



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 April 2020
EMA/222031/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: paricalcitol

Procedure no.: PSUSA/00002316/201908

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
Paracalcitolo SUN 2 microgrammi/ml soluzione iniettabile	DE/H/5528/001	043557014	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	IT
Paricalcitol SUN 2 microgramos/ml solución inyectable EFG	DE/H/5528/001	80445	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	ES
Paricalcitol SUN 2 Mikrogramm/ml Injektionslösung	DE/H/5528/001	90682.00.00	SUN PHARMACEUTICALS GERMANY GMBH	DE
Zemplar 1 µg kapsuly mäkké kapsuly	ES/H/0113/002	87/0467/07-S	ABBVIE S.R.O. (SLOVAKIA)	SK
Zemplar 1 microgram capsules, soft	ES/H/0113/002	PA 1824/5/1	ABBVIE LIMITED	IE
Zemplar 1 microgram capsules, soft	ES/H/0113/002	PL 41042/0011	ABBVIE LTD (UK)	UK
Zemplar 1 microgram capsules, zacht	ES/H/0113/002	RVG 100436	ABBVIE B.V.	NL
Zemplar 1 microgram, capsule moi	ES/H/0113/002	6703/2014/01	ABBVIE SPAIN S.L.U.	RO
Zemplar 1 microgram, capsule moi	ES/H/0113/002	6703/2014/02	ABBVIE SPAIN S.L.U.	RO

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Zemplar 1 microgram, capsule moi	ES/H/0113/002	6703/2014/03	ABBVIE SPAIN S.L.U.	RO
Zemplar 1 micrograma cápsulas moles	ES/H/0113/002	5074604	ABBVIE, LDA.	PT
Zemplar 1 microgrammo capsule molli	ES/H/0113/002	036374039	ABBVIE S.R.L.	IT
Zemplar 1 microgrammo capsule molli	ES/H/0113/002	036374041	ABBVIE S.R.L.	IT
Zemplar 1 microgrammo capsule molli	ES/H/0113/002	036374054	ABBVIE S.R.L.	IT
Zemplar 1 microgramo cápsulas blandas	ES/H/0113/002	68022	ABBVIE SPAIN S.L.U.	ES
Zemplar 1 mikrogram kapsel, mjuk	ES/H/0113/002	25671	ABBVIE AB	SE
Zemplar 1 mikrogram mehke kapsule	ES/H/0113/002	H/08/01700/001	ABBVIE BIOFARMACEVTSKA DRUŽBA D.O.O.	SI
Zemplar 1 mikrogram mehke kapsule	ES/H/0113/002	H/08/01700/003	ABBVIE BIOFARMACEVTSKA	SI

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
			DRUŽBA D.O.O.	
Zemplar 1 mikrogram mehke kapsule	ES/H/0113/002	H/08/01700/002	ABBVIE BIOFARMACEVTSKA DRUŽBA D.O.O.	SI
Zemplar 1 mikrogram meke kapsule	not available	HR-H-316273011	ABBVIE D.O.O. (CROATIA)	HR
Zemplar 1 mikrograma mīkstās kapsulas	ES/H/0113/002	07-0350	ABBVIE SIA	LV
Zemplar 1 mikrogramas minkštosios kapsulės	ES/H/0113/002	LT/1/08/1042/001	ABBVIE SIA	LT
Zemplar 1 mikrogramas minkštosios kapsulės	ES/H/0113/002	LT/1/08/1042/002	ABBVIE SIA	LT
Zemplar 1 mikrogramas minkštosios kapsulės	ES/H/0113/002	LT/1/08/1042/003	ABBVIE SIA	LT
Zemplar 1 mikrogramm lágy kapszula	ES/H/0113/002	OGYI-T-9951/03	ABBVIE KFT	HU
Zemplar 1 mikrogramm lágy kapszula	ES/H/0113/002	OGYI-T-9951/04	ABBVIE KFT	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
Zemplar 1 mikrogramm lágy kapszula	ES/H/0113/002	OGYI-T-9951/05	ABBVIE KFT	HU
Zemplar 1 Mikrogramm Weichkapseln	ES/H/0113/002	68911.00.00	ABBVIE DEUTSCHLAND GMBH & CO. KG	DE
Zemplar 1 μκρογραμμάριο καψάκια, μαλακά	ES/H/0113/002	54914/10-07-2013	ABBVIE PHARMACEUTICALS S.A.	GR
Zemplar 2 μg kapsuly mäkké kapsuly	ES/H/0113/003	87/0468/07-S	ABBVIE S.R.O. (SLOVAKIA)	SK
Zemplar 2 microgramas cápsulas moles	ES/H/0113/003	5074612	ABBVIE, LDA.	PT
Zemplar 2 microgramas/ml Solu ^{テア} ^テ o Injet ^テ .vel	ES/H/0113/005	5278270	ABBVIE, LDA.	PT
Zemplar 2 micrograme, capsule moi	ES/H/0113/003	6704/2014/01	ABBVIE SPAIN S.L.U.	RO
Zemplar 2 micrograme, capsule moi	ES/H/0113/003	6704/2014/02	ABBVIE SPAIN S.L.U.	RO
Zemplar 2 micrograme, capsule moi	ES/H/0113/003	6704/2014/03	ABBVIE SPAIN S.L.U.	RO

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
Zemplar 2 microgrammi capsule molli	ES/H/0113/003	036374066	ABBVIE S.R.L.	IT
Zemplar 2 microgrammi capsule molli	ES/H/0113/003	036374078	ABBVIE S.R.L.	IT
Zemplar 2 microgrammi capsule molli	ES/H/0113/003	036374080	ABBVIE S.R.L.	IT
Zemplar 2 microgrammi/ml soluzione iniettabile	ES/H/0113/005	036374128	ABBVIE S.R.L.	IT
Zemplar 2 microgrammi/ml soluzione iniettabile	ES/H/0113/005	036374155	ABBVIE S.R.L.	IT
Zemplar 2 microgramos cápsulas blandas	ES/H/0113/003	68023	ABBVIE SPAIN S.L.U.	ES
Zemplar 2 microgramos/ml solución inyectable	ES/H/0113/005	68.362	ABBVIE SPAIN S.L.U.	ES
Zemplar 2 micrograms capsules, soft	ES/H/0113/003	PA 1824/5/2	ABBVIE LIMITED	IE
Zemplar 2 micrograms capsules, soft	ES/H/0113/003	PL 41042/0012	ABBVIE LTD (UK)	UK

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
Zemplar 2 mikrogram kapsel, mjak	ES/H/0113/003	25672	ABBVIE AB	SE
Zemplar 2 mikrograma mehke kapsule	ES/H/0113/003	H/08/01700/004	ABBVIE BIOFARMACEVTSKA DRUŽBA D.O.O.	SI
Zemplar 2 mikrograma mehke kapsule	ES/H/0113/003	H/08/01700/005	ABBVIE BIOFARMACEVTSKA DRUŽBA D.O.O.	SI
Zemplar 2 mikrograma mehke kapsule	ES/H/0113/003	H/08/01700/006	ABBVIE BIOFARMACEVTSKA DRUŽBA D.O.O.	SI
Zemplar 2 mikrograma meke kapsule	not available	HR-H-374239440	ABBVIE D.O.O. (CROATIA)	HR
Zemplar 2 mikrogramai minkštosios kapsules	ES/H/0113/003	LT/1/08/1042/004	ABBVIE SIA	LT
Zemplar 2 mikrogramai minkštosios kapsules	ES/H/0113/003	LT/1/08/1042/005	ABBVIE SIA	LT
Zemplar 2 mikrogramai minkštosios kapsules	ES/H/0113/003	LT/1/08/1042/006	ABBVIE SIA	LT
Zemplar 2 mikrogramm lágy kapszula	ES/H/0113/003	OGYI-T-9951/06	ABBVIE KFT	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
Zemplar 2 mikrogramm lágy kapszula	ES/H/0113/003	OGYI-T-9951/07	ABBVIE KFT	HU
Zemplar 2 mikrogramm lágy kapszula	ES/H/0113/003	OGYI-T-9951/08	ABBVIE KFT	HU
Zemplar 2 Mikrogramm Weichkapseln	ES/H/0113/003	68912.00.00	ABBVIE DEUTSCHLAND GMBH & CO. KG	DE
Zemplar 2 mikrogramu mīkstās kapsulas	ES/H/0113/003	07-0351	ABBVIE SIA	LV
Zemplar 2 mikrogramy/ml injekční roztok	ES/H/0113/005	56/391/10-C	ABBVIE S.R.O. (CZECH REPUBLIC)	CZ
Zemplar 2 μικρογραμμάρια καψάκια, μαλακά	ES/H/0113/003	54915/10-07-2013	ABBVIE PHARMACEUTICALS S.A.	GR
Zemplar 5 microgramas/ml Solu [®] Injet [®] vel	ES/H/0113/001	4435186	ABBVIE, LDA.	PT
Zemplar 5 microgramas/ml Solu [®] Injet [®] vel	ES/H/0113/001	4435285	ABBVIE, LDA.	PT
Zemplar 5 microgramas/ml Solu [®]	ES/H/0113/001	5603709	ABBVIE, LDA.	PT

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テロ Injet テロ vel				
Zemplar 5 micrograme/ml soluție injectabilă	not available	9420/2016/01	ABBVIE SPAIN S.L.U.	RO
Zemplar 5 micrograme/ml soluție injectabilă	not available	9420/2016/02	ABBVIE SPAIN S.L.U.	RO
Zemplar 5 micrograme/ml soluție injectabilă	not available	9420/2016/03	ABBVIE SPAIN S.L.U.	RO
Zemplar 5 micrograme/ml soluție injectabilă	not available	9420/2016/04	ABBVIE SPAIN S.L.U.	RO
Zemplar 5 microgrammi/ml soluzione iniettabile	ES/H/0113/001	036374015	ABBVIE S.R.L.	IT
Zemplar 5 microgrammi/ml soluzione iniettabile	ES/H/0113/001	036374027	ABBVIE S.R.L.	IT
Zemplar 5 microgrammi/ml soluzione iniettabile	ES/H/0113/001	036374130	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
Zemplar 5 microgrammi/ml soluzione iniettabile	ES/H/0113/001	036374142	ABBVIE S.R.L.	IT
Zemplar 5 microgramos/ml Solución inyectable	ES/H/0113/001	64.974	ABBVIE SPAIN S.L.U.	ES
Zemplar 5 micrograms/ml solution for injection	ES/H/0113/001	PA 1824/5/4	ABBVIE LIMITED	IE
Zemplar 5 micrograms/ml Solution for injection	ES/H/0113/001	PL 41042/0010	ABBVIE LTD (UK)	UK
Zemplar 5 mikrogram/ml injektionsvätska, lösning	ES/H/0113/001	21369	ABBVIE AB	SE
Zemplar 5 mikrograma/ml otopina za injekciju	not available	HR-H-799965648	ABBVIE D.O.O. (CROATIA)	HR
Zemplar 5 Mikrogramm/ml Injektionslösung	ES/H/0113/001	1-24969	ABBVIE GMBH	AT
Zemplar 5 Mikrogramm/ml -	ES/H/0113/001	1-24969	ABBVIE GMBH	AT

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Injektionslösung				
Zemplar 5 Mikrogramm/ml Injektionslösung	ES/H/0113/001	1-24969	ABBVIE GMBH	AT
Zemplar 5 Mikrogramm/ml Injektionslösung	ES/H/0113/001	1-24969	ABBVIE GMBH	AT
Zemplar 5 Mikrogramm/ml Injektionslösung	ES/H/0113/001	60822.00.00	ABBVIE DEUTSCHLAND GMBH & CO. KG	DE
Zemplar 5 mikrogramm/ml oldatos injekció	ES/H/0113/001	OGYI-T- 9951/01	ABBVIE KFT	HU
Zemplar 5 mikrogramm/ml oldatos injekció	ES/H/0113/001	OGYI-T- 9951/02	ABBVIE KFT	HU
Zemplar 5 mikrogramm/ml oldatos injekció	ES/H/0113/001	OGYI-T- 9951/12	ABBVIE KFT	HU
Zemplar 5 mikrogramm/ml oldatos injekció	ES/H/0113/001	OGYI-T- 9951/13	ABBVIE KFT	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
Zemplar 5 mikrogramů/ml injekční roztok	ES/H/0113/001	56/198/04-C	ABBVIE S.R.O. (CZECH REPUBLIC)	CZ
Zemplar 5 µg/ml injekčný roztok	ES/H/0113/001	87/0274/04-S	ABBVIE S.R.O. (SLOVAKIA)	SK
Zemplar, 1 mikrogramm pehmekapslid	ES/H/0113/002	564707	ABBVIE SIA	EE
Zemplar, 2 mikrogrammi pehmekapslid	ES/H/0113/003	564907	ABBVIE SIA	EE
Zemplar, 5 microgram/ml oplossing voor injectie	ES/H/0113/001	RVG 31535	ABBVIE B.V.	NL