



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 October 2021
EMA/382258/2015
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: Nitrazepam

Procedure no.: PSUSA/00010292/202103

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

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| 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| Mogadan 5 mg Tabletten | not available | 6037109.00.00 | MEDA PHARMA GMBH & CO. KG | DE |
| Mogadon 5 mg - Tabletten | not available | 13096 | MYLAN ÖSTERREICH GMBH | AT |
| Mogadon 5 mg compresse | not available | 020731081 | MEDA PHARMA S.P.A. | IT |
| Mogadon 5 mg Tablets | not available | PA2010/024/001 | MYLAN IRE HEALTHCARE LIMITED | IE |
| Mogadon 5 mg Tablets | not available | MA1187/02901 | MYLAN IRE HEALTHCARE LIMITED | MT |
| Mogadon 5 mg Tablets | not available | PL 46302/0135 | MYLAN PRODUCTS LIMITED | XI |
| Mogadon 5 mg tabletter | not available | 0000/04963 | MEDA AS | NO |
| MOGADON 5 mg, comprimé sécable | not available | 562 204-8 | MEDA PHARMA SAS | FR |
| MOGADON 5 mg, comprimé sécable | not available | 562 203-1 | MEDA PHARMA SAS | FR |
| MOGADON 5 mg, comprimé sécable | not available | 355 396-9 | MEDA PHARMA SAS | FR |

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|--|-------------------------------------|--------------------------------------|---|---|
| MOGADON 5 mg, comprimé sécable | not available | 275 970-0 | MEDA PHARMA SAS | FR |
| MOGADON 5 mg, comprimé sécable | not available | 275 971-7 | MEDA PHARMA SAS | FR |
| Nitrazepam Mixture 2.5mg/5ml Oral suspension BP | not available | PL 41871/0004 | ESSENTIAL PHARMA | XI |