



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 February 2019
EMA/118356/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: calcitonin salmon, synthetic analogue of eel calcitonin

Procedure no.: PSUSA/00000494/201806



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
CALSYN 100 U.I./1 ml, solution injectable en ampoule	not available	340 658-2	SANOFI-AVENTIS FRANCE	FR
CALSYN 50 U.I./0,5 ml, solution injectable en ampoule	not available	343 507-5	SANOFI-AVENTIS FRANCE	FR
CALSYN 50 U.I./0,5 ml, solution injectable en ampoule	not available	340 657-6	SANOFI-AVENTIS FRANCE	FR
CALSYN 50 U.I./0,5 ml, solution injectable en ampoule	not available	343 506-9	SANOFI-AVENTIS FRANCE	FR
CALSYN 100 U.I./1 ml, solution injectable en ampoule	not available	343 504-6	SANOFI-AVENTIS FRANCE	FR
CALSYN 100 U.I./1 ml, solution injectable en ampoule	not available	343 505-2	SANOFI-AVENTIS FRANCE	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
CALSYN 100 U.I./1 ml, solution injectable en ampoule	not available	343 502-3	SANOFI-AVENTIS FRANCE	FR
CALSYN 50 U.I./0,5 ml, solution injectable en ampoule	not available	343 508-1	SANOFI-AVENTIS FRANCE	FR
MIACALCIC 50 UI/ML SOLUTIE INJECTABILĂ	not available	5400/2005/01	NOVARTIS PHARMA GMBH	RO
Miacalcic, injektions- og infusionsvæske, opløsning	IE/H/0117/003	6594	ESSENTIAL PHARMA	DK
Calcitonin Essential Pharma 100 I.E./ml – Lösung zur Injektion und Infusion	IE/H/0117/003	16.880	ESSENTIAL PHARMA	AT
Miacalcic 100 a.e./ml stungulyf, lausn og innrennsislyf, lausn	IE/H/0117/003	761970	ESSENTIAL PHARMA	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
Calcitonine-EssPharma 100 IE/ml, oplossing voor injectie en infusie	IE/H/0117/003	RVG 08201	ESSENTIAL PHARMA	NL
MIACALCIC 100 IE/ml injeksjons- og infusjonsvæske, oppløsning	IE/H/0117/003	6184	ESSENTIAL PHARMA	NO
Miacalcic 100 IE/ml injektions-/infusionsvätska, lösning	IE/H/0117/003	9290	ESSENTIAL PHARMA	SE
Miacalcic 100 IU/ml injektio- ja infuusioneste, liuos	IE/H/0117/003	7325	ESSENTIAL PHARMA	FI
Miacalcic 100 IU/ml injektions-/infusionsvätska, lösning	IE/H/0117/003	7325	ESSENTIAL PHARMA	FI
Miacalcic 100 UI/ml solución inyectable y para perfusión	IE/H/117/003	56.198	ESSENTIAL 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
Miacalcic 200 i.e./odmerek prsilo za nos, raztopina	not available	5363-I-561/10	NOVARTIS PHARMA GMBH	SI
MIACALCIC NASAL 200 IU/ANNOS NENÄSUMUTE, LIUOS	IE/H/0117/001	15421	NOVARTIS FINLAND OY	FI
Miacalcic Nasal 200 IE/dos nässpray, lösning	IE/H/0117/001	15421	NOVARTIS FINLAND OY	FI
Miacalcic 200 UI solución para pulverización nasal	IE/H/0117/001	61699	NOVARTIS FARMACÉUTICA S.A.	ES
Oseototal 200 UI solución para pulverización nasal	IE/H/0122/001	62538	NOVARTIS FARMACÉUTICA S.A.	ES
Miacalcic 200 NE oldatos orrspray	not available	OGYI-T-1342/03	NOVARTIS HUNGÁRIA KFT. PHARMA	HU

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
Miacalcic 200 NE oldatos orrspray	not available	OGYI-T-1342/04	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
МИАКАЛЦИК НАЗАЛ 200 IU СПРЕЙ ЗА НОС, РАЗТВОР	not available	20000525	NOVARTIS PHARMA GMBH	BG
Calcitonin „Novartis“ 100 I.E. - Nasalspray	IE/H/0117/002	1-20665	NOVARTIS PHARMA GMBH	AT
MIACALCIC® 200 I.U. NASAL SPRAY	not available	18426	NOVARTIS PHARMACEUTICALS UK LIMITED	CY
Miacalcic 200 IU Nasal Spray, solution	IE/H/0117/001	PA0896/020/002	NOVARTIS IRELAND LIMITED	IE
Miacalcic 200 UI Solução para pulverização nasal	IE/H/0117/001	3068384	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	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
Miacalcic 200 UI Solução para pulverização nasal	IE/H/0117/001	8668525	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Calcitonin „Novartis“ 200 I.E. - Nasalspray	IE/H/0117/001	1-23961	NOVARTIS PHARMA GMBH	AT
Calcitonin Sandoz® 100 I.E. / Sprühstoß Nasenspray	not available	26592.00.00	HEXAL AG	DE
Miacalcic 100 NE/ml oldatos injekció és infúzió	not available	OGYT-T/23145/02	ESSENTIAL PHARMA	HU
Miacalcic 100 I.E./ml Injektionslösung in einer Fertigspritze	not available	BE173031	ESSENTIAL PHARMA	BE
Miacalcic 100 UI/ml, solution injectable en seringue préremplie	not available	BE173031	ESSENTIAL PHARMA	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
Miacalcic 100 I.E./ml, oplossing voor injectie in een voorgevulde spuit	not available	BE173031	ESSENTIAL PHARMA	BE
Miacalcic 50 NE/ml oldatos injekció és infúzió	not available	OGYT-T/23145/01	ESSENTIAL PHARMA	HU
Miacalcic 50 I.E./0,5 ml Injektionslösung in einer Fertigspritze	not available	BE168524	ESSENTIAL PHARMA	BE
Miacalcic 50 UI/0,5 ml, solution injectable en seringue préremplie	not available	BE168524	ESSENTIAL PHARMA	BE
Miacalcic 50 I.E./0,5 ml, oplossing voor injectie in een voorgevulde spuit	not available	BE168524	ESSENTIAL PHARMA	BE
Miacalcic® Ampoules 100IU/mL (1mL) solution for injection or infusion	not available	1149/00101	ESSENTIAL PHARMA	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
Miacalcic 200 i.e./odmerek prsilo za nos, raztopina	not available	5363-I-561/10	NOVARTIS PHARMA GMBH	SI
MIACALCIC NASAL 200 IU/ANNOS NENÄSUMUTE, LIUOS	IE/H/0117/001	15421	NOVARTIS FINLAND OY	FI
Miacalcic Nasal 200 IE/dos nässpray, lösning	IE/H/0117/001	15421	NOVARTIS FINLAND OY	FI
Miacalcic 200 UI solución para pulverización nasal	IE/H/0117/001	61699	NOVARTIS FARMACÉUTICA S.A.	ES
Oseototal 200 UI solución para pulverización nasal	IE/H/0122/001	62538	NOVARTIS FARMACÉUTICA S.A.	ES
Miacalcic 200 NE oldatos orrspray	not available	OGYI-T-1342/03	NOVARTIS HUNGÁRIA KFT. PHARMA	HU

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
Miacalcic 200 NE oldatos orrspray	not available	OGYI-T-1342/04	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
МИАКАЛЦИК НАЗАЛ 200 IU СПРЕЙ ЗА НОС, РАЗТВОР	not available	20000525	NOVARTIS PHARMA GMBH	BG
Calcitonin „Novartis“ 100 I.E. - Nasalspray	IE/H/0117/002	1-20665	NOVARTIS PHARMA GMBH	AT
MIACALCIC® 200 I.U. NASAL SPRAY	not available	18426	NOVARTIS PHARMACEUTICALS UK LIMITED	CY
Miacalcic 200 IU Nasal Spray, solution	IE/H/0117/001	PA0896/020/002	NOVARTIS IRELAND LIMITED	IE
Miacalcic 200 UI Solução para pulverização nasal	IE/H/0117/001	3068384	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	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
Miacalcic 200 UI Solução para pulverização nasal	IE/H/0117/001	8668525	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Calcitonin „Novartis“ 200 I.E. - Nasalspray	IE/H/0117/001	1-23961	NOVARTIS PHARMA GMBH	AT
Miacalcic 50 I.E./ml Injektions- und Infusionslösung	IE/H/0117/004	BE126901	ESSENTIAL PHARMA	BE
Miacalcic 50 UI/ml solution injectable/pour perfusion	IE/H/0117/004	BE126901	ESSENTIAL PHARMA	BE
Calcitonin 50 IU/ml solution for injection and infusion	IE/H/0117/004	PL 41871/0008	ESSENTIAL PHARMA	UK
Calcitonin Essential Pharma 50 I.E./ml – Lösung zur Injektion und Infusion	IE/H/0117/004	1-18623	ESSENTIAL PHARMA	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
MIACALCIC 50 U.I./1 ml, solution injectable ou pour perfusion	IE/H/0117/004	34009 330 203 2 3	ESSENTIAL PHARMA	FR
MIACALCIC 50 U.I./1 ml, solution injectable ou pour perfusion	IE/H/0117/004	34009 573 832 5 1	ESSENTIAL PHARMA	FR
MIACALCIC 50 U.I./1 ml, solution injectable ou pour perfusion	IE/H/0117/004	34009 573 833 1 2	ESSENTIAL PHARMA	FR
MIACALCIC 50 U.I./1 ml, solution injectable ou pour perfusion	IE/H/0117/004	34009 573 834 8 0	ESSENTIAL PHARMA	FR