



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

06 September 2018
EMA/620439/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: levobupivacaine

Procedure no.: PSUSA/00001848/201712



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
Chirocaine 5 mg/ml šķīdums injekcijām/koncentrāts infūziju šķīduma pagatavošanai	not available	04-0117	ABBVIE SIA	LV
Chirocaine 2,5 mg /ml – Injektionslösung und Konzentrat zur Herstellung einer Infusionslösung	SE/H/0183/001	1-23474	ABBVIE GMBH	AT
Chirocaine 5,0 mg /ml – Injektionslösung und Konzentrat zur Herstellung einer Infusionslösung	SE/H/0183/002	1-23475	ABBVIE GMBH	AT
Chirocaine 2,5 mg/ml, oplossing voor injectie / concentraat voor oplossing voor infusie	SE/H/0183/001	BE207392	ABBVIE S.A.	BE
Chirocaine 5 mg/ml, oplossing voor injectie / concentraat voor oplossing voor infusie	SE/H/0183/002	BE207401	ABBVIE S.A.	BE
Chirocaine 7,5 mg/ml, oplossing voor injectie / concentraat voor oplossing voor infusie	SE/H/0183/003	BE207417	ABBVIE S.A.	BE
CHIROCAINE 2,5 mg/ml, solution injectable/solution à diluer pour perfusion	SE/H/0183/001	BE207392	ABBVIE S.A.	BE
CHIROCAINE 5,0 mg/ml, solution injectable/solution à diluer pour perfusion	SE/H/0183/002	BE207401	ABBVIE S.A.	BE
CHIROCAINE 7,5 mg/ml, solution injectable/solution à diluer pour perfusion	SE/H/0183/003	BE207417	ABBVIE S.A.	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
Chirocaine 1,25 mg/ml, oplossing voor infusie	SE/H/0183/005	BE257065	ABBVIE S.A.	BE
Chirocaine 1,25 mg/ml, oplossing voor infusie	SE/H/0183/005	BE257074	ABBVIE S.A.	BE
CHIROCAINE 1.25 mg/ml, solution pour perfusion	SE/H/0183/005	BE257065	ABBVIE S.A.	BE
CHIROCAINE 1.25 mg/ml, solution pour perfusion	SE/H/0183/005	BE257074	ABBVIE S.A.	BE
Chirocaine 2,5 mg/ml injektioneste, liuos / infuusiokonsentraatti, liuosta varten	SE/H/0183/001	14675	ABBVIE OY	FI
Chirocaine 5 mg/ml injektioneste, liuos / infuusiokonsentraatti, liuosta varten	SE/H/0183/002	14676	ABBVIE OY	FI
Chirocaine 7,5 mg/ml injektioneste, liuos / infuusiokonsentraatti, liuosta varten	SE/H/0183/003	14677	ABBVIE OY	FI
Chirocaine 0,625 mg/ml infuusioneste, liuos	SE/H/0183/004	18028	ABBVIE OY	FI
Chirocaine 1,25 mg/ml infuusioneste, liuos	SE/H/0183/005	18029	ABBVIE OY	FI
CHIROCAINE 0,625 mg/ml, solution pour perfusion	SE/H/0183/004	34009 566 823 4 8	ABBVIE	FR
CHIROCAINE 0,625 mg/ml, solution pour perfusion	SE/H/0183/004	34009 566 824 0 9	ABBVIE	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
CHIROCAINE 0,625 mg/ml, solution pour perfusion	SE/H/0183/004	34009 566 825 7 7	ABBVIE	FR
CHIROCAINE 0,625 mg/ml, solution pour perfusion	SE/H/0183/004	34009 566 826 3 8	ABBVIE	FR
CHIROCAINE 0,625 mg/ml, solution pour perfusion	SE/H/0183/004	34009 566 828 6 7	ABBVIE	FR
CHIROCAINE 0,625 mg/ml, solution pour perfusion	SE/H/0183/004	34009 566 829 2 8	ABBVIE	FR
CHIROCAINE 1,25 mg/ml, solution pour perfusion	SE/H/0183/005	34009 566 830 0 0	ABBVIE	FR
CHIROCAINE 1,25 mg/ml, solution pour perfusion	SE/H/0183/005	34009 566 831 7 8	ABBVIE	FR
CHIROCAINE 1,25 mg/ml, solution pour perfusion	SE/H/0183/005	34009 566 832 3 9	ABBVIE	FR
CHIROCAINE 1,25 mg/ml, solution pour perfusion	SE/H/0183/005	34009 566 834 6 8	ABBVIE	FR
CHIROCAINE 1,25 mg/ml, solution pour perfusion	SE/H/0183/005	34009 566 835 2 9	ABBVIE	FR
CHIROCAINE 1,25 mg/ml, solution pour perfusion	SE/H/0183/005	34009 566 836 9 7	ABBVIE	FR
CHIROCAINE 2,5 mg/ml, solution injectable ou solution à diluer pour perfusion	SE/H/0183/001	34009 565 699 8 4	ABBVIE	FR
CHIROCAINE 2,5 mg/ml, solution injectable ou solution à diluer pour perfusion	SE/H/0183/001	34009 565 700 6 5	ABBVIE	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
CHIROCAINE 2,5 mg/ml, solution injectable ou solution à diluer pour perfusion	SE/H/0183/001	34009 565 701 2 6	ABBVIE	FR
CHIROCAINE 2,5 mg/ml, solution injectable ou solution à diluer pour perfusion	SE/H/0183/001	34009 565 702 9 4	ABBVIE	FR
CHIROCAINE 2,5 mg/ml, solution injectable ou solution à diluer pour perfusion	SE/H/0183/001	34009 565 703 5 5	ABBVIE	FR
CHIROCAINE 2,5 mg/ml, solution injectable ou solution à diluer pour perfusion	SE/H/0183/001	34009 565 704 1 6	ABBVIE	FR
CHIROCAINE 5 mg/ml, solution injectable ou solution à diluer pour perfusion	SE/H/0183/002	34009 565 712 4 6	ABBVIE	FR
CHIROCAINE 5 mg/ml, solution injectable ou solution à diluer pour perfusion	SE/H/0183/002	34009 565 713 0 7	ABBVIE	FR
CHIROCAINE 5 mg/ml, solution injectable ou solution à diluer pour perfusion	SE/H/0183/002	34009 565 714 7 5	ABBVIE	FR
CHIROCAINE 5 mg/ml, solution injectable ou solution à diluer pour perfusion	SE/H/0183/002	34009 565 715 3 6	ABBVIE	FR
CHIROCAINE 5 mg/ml, solution injectable ou solution à diluer pour perfusion	SE/H/0183/002	34009 565 717 6 5	ABBVIE	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
CHIROCAINE 5 mg/ml, solution injectable ou solution à diluer pour perfusion	SE/H/0183/002	34009 565 718 2 6	ABBVIE	FR
Chirocaine 0.625 mg/ml solution for infusion	SE/H/0183/004	PA 1824/003/004	ABBVIE LIMITED	IE
Chirocaine 1.25 mg/ml solution for infusion	SE/H/0183/005	PA 1824/003/005	ABBVIE LIMITED	IE
Chirocaine 2.5 mg/ml solution for injection/concentrate for solution for infusion.	SE/H/0183/001	PA 1824/003/001	ABBVIE LIMITED	IE
Chirocaine 5 mg/ml solution for injection/concentrate for solution for infusion	SE/H/0183/002	PA 1824/003/002	ABBVIE LIMITED	IE
Chirocaine 7.5 mg/ml solution for injection/concentrate for solution for infusion	SE/H/0183/003	PA 1824/003/003	ABBVIE LIMITED	IE
Chirocaine 0,625 mg/ml, oplossing voor infusie	SE/H/0183/004	RVG 29119	ABBVIE B.V.	NL
Chirocaine 1,25 mg/ml, oplossing voor infusie	SE/H/0183/005	RVG 29120	ABBVIE B.V.	NL
Chirocaine 2,5 mg/ml, oplossing voor injectie / concentraat voor oplossing voor infusie	SE/H/0183/001	RVG 24617	ABBVIE B.V.	NL
Chirocaine 5 mg/ml, oplossing voor injectie / concentraat voor oplossing voor infusie	SE/H/0183/002	RVG 24618	ABBVIE B.V.	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
Chirocaine 7,5 mg/ml, oplossing voor injectie / concentraat voor oplossing voor infusie	SE/H/0183/003	RVG 24619	ABBVIE B.V.	NL
Chirocaine 0,625 mg/ml διάλυμα για έγχυση	SE/H/0183/004	59873/08-09-2010	ABBVIE PHARMACEUTICALS S.A.	GR
Chirocaine 1,25 mg/ml διάλυμα για έγχυση	SE/H/0183/005	59874/08-09-2010	ABBVIE PHARMACEUTICALS S.A.	GR
Chirocaine 2,5 mg/ml ενέσιμο διάλυμα /πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση	SE/H/0183/001	59869/08-09-2010	ABBVIE PHARMACEUTICALS S.A.	GR
Chirocaine 5,0 mg/ml ενέσιμο διάλυμα /πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση	SE/H/0183/002	59870/08-09-2010	ABBVIE PHARMACEUTICALS S.A.	GR
Chirocaine 7,5 mg/ml ενέσιμο διάλυμα /πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση	SE/H/0183/003	59871/08-09-2010	ABBVIE PHARMACEUTICALS S.A.	GR
Chirocaine 0,625 mg/ml Soluzione per infusione	SE/H/0183/004	034769378	ABBVIE S.R.L.	IT
Chirocaine 0,625 mg/ml Soluzione per infusione	SE/H/0183/004	034769380	ABBVIE S.R.L.	IT
Chirocaine 0,625 mg/ml Soluzione per infusione	SE/H/0183/004	034769392	ABBVIE S.R.L.	IT
Chirocaine 0,625 mg/ml Soluzione per infusione	SE/H/0183/004	034769404	ABBVIE 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
Chirocaine 0,625 mg/ml Soluzione per infusione	SE/H/0183/004	034769416	ABBVIE S.R.L.	IT
Chirocaine 0,625 mg/ml Soluzione per infusione	SE/H/0183/004	034769428	ABBVIE S.R.L.	IT
Chirocaine 1,25 mg/ml Soluzione per infusione	SE/H/0183/005	034769430	ABBVIE S.R.L.	IT
Chirocaine 1,25 mg/ml Soluzione per infusione	SE/H/0183/005	034769442	ABBVIE S.R.L.	IT
Chirocaine 1,25 mg/ml Soluzione per infusione	SE/H/0183/005	034769455	ABBVIE S.R.L.	IT
Chirocaine 1,25 mg/ml Soluzione per infusione	SE/H/0183/005	034769467	ABBVIE S.R.L.	IT
Chirocaine 1,25 mg/ml Soluzione per infusione	SE/H/0183/005	034769479	ABBVIE S.R.L.	IT
Chirocaine 1,25 mg/ml Soluzione per infusione	SE/H/0183/005	034769481	ABBVIE S.R.L.	IT
Chirocaine 2,5 mg/ml soluzione iniettabile/concentrato per soluzione per infusione	SE/H/0183/001	034769075	ABBVIE S.R.L.	IT
Chirocaine 2,5 mg/ml soluzione iniettabile/concentrato per soluzione per infusione	SE/H/0183/001	034769087	ABBVIE S.R.L.	IT
Chirocaine 2,5 mg/ml soluzione iniettabile/concentrato per soluzione per infusione	SE/H/0183/001	034769099	ABBVIE S.R.L.	IT
Chirocaine 2,5 mg/ml soluzione iniettabile/concentrato per soluzione per infusione	SE/H/0183/001	034769101	ABBVIE 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
Chirocaine 2,5 mg/ml soluzione iniettabile/concentrato per soluzione per infusione	SE/H/0183/001	034769113	ABBVIE S.R.L.	IT
Chirocaine 2,5 mg/ml soluzione iniettabile/concentrato per soluzione per infusione	SE/H/0183/001	034769125	ABBVIE S.R.L.	IT
Chirocaine 5 mg/ml soluzione iniettabile/concentrato per soluzione per infusione	SE/H/0183/002	034769190	ABBVIE S.R.L.	IT
Chirocaine 5 mg/ml soluzione iniettabile/concentrato per soluzione per infusione	SE/H/0183/002	034769202	ABBVIE S.R.L.	IT
Chirocaine 5 mg/ml soluzione iniettabile/concentrato per soluzione per infusione	SE/H/0183/002	034769214	ABBVIE S.R.L.	IT
Chirocaine 5 mg/ml soluzione iniettabile/concentrato per soluzione per infusione	SE/H/0183/002	034769226	ABBVIE S.R.L.	IT
Chirocaine 5 mg/ml soluzione iniettabile/concentrato per soluzione per infusione	SE/H/0183/002	034769238	ABBVIE S.R.L.	IT
Chirocaine 5 mg/ml soluzione iniettabile/concentrato per soluzione per infusione	SE/H/0183/002	034769240	ABBVIE S.R.L.	IT
Chirocaine 7,5 mg/ml soluzione iniettabile/concentrato per soluzione per infusione	SE/H/0183/003	034769315	ABBVIE 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
Chirocaine 7,5 mg/ml soluzione iniettabile/concentrato per soluzione per infusione	SE/H/0183/003	034769327	ABBVIE S.R.L.	IT
Chirocaine 7,5 mg/ml soluzione iniettabile/concentrato per soluzione per infusione	SE/H/0183/003	034769339	ABBVIE S.R.L.	IT
Chirocaine 7,5 mg/ml soluzione iniettabile/concentrato per soluzione per infusione	SE/H/0183/003	034769341	ABBVIE S.R.L.	IT
Chirocaine 7,5 mg/ml soluzione iniettabile/concentrato per soluzione per infusione	SE/H/0183/003	034769354	ABBVIE S.R.L.	IT
Chirocaine 7,5 mg/ml soluzione iniettabile/concentrato per soluzione per infusione	SE/H/0183/003	034769366	ABBVIE S.R.L.	IT
CHIROCANE 0,625 mg/ml solución para perfusión	SE/H/0183/004	65.434	ABBVIE SPAIN S.L.U.	ES
CHIROCANE 1,25 mg/ml solución para perfusión	SE/H/0183/005	65.433	ABBVIE SPAIN S.L.U.	ES
CHIROCANE 2,5 mg/ml solución inyectable y para perfusión	SE/H/0183/001	63.171	ABBVIE SPAIN S.L.U.	ES
CHIROCANE 5 mg/ml solución inyectable y para perfusión	SE/H/0183/002	63.172	ABBVIE SPAIN S.L.U.	ES
CHIROCANE 7,5 mg/ml solución inyectable y para perfusión	SE/H/0183/003	63.173	ABBVIE SPAIN S.L.U.	ES
Chirocaine 0,625 mg/ml infusionsvätska, lösning	SE/H/0183/004	18143	ABBVIE AB	SE

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
Chirocaine 1,25 mg/ml infusionsvätska, lösning	SE/H/0183/005	18144	ABBVIE AB	SE
Chirocaine 2,5 mg/ml injektionsvätska, lösning / koncentrat till infusionsvätska, lösning	SE/H/0183/001	14127	ABBVIE AB	SE
Chirocaine 5 mg/ml injektionsvätska, lösning / koncentrat till infusionsvätska, lösning	SE/H/0183/002	14128	ABBVIE AB	SE
Chirocaine 7,5 mg/ml injektionsvätska, lösning / koncentrat till infusionsvätska, lösning	SE/H/0183/003	14129	ABBVIE AB	SE
Chirocaine 1.25 mg/ml solution for infusion	SE/H/0183/005	PL 41042/0009	ABBVIE LTD (UK)	UK
Chirocaine 2.5 mg/ml solution for injection/concentrate for solution for infusion	SE/H/0183/001	PL 41042/0005	ABBVIE LTD (UK)	UK
Chirocaine 5 mg/ml solution for injection/concentrate for solution for infusion	SE/H/0183/002	PL41042/0006	ABBVIE LTD (UK)	UK
Chirocaine 7.5 mg/ml solution for injection/concentrate for solution for infusion	SE/H/0183/003	PL 41042/0007	ABBVIE LTD (UK)	UK
Chirocaine 0,625 mg/ml infusionsvätska, lösning	SE/H/0183/004	18028	ABBVIE OY	FI

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
Chirocaine 1,25 mg/ml infusionsvätska, lösning	SE/H/0183/004	18029	ABBVIE OY	FI
Chirocaine 2,5 mg/ml injektionsvätska, lösning/koncentrat till infusionsvätska, lösning	SE/H/0183/001	14675	ABBVIE OY	FI
Chirocaine 5,0 mg/ml injektionsvätska, lösning/koncentrat till infusionsvätska, lösning	SE/H/0183/002	14676	ABBVIE OY	FI
Chirocaine 7,5 mg/ml injektionsvätska, lösning/koncentrat till infusionsvätska, lösning	SE/H/0183/003	14677	ABBVIE OY	FI
Chirocaine 7,5 mg/ml, Injektionslösung/Konzentrat zur Herstellung einer Infusionslösung	SE/H/0183/003	BE207417	ABBVIE S.A.	BE
Chirocaine 1,25 mg/ml Infusionslösung	SE/H/0183/005	BE257065	ABBVIE S.A.	BE
Chirocaine 1,25 mg/ml Infusionslösung	SE/H/0183/005	BE257074	ABBVIE S.A.	BE
Chirocaine 2,5 mg/ml, Injektionslösung/Konzentrat zur Herstellung einer Infusionslösung	SE/H/0183/001	BE207392	ABBVIE S.A.	BE
Chirocaine 5,0 mg/ml, Injektionslösung/Konzentrat zur Herstellung einer Infusionslösung	SE/HL/0183/002	BE207401	ABBVIE S.A.	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
CHIROCAINE 2,5 mg/ml, solution injectable/solution à diluer pour perfusion	SE/H/0183/001	2010050780	ABBVIE S.A.	LU
Chirocaine 2,5 mg/ml, Injektionslösung/Konzentrat zur Herstellung einer Infusionslösung	SE/H/0183/001	2010050780	ABBVIE S.A.	LU
CHIROCAINE 5,0 mg/ml, solution injectable/solution à diluer pour perfusion	SE/H/0183/002	2010050781	ABBVIE S.A.	LU
Chirocaine 5,0 mg/ml, Injektionslösung/Konzentrat zur Herstellung einer Infusionslösung	SE/H/0183/002	2010050781	ABBVIE S.A.	LU
CHIROCAINE 7,5 mg/ml, solution injectable/solution à diluer pour perfusion	SE/H/0183/003	2010050782	ABBVIE S.A.	LU
Chirocaine 7,5 mg/ml, Injektionslösung/Konzentrat zur Herstellung einer Infusionslösung	SE/H/0183/003	2010050782	ABBVIE S.A.	LU
CHIROCAINE 1.25 mg/ml, solution pour perfusion	SE/H/0183/005	2010050783	ABBVIE S.A.	LU
Chirocaine 1,25 mg/ml Infusionslösung	SE/H/0183/005	2010050783	ABBVIE S.A.	LU
CHIROCAINE 5 mg/ml Injekční roztok	not available	01/389/01-C	ABBVIE S.R.O. (CZECH REPUBLIC)	CZ
CHIROCAINE 7,5 mg/ml Injekční roztok	not available	01/390/01-C	ABBVIE S.R.O. (CZECH REPUBLIC)	CZ

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
Chirocaine 2,5 mg/ml raztopina za injiciranje/koncentrat za raztopino za infundiranje	not available	H/04/00374/001	ABBVIE BIOFARMACEVTSKA DRUŽBA D.O.O.	SI
Chirocaine 5 mg/ml raztopina za injiciranje/koncentrat za raztopino za infundiranje	not available	H/04/00374/002	ABBVIE BIOFARMACEVTSKA DRUŽBA D.O.O.	SI
Chirocaine 7,5 mg/ml raztopina za injiciranje/koncentrat za raztopino za infundiranje	not available	H/04/00374/003	ABBVIE BIOFARMACEVTSKA DRUŽBA D.O.O.	SI
CHIROCAINE 5 mg infúzny koncentrát	not available	01/0361/03-S	ABBVIE S.R.O. (SLOVAKIA)	SK
Chirocaine 5 mg/ml otopina za injekciju/koncentrat za otopinu za infuziju	not available	HR-H-753467767	ABBVIE D.O.O. (CROATIA)	HR