



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 January 2024
EMA/21143/2024
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): Zuclopenthixol

Procedure No. PSUSA/00003155/202305



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
Ciatyl-Z 10 mg-Filmtabletten	not available	4105.01.00	H. LUNDBECK A/S	DE
Ciatyl-Z 2 mg Filmtabletten	not available	4105.00.00	H. LUNDBECK A/S	DE
Ciatyl-Z 25 mg Filmtabletten	not available	4105.02.00	H. LUNDBECK A/S	DE
Ciatyl-Z Tropfen 20 mg/ml	not available	4105.00.01	H. LUNDBECK A/S	DE
Ciatyl-Z Acuphase 50 mg/ml Injektionslösung	not available	17864.00.00	H. LUNDBECK A/S	DE
Ciatyl-Z Depot 200 mg/ml Injektionslösung	not available	1378.00.00	H. LUNDBECK A/S	DE
Cisordinol	not available	10685	H. LUNDBECK A/S	DK
Cisordinol	not available	10688	H. LUNDBECK A/S	DK
Cisordinol	not available	10689	H. LUNDBECK A/S	DK
Cisordinol 10 mg apvalkotās tabletes	not available	02-0056	H. LUNDBECK A/S	LV
Cisordinol 10 mg filmdragerade tabletter	not available	9852	H. LUNDBECK A/S	SE
Cisordinol 10 mg filmom obalené tablety	not available	68/0167/85-CS	H. LUNDBECK A/S	SK
Cisordinol 10 mg filmomhulde tabletten	not available	RVG 04295	LUNDBECK B.V.	NL
Cisordinol 10 mg filmtabletta	not available	OGYI-T-1688/06	LUNDBECK HUNGARIA KFT.	HU
Cisordinol 10 mg filmuhúðaðar töflur.	not available	822953(IS)	H. LUNDBECK A/S	IS
Cisordinol 10 mg plėvele dengtos tabletės	not available	LT/1/98/2199/002	H. LUNDBECK A/S	LT
Cisordinol 10 mg potahované tablety	not available	68/167/85 - B/C	H. LUNDBECK A/S	CZ
Cisordinol 10 mg tablett, filmdragerad	not available	8737	H. LUNDBECK A/S	FI
Cisordinol 10 mg tabletti, kalvopäällysteinen	not available	8737	H. LUNDBECK A/S	FI
Cisordinol 10 mg-	not available	17.533	LUNDBECK AUSTRIA GMBH	AT

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
Filmtabletten				
Cisordinol 2 mg filmdragerade tabletter	not available	9851	H. LUNDBECK A/S	SE
Cisordinol 2 mg filmomhulde tabletten	not available	RVG 04294	LUNDBECK B.V.	NL
Cisordinol 2 mg filmuhúðaðar töflur.	not available	822952(IS)	H. LUNDBECK A/S	IS
Cisordinol 2 mg tablett, filmdragerad	not available	8736	H. LUNDBECK A/S	FI
Cisordinol 2 mg tabletti, kalvopäällysteinen	not available	8736	H. LUNDBECK A/S	FI
Cisordinol 2 mg- Filmtabletten	not available	17.532	LUNDBECK AUSTRIA GMBH	AT
Cisordinol 20 mg/ml dråper, oppløsning	not available	6774	H. LUNDBECK A/S	NO
Cisordinol 20 mg/ml druppelvloeistof	not available	RVG 09287	LUNDBECK B.V.	NL
Cisordinol 20 mg/ml orala droppar, lösning	not available	9848	H. LUNDBECK A/S	SE
Cisordinol 25 mg filmdragerade tabletter	not available	9853	H. LUNDBECK A/S	SE
Cisordinol 25 mg filmomhulde tabletten	not available	RVG 04296	LUNDBECK B.V.	NL
Cisordinol 25 mg filmtablett	not available	OGYI-T-1688/07	LUNDBECK HUNGARIA KFT.	HU
Cisordinol 25 mg potahované tablety	not available	68/167/85 - C/C	H. LUNDBECK A/S	CZ
Cisordinol 25 mg tablett, filmdragerad	not available	8738	H. LUNDBECK A/S	FI
Cisordinol 25 mg tabletti, kalvopäällysteinen	not available	8738	H. LUNDBECK A/S	FI
Cisordinol 25 mg- Filmtabletten	not available	17.534	LUNDBECK AUSTRIA GMBH	AT
Cisordinol Acutard 50 mg/1 ml solução injetável	not available	2261584	H. LUNDBECK A/S	PT
Cisordinol Acutard 50 mg Ampullen	not available	1-18331	LUNDBECK AUSTRIA GMBH	AT

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
Cisordinol Depot	not available	06733	H. LUNDBECK A/S	DK
Cisordinol Depot	not available	12886	H. LUNDBECK A/S	DK
Cisordinol Depot 200 mg injekčný roztok	not available	68/0162/81-CS	H. LUNDBECK A/S	SK
Cisordinol Depot 200 mg/1 ml solução injetável	not available	2261485	H. LUNDBECK A/S	PT
Cisordinol Depot 200 mg/ml injectievløestof	not available	RVG 07288	LUNDBECK B.V.	NL
Cisordinol Depot 200 mg/ml injekcinis tirpalas	not available	LT/1/98/2201/002	H. LUNDBECK A/S	LT
Cisordinol Depot 200 mg/ml injekční roztok	not available	68/162/81-C	H. LUNDBECK A/S	CZ
Cisordinol Depot 200 mg/ml injeksjonsvæske, oppløsning	not available	6226	H. LUNDBECK A/S	NO
CISORDINOL DEPOT 200 MG/ML INJEKTIONESTE, LIUOS	not available	7443	H. LUNDBECK A/S	FI
CISORDINOL DEPOT 200 MG/ML INJEKTIONSVÄTSKA, LÖSNING	not available	7443	H. LUNDBECK A/S	FI
Cisordinol Depot 200 mg/ml injektionsvätska, lösning	not available	9627	H. LUNDBECK A/S	SE
Cisordinol Depot 200 mg/ml oldatos injekció	not available	OGYI-T-1688/04	LUNDBECK HUNGARIA KFT.	HU
Cisordinol Depot 200 mg/ml šķīdums injekcijām	not available	96-0260	H. LUNDBECK A/S	LV
Cisordinol Depot 200 mg/ml stungulyf lausn.	not available	782263(IS)	H. LUNDBECK A/S	IS
Cisordinol Depot 200 mg-Ampullen	not available	15.952	LUNDBECK AUSTRIA GMBH	AT
Cisordinol Depot 500 mg/ml injectievløestof	not available	RVG 13150	LUNDBECK B.V.	NL
CISORDINOL DEPOT 500 MG/ML INJEKTIONESTE,	not available	9815	H. LUNDBECK A/S	FI

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LIUOS				
CISORDINOL DEPOT 500 MG/ML INJEKTIONSVÄTSKA, LÖSNING	not available	9815	H. LUNDBECK A/S	FI
Cisordinol Depot 500 mg-Ampullen	not available	1-19866	LUNDBECK AUSTRIA GMBH	AT
Cisordinol Depot, 200 mg/ml süstelahus	not available	227598	H. LUNDBECK A/S	EE
Cisordinol tablett, filmdrasjert 10 mg	not available	6778	H. LUNDBECK A/S	NO
Cisordinol tablett, filmdrasjert 2 mg	not available	6777	H. LUNDBECK A/S	NO
Cisordinol tablett, filmdrasjert 25 mg	not available	6779	H. LUNDBECK A/S	NO
Cisordinol, 10 mg õhukese polümeerikattega tabletid	not available	227198	H. LUNDBECK A/S	EE
Cisordinol-Acutard	not available	12277	H. LUNDBECK A/S	DK
Cisordinol-Acutard 50 mg/ml injectievloeistof	not available	RVG 14175	LUNDBECK B.V.	NL
Cisordinol-Acutard 50 mg/ml injekcinis tirpalas.	not available	LT/1/98/2200/001	H. LUNDBECK A/S	LT
Cisordinol-Acutard 50 mg/ml injekční roztok	not available	68/142/88-C	H. LUNDBECK A/S	CZ
CISORDINOL-ACUTARD 50 mg/ml INJEKTIONESTE, LIUOS	not available	9386	H. LUNDBECK A/S	FI
CISORDINOL-ACUTARD 50 mg/ml INJEKTIONSVÄTSKA, LÖSNING	not available	9386	H. LUNDBECK A/S	FI
Cisordinol-Acutard 50 mg/ml injektionsvätska, lösning	not available	10631	H. LUNDBECK A/S	SE
Cisordinol-Acutard 50 mg/ml oldatos injekció	not available	OGYI-T-1688/05	LUNDBECK HUNGARIA KFT.	HU
Cisordinol-Acutard 50	not available	07-0122	H. LUNDBECK A/S	LV

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mg/ml šķīdums injekcijām				
Cisordinol-Acutard 50 mg/ml stungulyf, lausn.	not available	890004(IS)	H. LUNDBECK A/S	IS
Cisordinol-Acutard 50 mg/ml, injeksjonsvæske, oppløsning	not available	7543	H. LUNDBECK A/S	NO
Cisordinol-Acutard, 50 mg/ml süstelahus	not available	227698	H. LUNDBECK A/S	EE
CLOPIXOL 10 mg compresse rivestite con film	not available	026890107	LUNDBECK ITALIA SPA, IT	IT
Clopixol 10 mg comprimato filmate	not available	1842/2009/01-02	H. LUNDBECK A/S	RO
Clopixol 10 mg comprimés pelliculés	not available	BE 128834	LUNDBECK SA - N.V.	BE
Clopixol 10 mg comprimés pelliculés	not available	0482/05088293	LUNDBECK SA - N.V.	LU
Clopixol 10 mg comprimés pelliculés	not available	0482/05088294	LUNDBECK SA - N.V.	LU
Clopixol 10 mg comprimidos recubiertos con película	not available	60.872	LUNDBECK ESPANA, S.A.	ES
Clopixol 10 mg film-coated Tablets	not available	PA0776/002/003	LUNDBECK LTD., IE	IE
Clopixol 10 mg filmsko obložene tablete	not available	H/96/00402/002	LUNDBECK PHARMA D.O.O	SI
Clopixol 10 mg Filmtabletten	not available	BE128834	LUNDBECK SA - N.V.	BE
Clopixol 10 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	S00290	LUNDBECK HELLAS, GR	CY
Clopixol 10 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	55093/15/27-01-2017	LUNDBECK HELLAS, GR	GR
CLOPIXOL 10 mg, comprimé pelliculé	not available	NL 13514	LUNDBECK SAS	FR
Clopixol 10 mg,	not available	BE128834	LUNDBECK SA - N.V.	BE

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
filmomhulde tabletten				
Clopixol 2 mg comprimés pelliculés	not available	BE 128825	LUNDBECK SA - N.V.	BE
Clopixol 2 mg comprimés pelliculés	not available	0482/05088292	LUNDBECK SA - N.V.	LU
Clopixol 2 mg Filmtabletten	not available	BE128825	LUNDBECK SA - N.V.	BE
Clopixol 2 mg, filmomhulde tabletten	not available	BE128825	LUNDBECK SA - N.V.	BE
CLOPIXOL 2 POUR CENT, solution buvable en gouttes	not available	NL 13515	LUNDBECK SAS	FR
Clopixol 20 mg/ml druppels voor oraal gebruik, oplossing	not available	BE128843	LUNDBECK SA - N.V.	BE
CLOPIXOL 20 mg/ml gocce orali, soluzione	not available	026890172	LUNDBECK ITALIA SPA, IT	IT
Clopixol 20 mg/ml Gotas orales en solución	not available	60.871	LUNDBECK ESPANA, S.A.	ES
Clopixol 20 mg/ml picături orale soluție	not available	1844/2009/01	H. LUNDBECK A/S	RO
Clopixol 20 mg/ml solution buvable en gouttes	not available	BE 128843	LUNDBECK SA - N.V.	BE
Clopixol 20 mg/ml solution buvable en gouttes	not available	0482/05088295	LUNDBECK SA - N.V.	LU
Clopixol 20 mg/ml Tropfen zum Einnehmen, Lösung	not available	BE128843	LUNDBECK SA - N.V.	BE
Clopixol 20 mg/ml πόσιμες σταγόνες, διάλυμα	not available	S00292	LUNDBECK HELLAS, GR	CY
Clopixol 20 mg/ml πόσιμες σταγόνες, διάλυμα	not available	65322/13/22-07-2016	LUNDBECK HELLAS, GR	GR
Clopixol 200 mg/ml Solution for Injection	not available	PA0776/002/001	LUNDBECK LTD., IE	IE
Clopixol 200 mg/ml Solution for Injection	not available	MA1323/00101	LUNDBECK LTD., IE	MT

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
Clopixol 200 mg/ml soluzione iniettabile a rilascio prolungato per uso intramuscolare	not available	026890158	LUNDBECK ITALIA SPA, IT	IT
CLOPIXOL 25 mg compresse rivestite con film	not available	026890119	LUNDBECK ITALIA SPA, IT	IT
Clopixol 25 mg comprimate filmate	not available	1843/2009/01-02	H. LUNDBECK A/S	RO
Clopixol 25 mg comprimés pelliculés	not available	BE 128852	LUNDBECK SA - N.V.	BE
Clopixol 25 mg comprimidos recubiertos con película	not available	60.873	LUNDBECK ESPANA, S.A.	ES
Clopixol 25 mg Filmtabletten	not available	BE128852	LUNDBECK SA - N.V.	BE
Clopixol 25 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	S00291	LUNDBECK HELLAS, GR	CY
Clopixol 25 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	39282/16/27-01-2017	LUNDBECK HELLAS, GR	GR
CLOPIXOL 25 mg, comprimé pelliculé	not available	NL 13513	LUNDBECK SAS	FR
CLOPIXOL 25 mg, comprimé pelliculé	not available	302 354 3	LUNDBECK SAS	FR
Clopixol 25 mg, filmomhulde tabletten	not available	BE128852	LUNDBECK SA - N.V.	BE
Clopixol 50 mg/ml soluzione iniettabile per uso intramuscolare	not available	026890083	LUNDBECK ITALIA SPA, IT	IT
CLOPIXOL A ACTION SEMI-PROLONGEE 50 mg/ml, solution injectable I.M.	not available	NL 14874	LUNDBECK SAS	FR
CLOPIXOL ACTION PROLONGEE 200 mg/1 ml, solution injectable I.M.	not available	NL 13516	LUNDBECK SAS	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
Clopixol Acufase 50 mg/ml, solución inyectable	not available	60.875	LUNDBECK ESPANA, S.A.	ES
Clopixol Acuphase 50 mg/ml solutie injectabila	not available	1845/2009/01	H. LUNDBECK A/S	RO
Clopixol Acuphase, 50 mg/ml, roztwór do wstrzykiwań	not available	R/1269	H. LUNDBECK A/S	PL
Clopixol Acutard 50 mg/ml Injektionslösung	not available	BE140987	LUNDBECK SA - N.V.	BE
Clopixol Acutard 50 mg/ml oplossing voor injectie	not available	BE 140987	LUNDBECK SA - N.V.	BE
Clopixol Acutard 50 mg/ml solution injectable	not available	BE 140987	LUNDBECK SA - N.V.	BE
Clopixol Acutard 50 mg/ml solution injectable	not available	0482/05088296	LUNDBECK SA - N.V.	LU
Clopixol Acutard 50 mg/ml ενέσιμο ελαιώδες διάλυμα	not available	11211	LUNDBECK HELLAS, GR	CY
Clopixol Acutard 50 mg/ml ενέσιμο ελαιώδες διάλυμα	not available	65322/13/22-07-2016	LUNDBECK HELLAS, GR	GR
Clopixol Conc. 500 mg/ml Solution for Injection	not available	PA0776/002/002	LUNDBECK LTD., IE	IE
Clopixol Depot 200 mg/ml Injektionslösung	not available	BE104736	LUNDBECK SA - N.V.	BE
Clopixol Depot 200 mg/ml oplossing voor injectie	not available	BE104736	LUNDBECK SA - N.V.	BE
Clopixol Depot 200 mg/ml raztopina za injiciranje	not available	H/96/00402/001	LUNDBECK PHARMA D.O.O	SI
Clopixol Depot 200 mg/ml soluție injectabilă	not available	1846/2009/01	H. LUNDBECK A/S	RO
Clopixol Depot 200 mg/ml solution injectable	not available	BE 104736	LUNDBECK SA - N.V.	BE
Clopixol Depot 200 mg/ml solution injectable	not available	2005068794	LUNDBECK SA - N.V.	LU
Clopixol Depot 200 mg/ml ενέσιμο διάλυμα	not available	8398	LUNDBECK HELLAS, GR	CY
Clopixol Depot 200 mg/ml	not available	38632/14/22-01-2018	LUNDBECK HELLAS, GR	GR

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ενέσιμο διάλυμα				
Clopixol Depot 200 mg/ml, solución inyectable	not available	60.874	LUNDBECK ESPANA, S.A.	ES
Clopixol Depot, 200 mg/ml, roztwór do wstrzykiwań	not available	R/1892	H. LUNDBECK A/S	PL
Clopixol, 10 mg, tabletki powlekane	not available	R/1267	H. LUNDBECK A/S	PL
Clopixol, 25 mg, tabletki powlekane	not available	R/1268	H. LUNDBECK A/S	PL
Clopixol-Acuphase 50 mg/ml raztopina za injiciranje	not available	H/96/00402/003	LUNDBECK PHARMA D.O.O	SI
Клопиксол 10 mg филмирани таблетки	not available	20010041	LUNDBECK EXPORT A/S	BG
Клопиксол Депо 200 mg/ml инжекционен разтвор.	not available	20010042	LUNDBECK EXPORT A/S	BG
Клопиксол-Акюфейз 50 mg/ml инжекционен разтвор	not available	20010043	LUNDBECK EXPORT A/S	BG