



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 March 2021
EMA/146401/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: indometacin

Procedure no.: PSUSA/00001738/202007



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	UK
CHRONO-INDOCID 75 mg, gélule	not available	3400930525753	H.A.C. PHARMA	FR
DOLCIDIUM 100 mg Suppositoires	not available	BE124704	LABORATOIRES SMB S.A.	BE
DOLCIDIUM 100 mg Suppositoires	not available	0160/99/02/4825	LABORATOIRES SMB S.A.	LU
DOLCIDIUM 100 mg Zäpfchen	not available	BE124704	LABORATOIRES SMB S.A.	BE
DOLCIDIUM 100 mg Zäpfchen	not available	0160/99/02/4825	LABORATOIRES SMB S.A.	LU
DOLCIDIUM 100 mg Zetpillen	not available	BE124704	LABORATOIRES SMB S.A.	BE
DOLCIDIUM GE 50 mg Suppositoires	not available	BE126445	LABORATOIRES SMB S.A.	BE
DOLCIDIUM GE 50 mg Suppositoires	not available	0160/99/02/4824	LABORATOIRES SMB S.A.	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
DOLCIDIUM GE 50 mg Zäpfchen	not available	BE126445	LABORATOIRES SMB S.A.	BE
DOLCIDIUM GE 50 mg Zäpfchen	not available	0160/99/02/4824	LABORATOIRES SMB S.A.	LU
DOLCIDIUM GE 50 mg Zetpillen	not available	BE126445	LABORATOIRES SMB S.A.	BE
DOLCISPRAY 40 mg/ml Spray zur Anwendung auf der Haut, Lösung	not available	BE 160623	LABORATOIRES SMB S.A.	BE
DOLCISPRAY 40 mg/ml Spray zur Anwendung auf der Haut, Lösung	not available	1998064477	LABORATOIRES SMB S.A.	LU
DOLCISPRAY 40 mg/ml, Huidspray, oplossing	not available	BE 160623	LABORATOIRES SMB S.A.	BE
DOLCISPRAY 40 mg/ml, Solution pour pulvérisation cutanée	not available	BE 160623	LABORATOIRES SMB S.A.	BE
DOLCISPRAY 40 mg/ml, Solution pour pulvérisation cutanée	not available	1998064477	LABORATOIRES SMB S.A.	LU
Inacid 100 mg supositorios	not available	41.723	H.A.C.PHARMA	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
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, suppositoire	not available	3400930525753	H.A.C. PHARMA	FR
INDOCID 100mg suppositorios	not available	8158626	H.A.C. PHARMA	PT
INDOCID 25 mg capsula	not available	8421941	H.A.C. PHARMA	PT
Indocid 25 mg Kapseln	not available	12.789	H.A.C. PHARMA	AT
INDOCID 25 mg, capsula	not available	4616488	H.A.C. PHARMA	PT
INDOCID 25mg, GELULE	not available	3400930525692	H.A.C. PHARMA	FR
Indocid Capsules 25 mg	not available	PL 39699/012	ASPEN PHARMA TRADING LIMITED	UK

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
Indocid Capsules 50 mg	not available	PL 39699/013	ASPEN PHARMA TRADING LIMITED	UK
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
Indocid Suppositories 100 mg	not available	PL 39699/0015	ASPEN PHARMA TRADING LIMITED	UK
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
INDOCOLLYRE 0,1 %, collyre en solution	not available	34009 341 953 8 9	LABORATOIRE CHAUVIN	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
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 354 098 4 3	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 354 098 4 3	LABORATOIRE CHAUVIN	FR
Indocollyre 0,1% 0,35 mg/0,35 ml Colírio, solução Colírio, solução em recipiente dose única	not available	3975489	BAUSCH & LOMB, S.A.	PT
Indocollyre 0,1%, 1 mg/ml, krople do oczu, roztwór	not available	9881	BAUSCH HEALTH IRELAND LIMITED	PL
Indocollyre 0,1%, 1 mg/ml, krople do oczu, roztwór	not available	9881	BAUSCH HEALTH IRELAND LIMITED	PL

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
Indocollyre 1 mg/ml Augentropfen	not available	BE 148985	BAUSCH & LOMB PHARMA	BE
INDOCOLLYRE 1 mg/ml oční kapky, roztok	not available	64/089/03-C	BAUSCH HEALTH IRELAND LIMITED	CZ
Indocollyre 1 mg/ml oldatos szemcsepp	not available	OGYI-T-8840/01	BAUSCH HEALTH IRELAND LIMITED	HU
Indocollyre 1 mg/ml oogdruppels, oplossing	not available	BE 148985	BAUSCH & LOMB PHARMA	BE
Indocollyre 1 mg/ml picături oftalmice, soluție	not available	11813/2019/01	BAUSCH HEALTH IRELAND LIMITED	RO
Indocollyre 1mg/ml collyre en solution	not available	BE 148985	BAUSCH & LOMB PHARMA	BE
Indocollyre 1mg/ml collyre en solution	not available	2007079405	BAUSCH & LOMB PHARMA	LU
INDOCOLLYRE 1mg/ml, oogdruppels, oplossing	not available	RVG 16363	BAUSCH & LOMB PHARMA	NL
INDOCOLLYRE 1mg/ml, oogdruppels, oplossing	not available	RVG 16363	BAUSCH & LOMB PHARMA	NL

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
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 AL 50	not available	11226.00.00	ALIUD PHARMA GMBH	DE
Indometacin AL 50	not available	11226.00.00	ALIUD PHARMA GMBH	DE
INDOXEN 100 mg supposte	not available	020676045	ALFASIGMA S.P.A.	IT
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 intramuscolare ed endovenoso	not available	022559013	PROMEDICA S.R.L.	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
LIOMETACEN 50 mg/2 ml polvere e solvente per soluzione iniettabile per uso intramuscolare ed 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	ACTAVIS UK LIMITED	UK
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