



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 February 2022
EMA/PRAC/75101/2022
Pharmacovigilance Risk Assessment Committee (PRAC)

List of nationally authorised medicinal products

Active substance(s): calcitonin salmon, synthetic analogue of eel calcitonin

Procedure No.: PSUSA/00000494/202106



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 UI/1 ML, SOL. INJ. EN AMPOULE	not available	34009 340 658 2 8	SANOFI-AVENTIS FRANCE	FR
CALSYN 100 UI/1 ML, SOL. INJ. EN AMPOULE	not available	34009 343 504 6 7	SANOFI-AVENTIS FRANCE	FR
CALSYN 100 UI/1 ML, SOL. INJ. EN AMPOULE	not available	34009 343 505 2 8	SANOFI-AVENTIS FRANCE	FR
CALSYN 100 UI/1 ML, SOL. INJ. EN AMPOULE	not available	34009 343 502 3 8	SANOFI-AVENTIS FRANCE	FR
Miacalcic 50 I.E./0,5 ml, oplossing voor injectie in een voorgevulde spuit	not available	BE168524	ESSENTIAL PHARMA (M) LIMITED	BE
Miacalcic 50 I.E./0,5 ml Injektionslösung in einer Fertigspritze	not available	BE168524	ESSENTIAL PHARMA (M) LIMITED	BE
Miacalcic 50 UI/0,5 ml, solution injectable en seringue préremplie	not available	BE168524	ESSENTIAL PHARMA (M) LIMITED	BE
Calcitonina Hubber 100 UI solución inyectable	not available	57064	MEDA PHARMA S.L.	ES
Miacalcic, injektions- og infusionsvæske, opløsning	IE/H/0117/003	6594	ESSENTIAL PHARMA (M) LIMITED	DK
MIACALCIC 100 IE/ml injeksjons- og infusionsvæske, oppløsning	IE/H/0117/003	6184	ESSENTIAL PHARMA (M) LIMITED	NO
Calcitonin Essential Pharma 100 I.E./ml – Lösung zur Injektion und Infusion	IE/H/0117/003	16.880	ESSENTIAL PHARMA (M) LIMITED	AT
Miacalcic 100 IE/ml injektions-/infusionsvätska, lösning	IE/H/0117/003	9290	ESSENTIAL PHARMA (M) LIMITED	SE
Miacalcic 100 IU/ml injektio- ja infuusioneste, liuos	IE/H/0117/003	7325	ESSENTIAL PHARMA (M) LIMITED	FI
Miacalcic 100 IU/ml injektions-/infusionsvätska, lösning	IE/H/0117/003	7325	ESSENTIAL PHARMA (M) LIMITED	FI
Miacalcic 100 I.E./ml Injektions- und Infusionslösung	IE/H/0117/003	BE576035	ESSENTIAL PHARMA (M) LIMITED	BE
Miacalcic 100 UI/ml solution injectable/pour perfusion.	IE/H/0117/003	BE576035	ESSENTIAL PHARMA (M) LIMITED	BE
Miacalcic 100 IE/ml oplossing voor injectie en infusie.	IE/H/0117/003	BE576035	ESSENTIAL PHARMA (M) LIMITED	BE
Miacalcic 50 NE/ml oldatos injekció és	not available	OGYT-T/23145/01	ESSENTIAL PHARMA (M)	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
infúzió			LIMITED	
CALSYN 50 UI/0,5 ML, SOL. INJ. EN AMPOULE	not available	34009 343 507 5 7	SANOFI-AVENTIS FRANCE	FR
CALSYN 50 UI/0,5 ML, SOL. INJ. EN AMPOULE	not available	34009 340 657 67	SANOFI-AVENTIS FRANCE	FR
CALSYN 50 UI/0,5 ML, SOL. INJ. EN AMPOULE	not available	34009 343 506 9 6	SANOFI-AVENTIS FRANCE	FR
CALSYN 50 UI/0,5 ML, SOL. INJ. EN AMPOULE	not available	34009 343 508 1 8	SANOFI-AVENTIS FRANCE	FR
Calcitonin Essential Pharma 50 I.E./ml – Lösung zur Injektion und Infusion	IE/H/0117/004	1-18623	ESSENTIAL PHARMA (M) LIMITED	AT
Miacalcic 50 IE/ml oplossing voor injectie en infusie.	IE/H/0117/004	BE126901	ESSENTIAL PHARMA (M) LIMITED	BE
Miacalcic 50 I.E./ml Injektions- und Infusionslösung	IE/H/0117/004	BE126901	ESSENTIAL PHARMA (M) LIMITED	BE
Miacalcic 50 UI/ml solution injectable/pour perfusion.	IE/H/0117/004	BE126901	ESSENTIAL PHARMA (M) LIMITED	BE
MIACALCIC 50 U.I./1 ml, solution injectable ou pour perfusion	IE/H/0117/004	34009 330 203 2 3	ESSENTIAL PHARMA (M) LIMITED	FR
MIACALCIC 50 U.I./1 ml, solution injectable ou pour perfusion	IE/H/0117/004	34009 573 832 5 1	ESSENTIAL PHARMA (M) LIMITED	FR
MIACALCIC 50 U.I./1 ml, solution injectable ou pour perfusion	IE/H/0117/004	34009 573 833 1 2	ESSENTIAL PHARMA (M) LIMITED	FR
MIACALCIC 50 U.I./1 ml, solution injectable ou pour perfusion	IE/H/0117/004	34009 573 834 8 0	ESSENTIAL PHARMA (M) LIMITED	FR
Miacalcic 100 I.E./ml, oplossing voor injectie in een voorgevulde spuit	not available	BE173031	ESSENTIAL PHARMA (M) LIMITED	BE
Miacalcic 100 I.E./ml Injektionslösung in einer Fertigspritze	not available	BE173031	ESSENTIAL PHARMA (M) LIMITED	BE
Miacalcic 100 UI/ml, solution injectable en seringue préremplie	not available	BE173031	ESSENTIAL PHARMA (M) LIMITED	BE
Miacalcic 100 NE/ml oldatos injekció és infúzió	not available	OGYT-T/23145/02	ESSENTIAL PHARMA (M) LIMITED	HU