



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 July 2025
EMADOC-1700519818-2340504
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): methocarbamol / paracetamol

EURD list No. PSUSA/00002013/202412

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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
Distem 380 mg/300 mg compresse	MT/H/0565/001	050875018	FAES FARMA S.A.	IT
Distem 380 mg/300 mg compresse	MT/H/0565/001	050875020	FAES FARMA S.A.	IT
Distem 380 mg/300 mg tablets	MT/H/0565/001	MA1278/00401	FAES FARMA, S.A.	MT
Distem 380 mg/300 mg Tabletten	MT/H/0565/001	141942	FAES FARMA, S.A.	AT
Distem 380 mg/300 mg δισκία	MT/H/0565/001	023929	FAES FARMA S.A.	CY
Distem, 380 mg + 300 mg, tabletki	MT/H/0565/001	28168	FAES FARMA, S.A.	PL
Miderix 380 mg/300 mg tableta	not available	OGYI-T-23973/01	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Miderix 380 mg/300 mg tableta	not available	OGYI-T-23973/02	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Paracetamol + Methocarbamol APAP, 300 mg + 380 mg, tabletki	not available	28152	US PHARMACIA SP. Z O.O.	PL
Paracetamol + Methocarbamol APAP, 300 mg + 380 mg, tabletki	not available	28152	US PHARMACIA SP. Z O.O.	PL
Paracetamol + Methocarbamol APAP, 300 mg + 380 mg, tabletki	not available	28152	US PHARMACIA SP. Z O.O.	PL
Paracetamol + Methocarbamol APAP, 300 mg + 380 mg, tabletki	not available	28152	US PHARMACIA SP. Z O.O.	PL
Robaxisal compuesto 380 mg /300 mg comprimidos	not available	47.091	FAES FARMA, S.A.	ES

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
Robaxisal duo 380 mg/300 mg comprimidos	MT/H/0565/001	5864871	FAES FARMA PORTUGAL, S.A.	PT
Robaxisal duo 380 mg/300 mg comprimidos	MT/H/0565/001	5864905	FAES FARMA PORTUGAL, S.A.	PT
Robaxisal duo 380 mg/300 mg comprimidos	MT/H/0565/001	5883335	FAES FARMA PORTUGAL, S.A.	PT
Дистем 380 mg/300 mg таблетки	MT/H/0565/001	20240024	FAES FARMA S.A.	BG