



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 November 2024
EMA/PRAC/539781/2024
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): bupivacaine, bupivacaine / epinephrine

Procedure No. PSUSA/00010335/202404



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
Marcaïn-Adrenalin, injektionsvæske, opløsning	not available	04889	ASPEN PHARMA TRADING LIMITED	DK
MARCAINE HYPERBARE 0,5 %, Injektionslösung	not available	2006119109	ASPEN PHARMA TRADING LIMITED	LU
Bicain Pond Spinal 5 mg/ml injektioneste, liuos	not available	12055	ORION CORPORATION	FI
Bicain Pond Spinal 5 mg/ml injektionsvätska, lösning	not available	12055	ORION CORPORATION	FI
Bicain Spinal 5 mg/ml injektioneste, liuos	not available	12054	ORION CORPORATION	FI
Bicain Spinal 5 mg/ml injektionsvätska, lösning	not available	12054	ORION CORPORATION	FI
Bupinostrum 0,5% Hiperbárica Solução injectável	not available	3790581	BLUEMED UNIPessoal, LDA	PT
Bupinostrum 0,5% Isobárica Solução injectável	not available	3790482	BLUEMED UNIPessoal, LDA	PT
BUPIVACAÍNA BRAUN 0,25%	not available	3083383	B. BRAUN MEDICAL LDA.	PT
BUPIVACAÍNA BRAUN 0,25%	not available	3083581	B. BRAUN MEDICAL LDA.	PT
BUPIVACAÍNA BRAUN 0,25%	not available	3083680	B. BRAUN MEDICAL LDA.	PT
BUPIVACAÍNA BRAUN 0,25%	not available	3083789	B. BRAUN MEDICAL LDA.	PT
BUPIVACAÍNA BRAUN 0,25%	not available	3208584	B. BRAUN MEDICAL LDA.	PT
BUPIVACAÍNA BRAUN 0,25%	not available	3208683	B. BRAUN MEDICAL LDA.	PT
BUPIVACAÍNA BRAUN	not available	3208782	B. BRAUN MEDICAL LDA.	PT

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
0,25%				
BUPIVACAÍNA BRAUN 0,25%	not available	3208881	B. BRAUN MEDICAL LDA.	PT
BUPIVACAÍNA BRAUN 0,25%	not available	3083284	B. BRAUN MEDICAL LDA.	PT
BUPIVACAÍNA BRAUN 0,25%	not available	3083482	B. BRAUN MEDICAL LDA.	PT
BUPIVACAÍNA BRAUN 0,25%	not available	3208980	B. BRAUN MEDICAL LDA.	PT
BUPIVACAÍNA BRAUN 0,5%	not available	3134384	B. BRAUN MEDICAL LDA.	PT
BUPIVACAÍNA BRAUN 0,5%	not available	3134483	B. BRAUN MEDICAL LDA.	PT
BUPIVACAÍNA BRAUN 0,5%	not available	3134582	B. BRAUN MEDICAL LDA.	PT
BUPIVACAÍNA BRAUN 0,5%	not available	3134681	B. BRAUN MEDICAL LDA.	PT
BUPIVACAÍNA BRAUN 0,5%	not available	3134780	B. BRAUN MEDICAL LDA.	PT
BUPIVACAÍNA BRAUN 0,5%	not available	3463189	B. BRAUN MEDICAL LDA.	PT
BUPIVACAÍNA BRAUN 0,5%	not available	3463288	B. BRAUN MEDICAL LDA.	PT
BUPIVACAÍNA BRAUN 0,5%	not available	3463387	B. BRAUN MEDICAL LDA.	PT
BUPIVACAÍNA BRAUN 0,5%	not available	3463486	B. BRAUN MEDICAL LDA.	PT
BUPIVACAÍNA BRAUN 0,5%	not available	3463585	B. BRAUN MEDICAL LDA.	PT
BUPIVACAÍNA BRAUN 0,5%	not available	3463684	B. BRAUN MEDICAL LDA.	PT
BUPIVACAÍNA BRAUN 0,5%	not available	3134285	B. BRAUN MEDICAL LDA.	PT
Bupivacaine 0.5% w/v with glucose solution for injection	not available	PL 39699/0077	ASPEN PHARMA TRADING LIMITED	XI
Bupivacaine and	not available	PL 12762/0556	MERCURY	XI

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Adrenaline (Epinephrine) Injection 0.25% w/v, 1 in 200,000			PHARMACEUTICALS LTD.	
Bupivacaine and Adrenaline (Epinephrine) Injection 0.25% w/v, 1 in 200,000	not available	PL 12762/0556	MERCURY PHARMACEUTICALS LTD.	XI
Bupivacaine and Adrenaline (Epinephrine) Injection 0.5% w/v, 1 in 200,000	not available	PL 12762/0557	MERCURY PHARMACEUTICALS LTD.	XI
Bupivacaine and Adrenaline (Epinephrine) Injection 0.5% w/v, 1 in 200,000	not available	PL 12762/0557	MERCURY PHARMACEUTICALS LTD.	XI
Bupivacaine Hydrochloride 0.1% w/v Solution for Infusion	not available	PL 04416/1731	SANDOZ LTD	XI
Bupivacaine Hydrochloride 0.125% w/v Solution for Infusion	not available	PL 04416/1732	SANDOZ LTD	XI
Bupivacaine Hydrochloride 0.25% w/v solution for injection	not available	PL 39699/0078	ASPEN PHARMA TRADING LIMITED	XI
Bupivacaine Hydrochloride 0.25%w/v Solution for Injection	not available	PL 12762/0562	MERCURY PHARMACEUTICALS LTD.	XI
BUPIVACAINE VIATRIS 20 mg/4 ml, solution injectable pour voie intra rachidienne en ampoule	not available	3400956311651	VIATRIS SANTE	FR
BUPIVACAINE VIATRIS 20 mg/4 ml, solution injectable pour voie intra rachidienne en ampoule	not available	34009 562 602 3 2	VIATRIS SANTE	FR
Carbostesin 0,5 % - Lösung zur parenteralen	not available	14209	ASPEN PHARMA TRADING LIMITED	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
Anwendung				
Carbostesin® 0,25 %, Injektionslösung	not available	6077681.00.00	ASPEN PHARMA TRADING LIMITED	DE
Carbostesin® 0,5 % hyperbar, Injektionslösung	not available	9199.00.00	ASPEN PHARMA TRADING LIMITED	DE
Carbostesin® 0,5 %, Injektionslösung	not available	6077681.01.00	ASPEN PHARMA TRADING LIMITED	DE
Marcaïn 0.25% w/v with Adrenaline (Epinephrine, 5 micrograms per ml) (1:200,000) Solution for Injection	not available	PA 1691/025/001	ASPEN PHARMA TRADING LIMITED	IE
Marcaïn 0.5% w/v with Adrenaline (Epinephrine, 5 micrograms per ml) (1:200,000) Solution for Injection	not available	PA 1691/025/002	ASPEN PHARMA TRADING LIMITED	IE
Marcaïn 2,5 mg/ml injektionsvätska, lösning	not available	8613	ASPEN PHARMA TRADING LIMITED	SE
Marcaïn 2,5 mg/ml oldatos injekció	not available	OGYI-T-6777/03	ASPEN PHARMA TRADING LIMITED	HU
Marcaïn 2,5 mg/ml stungulyf, lausn	not available	792422 (IS)	ASPEN PHARMA TRADING LIMITED	IS
Marcaïn 5 mg/ml injektionsvätska, lösning	not available	8614	ASPEN PHARMA TRADING LIMITED	SE
Marcaïn 5 mg/ml oldatos injekció	not available	OGYI-T-6777/04	ASPEN PHARMA TRADING LIMITED	HU
Marcaïn 5 mg/ml stungulyf, lausn	not available	792423 (IS)	ASPEN PHARMA TRADING LIMITED	IS
Marcaïn adrenalin 2,5 mg/ml och 5 mikrogram/ml injektionsvätska, lösning	not available	7911	ASPEN PHARMA TRADING LIMITED	SE
Marcaïn adrenalin 2,5 mg/ml og 5 míkróg/ml stungulyf, lausn	not available	711403 (IS)	ASPEN PHARMA TRADING 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
Marcain adrenalin 5 mg/ml och 5 mikrogram/ml injektionsvätska, lösning	not available	7912	ASPEN PHARMA TRADING LIMITED	SE
Marcain adrenalin 5 mg/ml og 5 mikróg/ml stungulyf, lausn	not available	719005 (IS)	ASPEN PHARMA TRADING LIMITED	IS
Marcain Heavy Steripack, 0.5% w/v Solution for Injection	not available	MA955/01101	ASPEN PHARMA TRADING LIMITED	MT
Marcain Heavy Steripack, 0.5% w/v Solution for Injection	not available	MA955/01101	ASPEN PHARMA TRADING LIMITED	MT
Marcain Heavy Steripack, 0.5%w/v Solution for Injection	not available	PA 1691/024/003	ASPEN PHARMA TRADING LIMITED	IE
Marcain Polyamp Steripack 0.25% w/v Solution for Injection	not available	PA 1691/024/001	ASPEN PHARMA TRADING LIMITED	IE
Marcain Polyamp Steripack 0.5%	not available	PL 39699/0079	ASPEN PHARMA TRADING LIMITED	XI
Marcain Polyamp Steripack 0.5% w/v Solution for Injection	not available	PA 1691/024/002	ASPEN PHARMA TRADING LIMITED	IE
Marcain spinal 5 mg/ml injeksjonsvæske, oppløsning	not available	01-3828	ASPEN PHARMA TRADING LIMITED	NO
Marcain spinal 5 mg/ml injeksjonsvæske, oppløsning	not available	01-3828	ASPEN PHARMA TRADING LIMITED	NO
Marcain spinal 5 mg/ml injektionsvätska, lösning	not available	10255	ASPEN PHARMA TRADING LIMITED	SE
Marcain spinal 5 mg/ml injektionsvätska, lösning	not available	10255	ASPEN PHARMA TRADING LIMITED	SE
Marcain spinal 5 mg/ml oldatos injekció	not available	OGYI-T-6777/01	ASPEN PHARMA TRADING LIMITED	HU
Marcain spinal 5 mg/ml	not available	860003	ASPEN PHARMA TRADING	IS

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stungulyf, lausn.			LIMITED	
Marcain spinal heavy 5 mg/ml oldatos injekció	not available	OGYI-T-6777/02	ASPEN PHARMA TRADING LIMITED	HU
Marcain spinal tung 5 mg/ml injeksjonsvæske, oppløsning	not available	7043	ASPEN PHARMA TRADING LIMITED	NO
Marcain spinal tung 5 mg/ml injektionsvätska, lösning	not available	9999	ASPEN PHARMA TRADING LIMITED	SE
Marcain spinal tung 5 mg/ml stungulyf, lausn.	not available	860004	ASPEN PHARMA TRADING LIMITED	IS
Marcain Spinal tung, injektionsvæske, opløsning	not available	11008	ASPEN PHARMA TRADING LIMITED	DK
Marcain Spinal tung, injektionsvæske, opløsning	not available	11008	ASPEN PHARMA TRADING LIMITED	DK
Marcain Spinal, injektionsvæske, opløsning	not available	11429	ASPEN PHARMA TRADING LIMITED	DK
Marcain, injektionsvæske, opløsning	not available	09930	ASPEN PHARMA TRADING LIMITED	DK
Marcain, injektionsvæske, opløsning	not available	05721	ASPEN PHARMA TRADING LIMITED	DK
Marcain® adrenalin 2,5 mg/ml + 5 mikrog/ml injektioneste, liuos	not available	9341	ASPEN PHARMA TRADING LIMITED	FI
Marcain® adrenalin 2,5 mg/ml+5 mikrog/ml injektionsvästkor, lösning	not available	9341	ASPEN PHARMA TRADING LIMITED	FI
Marcain® adrenalin 5 mg/ml + 5 mikrog/ml injektioneste, liuos	not available	8227	ASPEN PHARMA TRADING LIMITED	FI
Marcain® adrenalin 5	not available	8227	ASPEN PHARMA TRADING	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
mg/ml+5 mikrog/ml injektionsvätskor, lösning			LIMITED	
Marcain® injeksjonsvæske: 2,5 mg/ml	not available	5744	ASPEN PHARMA TRADING LIMITED	NO
Marcain® injeksjonsvæske: 5,0 mg/ml	not available	5745	ASPEN PHARMA TRADING LIMITED	NO
Marcain®-adrenalin injeksjonsvæske: 2,5 mg/ml + 5 mikrogram/ml	not available	5136	ASPEN PHARMA TRADING LIMITED	NO
Marcain®-adrenalin injeksjonsvæske: 5,0 mg/ml + 5 mikrogram/ml	not available	5137	ASPEN PHARMA TRADING LIMITED	NO
MARCAINA 5 mg/ml iperbarica soluzione iniettabile	not available	021409418	ASPEN PHARMA TRADING LIMITED	IT
MARCAINA 5 mg/ml soluzione iniettabile	not available	021409356	ASPEN PHARMA TRADING LIMITED	IT
Marcaína Espinal Pesada 20 mg/4 ml solução injetável	not available	2308583	ASPEN PHARMA TRADING LIMITED	PT
Marcain-Adrenalin, injektionsvæske, opløsning	not available	10213	ASPEN PHARMA TRADING LIMITED	DK
Marcaine 0,25 % Adrenaline 1:200.000 Injektionslösung	not available	2006119103	ASPEN PHARMA TRADING LIMITED	LU
MARCAINE 0,25 % Adrenaline 1:200.000, Injektionslösung	not available	BE078172	ASPEN PHARMA TRADING LIMITED	BE
MARCAINE 0,25 % Adrénaline 1:200.000, solution injectable	not available	BE078172	ASPEN PHARMA TRADING LIMITED	BE

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MARCAINE 0,25 % Adrénaline 1:200.000, solution injectable	not available	2006119103	ASPEN PHARMA TRADING LIMITED	LU
MARCAINE 0,25% Adrenaline 1:200.000, oplossing voor injectie	not available	BE078172	ASPEN PHARMA TRADING LIMITED	BE
Marcaine 0,5 % Adrenaline 1:200.000 Injektionslösung	not available	BE078206	ASPEN PHARMA TRADING LIMITED	BE
MARCAINE 0,5 % Adrenaline 1:200.000, Injektionslösung	not available	2006119104	ASPEN PHARMA TRADING LIMITED	LU
MARCAINE 0,5 % Adrénaline 1:200.000, solution injectable	not available	BE078206	ASPEN PHARMA TRADING LIMITED	BE
MARCAINE 0,5 % Adrénaline 1:200.000, solution injectable	not available	2006119104	ASPEN PHARMA TRADING LIMITED	LU
Marcaine 0,5 % injekčný roztok	not available	01/0547/12-S	ASPEN PHARMA TRADING LIMITED	SK
MARCAINE 0,5 %, Injektionslösung	not available	BE078251	ASPEN PHARMA TRADING LIMITED	BE
MARCAINE 0,5 %, Injektionslösung	not available	2006119107	ASPEN PHARMA TRADING LIMITED	LU
MARCAINE 0,5 %, solution injectable	not available	BE078251	ASPEN PHARMA TRADING LIMITED	BE
MARCAINE 0,5 %, solution injectable	not available	2006119107	ASPEN PHARMA TRADING LIMITED	LU
MARCAINE 0,5% Adrenaline 1:200.000, oplossing voor injectie	not available	BE078206	ASPEN PHARMA TRADING LIMITED	BE
MARCAINE 0,5%, oplossing voor injectie	not available	BE078251	ASPEN PHARMA TRADING LIMITED	BE
Marcaine 2,5 mg/ml + 5 microg/ml adrenaline, oplossing voor injectie	not available	RVG 08030	ASPEN PHARMA TRADING LIMITED	NL
Marcaine 2,5 mg/ml + 5	not available	RVG 08030	ASPEN PHARMA TRADING	NL

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microg/ml adrenaline, oplossing voor injectie			LIMITED	
Marcaine 2,5 mg/ml, oplossing voor injectie	not available	RVG 08028	ASPEN PHARMA TRADING LIMITED	NL
Marcaine 2,5 mg/ml, oplossing voor injectie	not available	RVG 08028	ASPEN PHARMA TRADING LIMITED	NL
Marcaine 5 mg/ml Glucose oplossing voor injectie voor intrathecale toediening 20 mg/4 ml	not available	RVG 09869	ASPEN PHARMA TRADING LIMITED	NL
Marcaine 5 mg/ml Glucose oplossing voor injectie voor intrathecale toediening 20 mg/4 ml	not available	RVG 09869	ASPEN PHARMA TRADING LIMITED	NL
Marcaine 5 mg/ml injekční roztok	not available	01/246/71-C	ASPEN PHARMA TRADING LIMITED	CZ
Marcaine 5 mg/ml šķīdums injekcijām	not available	00-0359	ASPEN PHARMA TRADING LIMITED	LV
Marcaine 5 mg/ml Spinaal oplossing voor injectie voor intrathecale toediening	not available	RVG 10970	ASPEN PHARMA TRADING LIMITED	NL
Marcaine 5,0 mg/ml + 5 microg/ml adrenaline, oplossing voor injectie	not available	RVG 08031	ASPEN PHARMA TRADING LIMITED	NL
Marcaine 5,0 mg/ml + 5 microg/ml adrenaline, oplossing voor injectie	not available	RVG 08031	ASPEN PHARMA TRADING LIMITED	NL
Marcaine 5,0 mg/ml oplossing voor injectie	not available	RVG 08029	ASPEN PHARMA TRADING LIMITED	NL
Marcaine 5,0 mg/ml oplossing voor injectie	not available	RVG 08029	ASPEN PHARMA TRADING LIMITED	NL
Marcaine Adrenaline 0,5%, (5 mg + 0,005 mg)/ml, roztwór do wstrzykiwań	not available	R/1316	ASPEN PHARMA TRADING LIMITED	PL
MARCAINE HYPERBARE	not available	BE126253	ASPEN PHARMA TRADING	BE

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0,5 %, Injektionslösung			LIMITED	
MARCAINE HYPERBARE 0,5 %, solution injectable	not available	BE126253	ASPEN PHARMA TRADING LIMITED	BE
MARCAINE HYPERBARE 0,5 %, solution injectable	not available	2006119109	ASPEN PHARMA TRADING LIMITED	LU
MARCAINE HYPERBARE 0,5%, oplossing voor injectie	not available	BE126253	ASPEN PHARMA TRADING LIMITED	BE
Marcaine spinal 0,5 % heavy 5 mg/ml injekčný roztok	not available	01/0200/85-CS	ASPEN PHARMA TRADING LIMITED	SK
Marcaine Spinal 0,5% Heavy, 5 mg/ml, roztwór do wstrzykiwań	not available	R /1317	ASPEN PHARMA TRADING LIMITED	PL
Marcaine Spinal 0.5% šķīdums injekcijām	not available	96-0598	ASPEN PHARMA TRADING LIMITED	LV
Marcaine spinal 5 mg/ml injekční roztok	not available	01/200/85-A/C	ASPEN PHARMA TRADING LIMITED	CZ
MARCAINE SPINAL 5 mg/ml soluție injectabilă	not available	6019/2013/01	ASPEN PHARMA TRADING LIMITED	RO
MARCAINE SPINAL 5 mg/ml, süstelahus	not available	112495	ASPEN PHARMA TRADING LIMITED	EE
Marcaine Spinal Heavy 0.5% šķīdums injekcijām	not available	96-0597	ASPEN PHARMA TRADING LIMITED	LV
Marcaine Spinal Heavy 0.5% šķīdums injekcijām	not available	96-0597	ASPEN PHARMA TRADING LIMITED	LV
Marcaine Spinal Heavy 5 mg/ml injekcinis tirpalas	not available	LT/1/96/1669/002	ASPEN PHARMA TRADING LIMITED	LT
Marcaine spinal heavy 5 mg/ml injekční roztok	not available	01/200/85-B/C	ASPEN PHARMA TRADING LIMITED	CZ
MARCAINE SPINAL HEAVY 5 mg/ml soluție injectabilă	not available	6020/2013/01	ASPEN PHARMA TRADING LIMITED	RO
MARCAINE SPINAL HEAVY 5 mg/ml,	not available	112595	ASPEN PHARMA TRADING LIMITED	EE

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süstelahus				
Маркаин Спинал 5 mg/ml, инжекционен разтвор	not available	9700562	ASPEN PHARMA TRADING LIMITED	BG
Маркаин Спинал Хеви 5 mg/ml, инжекционен разтвор	not available	9700565	ASPEN PHARMA TRADING LIMITED	BG
Маркаин Спинал Хеви 5 mg/ml, инжекционен разтвор	not available	9700565	ASPEN PHARMA TRADING LIMITED	BG