



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 February 2021
EMA/93946/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: alfacalcidol

Procedure no.: PSUSA/00000080/202006



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
1-Alpha LEO 0,25 microgram zachte capsules	not available	BE118456	LEO PHARMA NV/SA	BE
1-Alpha LEO 0,25 microgramme capsules molles	not available	2008099003	LEO PHARMA NV/SA	LU
1-Alpha LEO 0,25 microgramme capsules, molles	not available	BE118456	LEO PHARMA NV/SA	BE
1-Alpha LEO 0,25 Mikrogramm Weichkapseln	not available	BE118456	LEO PHARMA NV/SA	BE
1-Alpha LEO 1 microgram zachte capsules	not available	BE233834	LEO PHARMA NV/SA	BE
1-Alpha LEO 1 microgramme capsules molles	not available	BE233834	LEO PHARMA NV/SA	BE
1-Alpha LEO 1 microgramme capsules molles	not available	2008099004	LEO PHARMA NV/SA	LU
1-Alpha LEO 1 Mikrogramm Weichkapseln	not available	BE233834	LEO PHARMA NV/SA	BE
1-Alpha LEO 2 microgram/ml druppels voor oraal gebruik, oplossing	not available	BE159187	LEO PHARMA NV/SA	BE

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1-Alpha LEO 2 microgrammes/ml solution buvable en gouttes	not available	BE159187	LEO PHARMA NV/SA	BE
1-Alpha LEO 2 microgrammes/ml solution buvable en gouttes	not available	2008090005	LEO PHARMA NV/SA	LU
1-Alpha LEO 2 Mikrogramm/ml Tropfen zum Einnehmen, Lösung	not available	BE159187	LEO PHARMA NV/SA	BE
1-Alpha LEO IV 1 microgram/0,5 ml oplossing voor injectie	not available	BE164595	LEO PHARMA NV/SA	BE
1-Alpha LEO IV 1 microgramme/0,5 ml solution injectable	not available	BE164595	LEO PHARMA NV/SA	BE
1-Alpha LEO IV 1 microgramme/0,5 ml solution injectable	not available	2008099006	LEO PHARMA NV/SA	LU
1-Alpha LEO IV 1 Mikrogramm/0,5 ml Injektionslösung	not available	BE164595	LEO PHARMA NV/SA	BE
Alfacalcidol Alvogen 0,25 mikrogrammai minkštosios kapsulės	not available	LT/1/97/3477/006	ALVOGEN PHARMA TRADING EUROPE EOOD	LT
Alfacalcidol Alvogen 0,25 mikrogrammai minkštosios kapsulės	not available	LT/1/97/3477/001	ALVOGEN PHARMA TRADING EUROPE EOOD	LT

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Alfacalcidol Alvogen 0,25 mikrogramai minkštosios kapsulės	not available	LT/1/97/3477/002	ALVOGEN PHARMA TRADING EUROPE EOOD	LT
Alfacalcidol Alvogen 1 mikrogramas minkštosios kapsulės	not available	LT/1/97/3477/003	ALVOGEN PHARMA TRADING EUROPE EOOD	LT
Alfacalcidol Alvogen 1 mikrogramas minkštosios kapsulės	not available	LT/1/97/3477/007	ALVOGEN PHARMA TRADING EUROPE EOOD	LT
Alfacalcidol Alvogen 1 mikrogramas minkštosios kapsulės	not available	LT/1/97/3477/004	ALVOGEN PHARMA TRADING EUROPE EOOD	LT
Alfacalcidol Alvogen 1 mikrogramas minkštosios kapsulės	not available	LT/1/97/3477/005	ALVOGEN PHARMA TRADING EUROPE EOOD	LT
Dediol 0,25 mcg capsule molli	not available	025487024	LEO PHARMA A/S	IT
DEDIOL 2 mcg/ml gocce orali, soluzione	not available	025487036	LEO PHARMA A/S	IT
DISERINAL 0,25 mcg capsule molli	not available	032333015	S.F. GROUP SRL	IT
DISERINAL 1,0 mcg capsule molli	not available	032333027	S.F. GROUP SRL	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
EinsAlpha® 0,25 µg Kapseln	not available	912.01.00	LEO PHARMA GMBH	DE
EinsAlpha® 0,5 µg Kapseln	not available	912.02.00	LEO PHARMA GMBH	DE
EinsAlpha® 1 µg Kapseln	not available	912.00.00	LEO PHARMA GMBH	DE
EinsAlpha® 2 µg/ml Injektionslösung	not available	24399.00.00	LEO PHARMA GMBH	DE
EinsAlpha® 2 µg/ml Injektionslösung	not available	24399.01.00	LEO PHARMA GMBH	DE
EinsAlpha® 2 µg/ml Tropfen	not available	42729.00.00	LEO PHARMA GMBH	DE
ETALPHA , 2 µg/ml, solução para perfusão	not available	4189080	LEO PHARMA A/S	PT
ETALPHA , 2 µg/ml, solução para perfusão	not available	4188983	LEO PHARMA A/S	PT
Etalpha „LEO“ 0,25 µg-Kapseln	not available	1-19669	LEO PHARMA GESELLSCHAFT M.B.H.	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
Etalpha „LEO“ 1 µg-Kapseln	not available	1-19671	LEO PHARMA GESELLSCHAFT M.B.H.	AT
Etalpha „LEO“ 1 µg-Ampullen	not available	1-20154	LEO PHARMA GESELLSCHAFT M.B.H.	AT
Etalpha „LEO“ 2 µg-Ampullen	not available	1-20155	LEO PHARMA GESELLSCHAFT M.B.H.	AT
Etalpha 0,25 µg cápsulas	not available	8532499	LEO PHARMA A/S	PT
Etalpha 0,25 µg cápsulas	not available	8532408	LEO PHARMA A/S	PT
Etalpha 0,25 µg cápsulas	not available	8532481	LEO PHARMA A/S	PT
Etalpha 0,25 mikrog kapseli, pehmeä	not available	7973	LEO PHARMA A/S	FI
Etalpha 0,25 mikrogram kapsel, myk	not available	6466	LEO PHARMA AS	NO
Etalpha 0,25 mikrogram kapslar, mjuka	not available	7973	LEO PHARMA A/S	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
Etalpha 0,25 mikrogram kapslar, mjuka	not available	9391	LEO PHARMA AB	SE
Etalpha 0,25 míkrógrömm og 1 míkrógramm mjúk hylki	not available	792367 (IS)	LEO PHARMA A/S	IS
Etalpha 0,5 mikrog kapseli, pehmeä	not available	13240	LEO PHARMA A/S	FI
Etalpha 0,5 mikrogram kapsel, myk	not available	97-3611	LEO PHARMA AS	NO
Etalpha 0,5 mikrogram kapslar, mjuka	not available	13240	LEO PHARMA A/S	FI
Etalpha 0,5 mikrogram kapslar, mjuka	not available	13971	LEO PHARMA AB	SE
Etalpha 0,5 µg cápsulas	not available	3256385	LEO PHARMA A/S	PT
Etalpha 1 microgramo solución inyectable	not available	61.022	LEO PHARMA A/S	ES
Etalpha 1 míkrógramm mjúk hylki.	not available	799001	LEO PHARMA A/S	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
Etalpha 1 µg cápsulas	not available	8532416	LEO PHARMA A/S	PT
Etalpha 1 µg cápsulas	not available	8532473	LEO PHARMA A/S	PT
Etalpha 1 µg cápsulas	not available	8532465	LEO PHARMA A/S	PT
Etalpha 2 microgramos solución inyectable	not available	61.023	LEO PHARMA A/S	ES
Etalpha 2 microgramos/ml gotas orales en solución	not available	55.906	LABORATORIOS LEO PHARMA, S.A.	ES
Etalpha 2 mikrogram/ml dråper, oppløsning	not available	97-4690	LEO PHARMA AS	NO
Etalpha 2 mikrogram/ml injektionsvätska, lösning	not available	11367	LEO PHARMA AB	SE
Etalpha 2 mikrogram/ml orala droppar, lösning	not available	14055	LEO PHARMA AB	SE
Etalpha i.v. 2 microgram/ml oplossing voor injectie	NL/H/1929/001	RVG 14698	LEO PHARMA BV	NL

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
Etalpha LEO 0,25 microgram capsule, zacht	NL/H/1928/001	RVG 08318	LEO PHARMA BV	NL
Etalpha LEO 0,5 microgram capsule, zacht	NL/H/1928/002	RVG 22263	LEO PHARMA BV	NL
Etalpha LEO 1 microgram capsule, zacht	NL/H/1928/003	RVG 07603	LEO PHARMA BV	NL
Etalpha LEO 2 microgram/ml druppels voor oraal gebruik, oplossing	not available	RVG 09284	LEO PHARMA BV	NL
Etalpha, injektionsvæske, opløsning	not available	13467	LEO PHARMA A/S	DK
Etalpha, kapsler, bløde	not available	19078	LEO PHARMA A/S	DK
Etalpha, kapsler, bløde	not available	09200	LEO PHARMA A/S	DK
Etalpha, kapsler, bløde	not available	09751	LEO PHARMA A/S	DK
Etalpha, orale dråber, opløsning	not available	12080	LEO PHARMA A/S	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
One-Alpha 0.25 micrograms soft capsules	not available	PA 46/24/2	LEO LABORATORIES LIMITED	IE
One-Alpha 0.5 microgram soft capsules	not available	PL 00043/0206	LEO LABORATORIES LTD	UK
One-Alpha 1 microgram soft capsules	not available	PA 46/24/1	LEO LABORATORIES LIMITED	IE
One-Alpha 2 microgram/ml injection	not available	PL 00043/0183	LEO LABORATORIES LTD	UK
One-Alpha 2 microgram/ml oral drops	not available	PL 00043/0207	LEO LABORATORIES LTD	UK
One-Alpha 2 micrograms/ml oral drops	not available	PA 46/24/9	LEO LABORATORIES LIMITED	IE
One-Alpha Capsules 0.25 microgram.	not available	MA024/00701	LEO PHARMA A/S	MT
One-Alpha* 0.25 microgram soft capsules	not available	PL 00043/0052	LEO LABORATORIES LTD	UK
One-Alpha* 1 microgram soft capsules	not available	PL 00043/0050	LEO LABORATORIES LTD	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
One-Alpha® 1 mcg καψάκιο μαλακό	not available	8766	LEO PHARMA A/S	CY
One-Alpha®/LEO 0,25 mcg, καψάκιο μαλακό	not available	98915/17/30-04-2018	LEO PHARMACEUTICAL HELLAS S.A.	GR
One-Alpha®/LEO 0,50 mcg, καψάκιο μαλακό	not available	10940/15-02-2018	LEO PHARMACEUTICAL HELLAS S.A.	GR
One-Alpha®/LEO 0,5ml ή 1 ml Ενέσιμο διάλυμα	not available	24802/16/11-1-2018	LEO PHARMACEUTICAL HELLAS S.A.	GR
One-Alpha®/LEO 0,5ml ή 1 ml Ενέσιμο διάλυμα	not available	2291/11-1-2018	LEO PHARMACEUTICAL HELLAS S.A.	GR
One-Alpha®/LEO 1 mcg καψάκιο μαλακό	not available	4312/17/15-02-2018	LEO PHARMACEUTICAL HELLAS S.A.	GR
One-Alpha®/LEO 2 mcg/ml πόσιμες σταγόνες, διάλυμα	not available	35890/16/14-02-2018	LEO PHARMACEUTICAL HELLAS S.A.	GR
OSTIDIL D3 0,25 microgrammi capsule molli	not available	032936015	S.F. GROUP SRL	IT
OSTIDIL D3 1 microgrammo capsule molli	not available	032936027	S.F. GROUP SRL	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
UN-ALFA 0,10 microgramme, solution buvable en gouttes	not available	34009 554 217 7 1	LABORATOIRES LEO	FR
UN-ALFA 0,10 microgramme, solution buvable en gouttes	not available	34009 326 084-2 3	LABORATOIRES LEO	FR
UN-ALFA 0,10 microgramme, solution buvable en gouttes	not available	34009 326 084-2 3	LABORATOIRES LEO	FR
UN-ALFA 0,25 microgramme, capsule orale	not available	34009 348 414 5 3	LABORATOIRES LEO	FR
UN-ALFA 0,25 microgramme, capsule orale	not available	34009 323 242 6 2	LABORATOIRES LEO	FR
UN-ALFA 0,50 microgramme, capsule molle	not available	34009 347 618-6 7	LABORATOIRES LEO	FR
UN-ALFA 0,50 microgramme, capsule molle	not available	34009 347 619-2 8	LABORATOIRES LEO	FR
UN-ALFA 0,50 microgramme, capsule molle	not available	34009 347 616-3 8	LABORATOIRES LEO	FR
UN-ALFA 1 microgramme, capsule orale	not available	34009 348 415 1 4	LABORATOIRES LEO	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
UN-ALFA 1 µg/0,5 ml, solution injectable IV en ampoule	not available	34009 557 299 4 5	LABORATOIRES LEO	FR
UN-ALFA 2 µg/1 ml, solution injectable IV en ampoule	not available	34009 557 298 8 4	LABORATOIRES LEO	FR