



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 March 2019
EMA/257224/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: Colchicine

Procedure no.: PSUSA/00000858/201807

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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
Colchicine 0,5, tabletten 0,5 mg	not available	RVG 21347	TIOFARMA BV	NL
Colchicine Tiofarma 1 mg tabletten	not available	RVG 115060	TIOFARMA BV	NL
Colchicin "Tiofarma", tabletter	NL/H/3863/001	59482	TIOFARMA BV	DK
Colchicin "Tiofarma", tabletter	NL/H/3863/002	59483	TIOFARMA BV	DK
Kolkicin Tiofarma 500 mikrogram tabletter	NL/H/3863/001	56354	TIOFARMA BV	SE
Kolkicin Tiofarma 1000 mikrogram tabletter	NL/H/3863/002	56355	TIOFARMA BV	SE
Colchicine Tiofarma 500 microgram tablets	NL/H/3863/001	PA2200/001/001	TIOFARMA BV	IE
Colchicine Tiofarma 1000 microgram tablets	NL/H/3863/002	PA2200/001/002	TIOFARMA BV	IE
Colchicin Tiofarma 0,5 mg Tabletten	NL/H/3863/001	138313	TIOFARMA BV	AT
Colchicin Tiofarma 1 mg Tabletten	NL/H/3863/002	138314	TIOFARMA BV	AT
Kolkisin Tiofarma 0,5 mg tabletter	NL/H/3863/001	17-11694	TIOFARMA BV	NO
Kolkisin Tiofarma 1 mg tabletter	NL/H/3863/002	17-11695	TIOFARMA BV	NO
Colchicine Tiofarma 500	NL/H/3863/001	PL 17299/0003	TIOFARMA BV	UK

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microgram Tablets				
Colchicine Tiofarma 1000 microgram Tablets	NL/H/3863/002	PL 17299/0004	TIOFARMA BV	UK
Colchicin Tiofarma 0,5 mg Tabletten	NL/H/3863/001	99030.00.00	TIOFARMA BV	DE
Colchicin Tiofarma 1 mg Tabletten	NL/H/3863/002	99031.00.00	TIOFARMA BV	DE
Colchicine Mylan 0,5 mg, tabletten	not available	RVG 103726	MYLAN B.V.	NL
COLCHICINA SEID 0,5 mg comprimidos	not available	78947	SEID, S.A.	ES
COLCHICINA SEID 1 mg COMPRIMIDOS	not available	33720	SEID, S.A.	ES
Colchicine CF 0,5 mg, tabletten	not available	RVG 107614	CENTRAFARM B.V.	NL
Colchicine 500microgram Tablets	UK/H/5726/001	PL 0142/0918	ACTAVIS UK LTD.	UK
Colchicine 500 microgram Tablets.	UK/H/6003/001	PA 2091/002/001	RENATA (UK) LIMITED	IE
Colchicine 500 microgram Tablets.	UK/H/6003/001	PL 42765/0002	RENATA (UK) LIMITED	UK
COLCHICINA LIRCA 1 mg compresse	not available	009964038	ACARPIA FARMACEUTICI S.R.L	IT
Colchicine CF 0,5 mg, tabletten	not available	RVG 107614	CENTRAFARM B.V.	NL
COLCHICINE OPOCALCIUM 1	not available	34009 362 750 9 6	LABORATOIRES MAYOLY SPINDLER	FR

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
mg, comprimé sécable				
COLCHICINE OPOCALCIUM 1 mg, comprimé sécable	not available	34009 300 409 3 5	LABORATOIRES MAYOLY SPINDLER	FR
Colchicine 500 micrograms Tablets	not available	PL 29831/0055	WOCKHARDT UK LTD	UK
Colchicine 500 micrograms Tablets	not available	MA 154/00901	WOCKHARDT UK LTD	MT
Colchicine 500 microgram Film-coated Tablets	UK/H/6554/001	PL 34771/0205	MACLEODS PHARMA UK LTD	UK
Colchicine 1000 microgram Film-coated Tablets	UK/H/6554/002	PL 34771/0206	MACLEODS PHARMA UK LTD	UK
Colchicine 500 microgram Film-coated Tablets	UK/H/6554/001	MA1111/00501	MACLEODS PHARMA UK LTD	UK
Colchicine 1000 microgram Film-coated Tablets	UK/H/6554/002	MA1111/00502	MACLEODS PHARMA UK LTD	UK
Colchicine 500microgram Tablets	not available	PL 20117/0262	MORNINGSIDE HEALTHCARE LTD	UK
Colchicum-Dispert	not available	29/1045/94-C	PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH	CZ
Colchicum-Dispert bevont tableta	not available	OGYI-T-1320/01	PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH	HU
Colchicum-Dispert	not available	29/0659/94-S	PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH	SK
Колхикум-Дисперт 0,5 mg обвити таблетки	not available	9600105	PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH	BG
Colchicum Dispert 0,5 mg	not available	16971	PHARMASELECT INTERNATIONAL	PL

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tabletki drażowane			BETEILIGUNGS GMBH	
Колхикум-Дисперт 0,5 mg обвити таблетки	not available	9600105/20.03.2008	PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH	BG
Colrefuz 500 mikrogramm tabletter	DK/H/2787/001	51060	ACTAVIS GROUP PTC EHF.	SE
Colrefuz 500 mikrogramm tabletter	DK/H/2787/001	14-10057	ACTAVIS GROUP PTC EHF.	NO
Colrefuz, tabletter	DK/H/2787/001	54081	ACTAVIS GROUP PTC EHF.	DK
Colrefuz 500 mikróg töflur	DK/H/2787/001	IS/1/15/012/01	ACTAVIS GROUP PTC EHF.	IS
Colrefuz 500 mikrogrammaa, tabletit	DK/H/2787/001	32225	ACTAVIS GROUP PTC EHF.	FI
Colchicine 500microgramm Tablets	DK/H/2787/001	MA628/15902	ACTAVIS GROUP PTC EHF.	MT
COLCHICINA LIRCA 1 mg compresse	not available	009964038	ACARPIA FARMACEUTICI S.R.L	IT
Colctab 1 mg Tabletten	not available	136766	KWIZDA PHARMA GMBH	AT
COLCHICINE, 1mg, comprimidos	not available	9949602	JABA RECORDATI, S.A.	PT
COLCHICINE, 1mg, comprimidos	not available	5998281	JABA RECORDATI, S.A.	PT
COLCHICINE, 1mg, comprimidos	not available	9949610	JABA RECORDATI, S.A.	PT
COLCHICINE OPOCALCIUM 1 mg Tabletten	not available	BE 260057	APPLICATIONS CHIMIQUES ET PHYTOTHÉRAPEUTIQUES (A.C.P)	BE
COLCHICINE OPOCALCIUM 1 mg comprimés	not available	BE 260057	APPLICATIONS CHIMIQUES ET PHYTOTHÉRAPEUTIQUES (A.C.P)	BE

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COLCHICINE OPOCALCIUM 1 mg Tabletten	not available	BE 260057	APPLICATIONS CHIMIQUES ET PHYTOTHÉRAPEUTIQUES (A.C.P)	BE
Colchicine Opocalcium 1 mg comprimés	not available	2000085961	APPLICATIONS CHIMIQUES ET PHYTOTHÉRAPEUTIQUES (A.C.P)	LU
Colchicine Opocalcium 1 mg tabletten	not available	2000085961	APPLICATIONS CHIMIQUES ET PHYTOTHÉRAPEUTIQUES (A.C.P)	LU
COLCHICINE OPOCALCIUM 1 mg Tabletten Colchicin	not available	2000085961	APPLICATIONS CHIMIQUES ET PHYTOTHÉRAPEUTIQUES (A.C.P)	LU
Colchicine Teva 0,5 mg, tabletten	not available	RVG 34100	TEVA NEDERLAND B.V.	NL
Colchicine Aurobindo 0,5 mg, tabletten	not available	RVG 102274	AUROBINDO PHARMA B.V.	NL
Colchicine Sandoz 0,5 mg, tabletten	not available	RVG 105820	SANDOZ B.V.	NL