | not available | BE067995 | SANOFI BELGIUM | 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 |
|---|-------------------------------------|--------------------------------------|---|---|
| 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 |
| NOVALGINE I.M./I.V. 1000 mg/2 ml solution injectable | not available | BE067986 | SANOFI BELGIUM | BE |
| NOVALGINE I.M./I.V. 1000 mg/2 ml solution injectable | not available | BE067986 | SANOFI BELGIUM | BE |
| NOVALGINE I.M./I.V. 1000 mg/2 ml solution injectable | not available | BE067986 | SANOFI BELGIUM | BE |
| NOVALGINE I.M./I.V. 1000 mg/2 ml solution injectable | not available | 0743491 | SANOFI BELGIUM | LU |
| NOVALGINE I.M./I.V. 1000 mg/2 ml solution injectable | not available | 0080239 | SANOFI BELGIUM | LU |
| NOVALGIN-TROPFEN | not available | 6.704 | SANOFI-AVENTIS GMBH OSTERREICH | AT |

| 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| NOVALGIN-TROPFEN | not available | 6.704 | SANOFI-AVENTIS GMBH OSTERREICH | AT |
| NOVALGIN-TROPFEN | not available | 6.704 | SANOFI-AVENTIS GMBH OSTERREICH | AT |