



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 November 2018
EMA/856410/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: epinephrine / mepivacaine hydrochloride, mepivacaine / norepinephrine, mepivacaine

Procedure no.: PSUSA/00001979/201803



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
BIOCAINE 3% PLAIN	not available	PL 08313/0023	SEPTODONT LTD.	UK
Carbocain 10 mg/ml injektionsvätska, lösning	not available	5969	ASPEN PHARMA TRADING LIMITED	SE
Carbocain 10 mg/ml stungulyf, lausn	not available	IS/1/02/135/01	ASPEN PHARMA TRADING LIMITED	IS
Carbocain 20 mg/ml injektionsvätska, lösning	not available	5970	ASPEN PHARMA TRADING LIMITED	SE
Carbocain 20 mg/ml stungulyf, lausn	not available	IS/1/02/135/02	ASPEN PHARMA TRADING LIMITED	IS
Carbocain adrenalin 10 mg/ml stungulyf, lausn	not available	719001 (IS)	ASPEN PHARMA TRADING LIMITED	IS
Carbocain adrenalin 10 mg/ml+5 mikrogram/ml injektionsvätska, lösning	not available	5972	ASPEN PHARMA TRADING LIMITED	SE
Carbocain adrenalin 20 mg/ml+5 mikrogram/ml injektionsvätska, lösning	not available	5973	ASPEN PHARMA TRADING LIMITED	SE
Carbocain adrenalin 5 mg/ml+5 mikrogram/ml injektionsvätska, lösning	not available	5971	ASPEN PHARMA TRADING LIMITED	SE
Carbocain Dental 30 mg/ml stungulyf, lausn	not available	792421	DENTSPLY LIMITED	IS

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
Carbocain Dental 30mg/ml injektionsvätska, lösning	not available	6751	DENTSPLY LIMITED	SE
Carbocain, injektionsvæske, opløsning	not available	10017	ASPEN PHARMA TRADING LIMITED	DK
Carbocain, injektionsvæske, opløsning	not available	10018	ASPEN PHARMA TRADING LIMITED	DK
Carbocain® dental, 30 mg/ml	not available	3949	DENTSPLY LIMITED	NO
CARBOCAINA 10 mg/ml soluzione iniettabile	not available	016691560	ASPEN PHARMA TRADING LIMITED	IT
CARBOCAINA 10 mg/ml soluzione iniettabile	not available	016691558	ASPEN PHARMA TRADING LIMITED	IT
CARBOCAINA 20 mg/ml soluzione iniettabile	not available	016691634	ASPEN PHARMA TRADING LIMITED	IT
Carbocain-Adrenalin, injektionsvæske, opløsning	not available	10020	ASPEN PHARMA TRADING LIMITED	DK
Carbocain-Adrenalin, injektionsvæske, opløsning	not available	10021	ASPEN PHARMA TRADING LIMITED	DK
Carbocain-Adrenalin, injektionsvæske, opløsning	not available	10019	ASPEN PHARMA TRADING LIMITED	DK

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
CARBOCAINE 10 mg/ml, solution injectable	not available	34009 341 693 6 6	ASPEN PHARMA TRADING LIMITED	FR
CARBOCAINE 10 mg/ml, solution injectable	not available	34009 352 428 7 7	ASPEN PHARMA TRADING LIMITED	FR
CARBOCAINE 20 mg/ml, solution injectable	not available	34009 352 429 3 8	ASPEN PHARMA TRADING LIMITED	FR
CARBOCAINE 20 mg/ml, solution injectable	not available	34009 341 694 2 7	ASPEN PHARMA TRADING LIMITED	FR
Scandicain® 1 % Fl. 50 ml Injektionslösung	not available	6444762.01.00	ASPEN PHARMA TRADING LIMITED	DE
Scandicain® 1 % Injektionslösung	not available	6076871.01.00	ASPEN PHARMA TRADING LIMITED	DE
Scandicain® 2 % Fl. 50 ml Injektionslösung	not available	6444762.02.00	ASPEN PHARMA TRADING LIMITED	DE
Scandicain® 2 % Injektionslösung	not available	6076871.00.00	ASPEN PHARMA TRADING LIMITED	DE
SCANDICAINE 1%, Injektionslösung	not available	BE078145	ASPEN PHARMA TRADING LIMITED	BE
SCANDICAINE 1%, Injektionslösung	not available	2009070476	ASPEN PHARMA TRADING LIMITED	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
SCANDICAINE 1%, oplossing voor injectie	not available	BE078145	ASPEN PHARMA TRADING LIMITED	BE
SCANDICAINE 1%, solution injectable	not available	BE078145	ASPEN PHARMA TRADING LIMITED	BE
SCANDICAINE 1%, solution injectable	not available	2009070476	ASPEN PHARMA TRADING LIMITED	LU
SCANDICAINE 2%, Injektionslösung	not available	BE078136	ASPEN PHARMA TRADING LIMITED	BE
SCANDICAINE 2%, Injektionslösung	not available	2009070477	ASPEN PHARMA TRADING LIMITED	LU
SCANDICAINE 2%, oplossing voor injectie	not available	BE078136	ASPEN PHARMA TRADING LIMITED	BE
SCANDICAINE 2%, solution injectable	not available	BE078136	ASPEN PHARMA TRADING LIMITED	BE
SCANDICAINE 2%, solution injectable	not available	2009070477	ASPEN PHARMA TRADING LIMITED	LU
SCANDICAINE 30 mg/ml raztopina za injiciranje	not available	H/94/01398/001	SEPTODONT	SI
SCANDONEST	not available	A6A/227/11642	JOHN TSAPRAZIS S.A.	GR

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
SCANDONEST , 30 mg/ml süstelahus kolbampullis	not available	342701	SEPTODONT	EE
SCANDONEST 2% con Adrenalina	not available	028527024	LABORATOIRES SEPTODONT	IT
Scandonest 2% Special	not available	A6A/233/11644	JOHN TSAPRAZIS S.A.	GR
SCANDONEST 2% SPECIAL	not available	PL 08313/0026	SEPTODONT LTD.	UK
Scandonest 2% Special soluție injectabilă	not available	7705/2015/01	SEPTODONT	RO
SCANDONEST 2% SPECIAL with adrenaline 1:100 000 solution for injection	not available	II-12157/23.02.2011	SEPTODONT	BG
SCANDONEST 20 mg/0,01 mg v 1ml raztopina za injiciranje	not available	H/94/01399/001	SEPTODONT	SI
SCANDONEST 20 mg/mL ADRENALINEE au 1/100 000, solution injectable à usage dentaire	not available	34009 559 362 5 1	LABORATOIRES SEPTODONT SA	FR
SCANDONEST 3 % 30 mg/ml, injekčný roztok	not available	01/0242/05-S	SEPTODONT	SK

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
SCANDONEST 3 % ZONDER VAATVERNAUWER, oplossing voor injectie	not available	BE 035944	SEPTODONT NV-SA	BE
Scandonest 3% ohne Vasokonstriktor - Zylinderampullen	not available	17.525	SEPTODONT GMBH	AT
SCANDONEST 3% OHNE VASOKONSTRIKTOR, Injektionslösung	not available	BE 035944	SEPTODONT NV-SA	BE
Scandonest 3% ohne Vasokonstriktor, Injektionslösung	not available	6433621.00.00	SEPTODONT GMBH	DE
Scandonest 3% Plain	not available	PL 08313/0023	SEPTODONT LTD.	UK
Scandonest 3% Plain soluție injectabilă	not available	9866/2017/01	LABORATOIRES SEPTODONT	RO
SCANDONEST 3% senza vasocostrittore	not available	028527012	LABORATOIRES SEPTODONT	IT
Scandonest 3% w/v Solution for Injection	not available	PA0196/015/001	SEPTODONT	IE
SCANDONEST 3% WITHOUT VASOCONSTRICTOR, solution for injection	not available	2006110007	SEPTODONT NV-SA	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
Scandonest 3% zonder vasoconstrictor, oplossing voor injectie	not available	RVG 09269	SEPTODONT NV-SA	NL
Scandonest 30 mg/ml injekcinis tirpalas užtaise	not available	LT/1/01/2595/001	SEPTODONT	LT
Scandonest 30 mg/ml oldatos injekció	not available	OGYI-T-5761/01	SEPTODONT	HU
SCANDONEST 30 mg/ml otopina za injekciju	not available	UP/I-530-09/12-01/472	APOLONIA D.O.O.	HR
Scandonest 30 mg/ml škidums injekcijam kartridža	not available	98-0447	SEPTODONT	LV
Scandonest 30 mg/ml solução injectável	SE/H/0610/001	5053608	SEPTODONT	PT
Scandonest 30 mg/ml solution for injection	not available	II-12162/23.02.2011	SEPTODONT	BG
Scandonest 30 mg/ml, injektionsvätska, lösning	SE/H/0610/001	23182	SEPTODONT	FI
Scandonest 30 mg/ml, injektionsvätska, lösning	SE/H/0610/001	14381	SEPTODONT	SE
SCANDONEST 30 mg/ml, roztwór do wstrzykiwań	not available	R/3031	SEPTODONT	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
Scandonest 30 mg/ml, solución inyectable	SE/H/0610/001	69095- C.R. 659534-3	SEPTODONT	ES
Scandonest 30 mg/ml, solution for injection	SE/H/610/001	MA035/00401	SEPTODONT	MT
SCANDONEST 30 mg/mL, solution injectable à usage dentaire	not available	34009 559 364 8 0	LABORATOIRES SEPTODONT SA	FR
Scandonest Plain 30 mg/ml injeksjonsvæske, oppløsning	not available	97-5252	SEPTODONT	NO
Scandonest, 30 mg/ml, injektionsvæske, opløsning	not available	15929	SPÉCIALITÉS SEPTODONT	DK
Scandonest-Adrenalin, injektionsvæske, opløsning	not available	15930	SPÉCIALITÉS SEPTODONT	DK