



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

7 March 2024
EMA/106682/2024
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): indometacin

Procedure No. PSUSA/00001738/202307



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
Berlind 75 Retard	not available	PL 11311/0452	TILLOMED LABORATORIES LTD	XI
CHRONO-INDOCID 75 mg, gélule	not available	3400930525753	H.A.C. PHARMA	FR
Elmetacin 10 mg/g Solução para pulverização cutânea	not available	8710509	CICLUM FARMA UNIPessoal LDA.	PT
Elmetacin 10 mg/g Solução para pulverização cutânea	not available	5155569	CICLUM FARMA UNIPessoal LDA.	PT
Inacid 100 mg supositorios	not available	41.723	H.A.C.PHARMA	ES
Inacid 25 mg capsulas duras	not available	40.537	H.A.C.PHARMA	ES
Inacid Retard 75 mg cápsulas duras de liberación prolongada	not available	58.356	H.A.C.PHARMA	ES
INDOCID 100 mg supositórios	not available	8158626	H.A.C. PHARMA	PT
INDOCID 100 mg, suppositoire	not available	34009 305 257 5 3	H.A.C. PHARMA	FR
INDOCID 25 mg cápsulas	not available	4616488	H.A.C. PHARMA	PT
INDOCID 25 mg cápsulas	not available	8421941	H.A.C. PHARMA	PT
Indocid 25 mg Kapseln	not available	12.789	H.A.C. PHARMA	AT
INDOCID 25mg, GELULE	not available	3400930525692	H.A.C. PHARMA	FR
INDOCID RETARD 75 mg cápsulas de libertação prolongada	not available	4616686	H.A.C. PHARMA	PT
INDOCID RETARD 75 mg cápsulas de libertação prolongada	not available	8108621	H.A.C. PHARMA	PT
Indocid retard 75 mg Kapseln	not available	16.728	H.A.C. PHARMA	AT

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INDOCOLLIRIO 0,1% collirio, soluzione	not available	028718029	BAUSCH & LOMB IOM S.P.A	IT
INDOCOLLIRIO 0,1% collirio, soluzione	not available	028718029	BAUSCH & LOMB IOM S.P.A	IT
INDOCOLLIRIO 0,1% collirio, soluzione	not available	028718031	BAUSCH & LOMB IOM S.P.A	IT
INDOCOLLIRIO 0,1% collirio, soluzione	not available	028718031	BAUSCH & LOMB IOM S.P.A	IT
INDOCOLLYRE 0,1 %, collyre en solution	not available	34009 341 953 8 9	LABORATOIRE CHAUVIN	FR
INDOCOLLYRE 0,1 %, collyre en solution	not available	34009 341 953 8 9	LABORATOIRE CHAUVIN	FR
INDOCOLLYRE 0,1 %, collyre en solution en récipient unidose	not available	34009 346 466 8 3	LABORATOIRE CHAUVIN	FR
INDOCOLLYRE 0,1 %, collyre en solution en récipient unidose	not available	34009 560 673 0 5	LABORATOIRE CHAUVIN	FR
INDOCOLLYRE 0,1 %, collyre en solution en récipient unidose	not available	34009 346 466 8 3	LABORATOIRE CHAUVIN	FR
INDOCOLLYRE 0,1 %, collyre en solution en récipient unidose	not available	34009 560 673 0 5	LABORATOIRE CHAUVIN	FR
Indocollyre 0,1%, 1 mg/ml, krople do oczu, roztwór	not available	9881	BAUSCH + LOMB IRELAND LIMITED	PL
Indocollyre 0,1%, 1 mg/ml, krople do oczu, roztwór	not available	9881	BAUSCH + LOMB IRELAND LIMITED	PL
Indocollyre 0,1%, 1 mg/ml, krople do oczu, roztwór	not available	9881	BAUSCH + LOMB IRELAND LIMITED	PL
Indocollyre 1 mg/ml Augentropfen	not available	BE 148985	BAUSCH + LOMB IRELAND LIMITED	BE
Indocollyre 1 mg/ml Augentropfen	not available	BE 148985	BAUSCH + LOMB IRELAND LIMITED	BE
INDOCOLLYRE 1 mg/ml	not available	64/089/03-C	BAUSCH + LOMB IRELAND	CZ

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oční kapky, roztok			LIMITED	
INDOCOLLYRE 1 mg/ml oční kapky, roztok	not available	64/089/03-C	BAUSCH + LOMB IRELAND LIMITED	CZ
Indocollyre 1 mg/ml oldatos szemcsepp	not available	OGYI-T-8840/01	BAUSCH + LOMB IRELAND LIMITED	HU
Indocollyre 1 mg/ml oldatos szemcsepp	not available	OGYI-T-8840/01	BAUSCH + LOMB IRELAND LIMITED	HU
Indocollyre 1 mg/ml oogdruppels, oplossing	not available	BE 148985	BAUSCH + LOMB IRELAND LIMITED	BE
Indocollyre 1 mg/ml oogdruppels, oplossing	not available	BE 148985	BAUSCH + LOMB IRELAND LIMITED	BE
Indocollyre 1 mg/ml picături oftalmice, soluție	not available	11813/2019/01	BAUSCH + LOMB IRELAND LIMITED	RO
Indocollyre 1 mg/ml picături oftalmice, soluție	not available	11813/2019/01	BAUSCH + LOMB IRELAND LIMITED	RO
Indocollyre 1mg/ml collyre en solution	not available	BE 148985	BAUSCH + LOMB IRELAND LIMITED	BE
Indocollyre 1mg/ml collyre en solution	not available	BE 148985	BAUSCH + LOMB IRELAND LIMITED	BE
Indocollyre 1mg/ml collyre en solution	not available	2007079405	BAUSCH + LOMB IRELAND LIMITED	LU
Indocollyre 1mg/ml collyre en solution	not available	2007079405	BAUSCH + LOMB IRELAND LIMITED	LU
Indocollyre 1mg/ml, oogdruppels, oplossing	not available	RVG 16363	BAUSCH + LOMB IRELAND LIMITED	NL
Indocollyre 1mg/ml, oogdruppels, oplossing	not available	RVG 16363	BAUSCH + LOMB IRELAND LIMITED	NL
INDOM 5 mg/ml collirio, sospensione	not available	028464016	ALFA INTES INDUSTRIA TERAPEUTICA SPLENDORE VIA FRATELLI	IT
INDOM 5 mg/ml collirio, sospensione	not available	028464028	ALFA INTES INDUSTRIA TERAPEUTICA SPLENDORE VIA FRATELLI	IT
Indometacin 100mg suppositories	not available	PL 39699/0015	ASPEN PHARMA TRADING LIMITED	XI
Indometacin AL 50	not available	11226.00.00	ALIUD PHARMA GMBH	DE
INDOXEN 100 mg supposte	not available	020676045	ALFASIGMA S.P.A.	IT

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INDOXEN 25 mg capsule rigide	not available	020676019	ALFASIGMA S.P.A.	IT
INDOXEN 50 mg capsule rigide	not available	020676021	ALFASIGMA S.P.A.	IT
INDOXEN 50 mg supposte	not available	020676033	ALFASIGMA S.P.A.	IT
LIOMETACEN 25 mg/2 ml polvere e solvente per soluzione iniettabile per uso endovenoso	not available	022559013	PROMEDICA S.R.L.	IT
LIOMETACEN 50 mg/2 ml polvere e solvente per soluzione iniettabile per uso endovenoso	not available	022559037	PROMEDICA S.R.L.	IT
Mobiflex 1 % Schmerzspray zur Anwendung auf der Haut, Lösung	not available	1-18955	STADA ARZNEIMITTEL GMBH	AT
PARDELPRIN MR CAPSULES 75mg	not available	PL 0142/0436	ACCORD-UK LIMITED	XI
REUSIN Spray	not available	56.980	LABORATORIO STADA, S.L.	ES
Sportflex 10 mg/g Huidspray-Oplossing	not available	BE134601	EUROGENERICS N.V./S.A.	BE
Sportflex 10 mg/g Solution pour pulvérisation cutanée	not available	BE134601	EUROGENERICS N.V./S.A.	BE
Sportflex 10 mg/g Solution pour pulvérisation cutanée	not available	1986120464	EUROGENERICS N.V./S.A.	LU
Sportflex 10 mg/g Spray zur Anwendung auf der Haut - Lösung	not available	BE134601	EUROGENERICS N.V./S.A.	BE