



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 February 2026
EMADOC-1700519818-2913530
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): alfacalcidol

EURD list No. PSUSA/00000080/202506

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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| Product full name (in authorisation country as per Art. 57 data) | MRP/DCP or CP Authorisation number (if not available then insert not available) | National Authorisation Number of product in the member state | MAH of product in the member state | Member State where product is authorised |
|--|---|---|---|---|
| Etalpa 0,25 µg-Kapseln | not available | 1-19669 | CHEPLAPHARM ARZNEIMITTEL GMBH | AT |
| Etalpa 1 µg-Ampullen | not available | 1-20154 | CHEPLAPHARM ARZNEIMITTEL GMBH | AT |
| Etalpa 1 µg-Kapseln | not available | 1-19671 | CHEPLAPHARM ARZNEIMITTEL GMBH | AT |
| Etalpa 2 µg-Ampullen | not available | 1-20155 | CHEPLAPHARM ARZNEIMITTEL GMBH | AT |
| Etalpa 0,25 microgram zachte capsules | not available | BE118456 | CHEPLAPHARM ARZNEIMITTEL GMBH | BE |
| Etalpa 0,25 microgram zachte capsules | not available | BE118456 | CHEPLAPHARM ARZNEIMITTEL GMBH | BE |

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|---|---------------|----------|-------------------------------------|----|
| Etalpa 0,25 microgramme capsules molles | not available | BE118456 | CHEPLAPHARM ARZNEIMITTEL GMBH | BE |
| Etalpa 0,25 microgramme capsules molles | not available | BE118456 | CHEPLAPHARM ARZNEIMITTEL GMBH | BE |
| Etalpa 0,25 Mikrogramm Weichkapseln | not available | BE118456 | CHEPLAPHARM ARZNEIMITTEL GMBH | BE |
| Etalpa 0,25 Mikrogramm Weichkapseln | not available | BE118456 | CHEPLAPHARM ARZNEIMITTEL GMBH | BE |
| Etalpa 1 microgram zachte capsules | not available | BE233834 | CHEPLAPHARM ARZNEIMITTEL GMBH | BE |
| Etalpa 1 microgram zachte capsules | not available | BE233834 | CHEPLAPHARM ARZNEIMITTEL GMBH | BE |
| Etalpa 1 microgram zachte capsules | not available | BE233834 | CHEPLAPHARM ARZNEIMITTEL GMBH | BE |

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|---|---------------|----------|-------------------------------------|----|
| Etalpa 1 microgram/0,5 ml oplossing voor injectie | not available | BE164595 | CHEPLAPHARM ARZNEIMITTEL GMBH | BE |
| Etalpa 1 microgramme capsules molles | not available | BE233834 | CHEPLAPHARM ARZNEIMITTEL GMBH | BE |
| Etalpa 1 microgramme capsules molles | not available | BE233834 | CHEPLAPHARM ARZNEIMITTEL GMBH | BE |
| Etalpa 1 microgramme capsules molles | not available | BE233834 | CHEPLAPHARM ARZNEIMITTEL GMBH | BE |
| Etalpa 1 microgramme/0,5 ml solution injectable | not available | BE164595 | CHEPLAPHARM ARZNEIMITTEL GMBH | BE |
| Etalpa 1 Mikrogramm Weichkapseln | not available | BE233834 | CHEPLAPHARM ARZNEIMITTEL GMBH | BE |
| Etalpa 1 Mikrogramm Weichkapseln | not available | BE233834 | CHEPLAPHARM ARZNEIMITTEL GMBH | BE |

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|--|---------------|----------|-------------------------------|----|
| Etalpa 1 Mikrogramm Weichkapseln | not available | BE233834 | CHEPLAPHARM ARZNEIMITTEL GMBH | BE |
| Etalpa 1 Mikrogramm/0,5 ml Injektionslösung | not available | BE164595 | CHEPLAPHARM ARZNEIMITTEL GMBH | BE |
| Etalpa 1 Mikrogramm/0,5 ml Injektionslösung | not available | BE164595 | CHEPLAPHARM ARZNEIMITTEL GMBH | BE |
| Etalpa 2 microgram/ml druppels voor oraal gebruik, oplossing | not available | BE159187 | CHEPLAPHARM ARZNEIMITTEL GMBH | BE |
| Etalpa 2 microgrammes/ml solution buvable en gouttes | not available | BE159187 | CHEPLAPHARM ARZNEIMITTEL GMBH | BE |
| Etalpa 2 Mikrogramm/ml Tropfen zum Einnehmen, Lösung | not available | BE159187 | CHEPLAPHARM ARZNEIMITTEL GMBH | BE |

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|---------------------------------------|---------------|-------------|-------------------------------------|----|
| One-Alpha® 1 mcg καψάκιο μαλακό | not available | 8766 | CHEPLAPHARM ARZNEIMITTEL GMBH | CY |
| EinsAlpha 2 µg/ml Injektionslösung | not available | 24399.00.00 | CHEPLAPHARM ARZNEIMITTEL GMBH | DE |
| EinsAlpha 2 µg/ml Injektionslösung | not available | 24399.01.00 | CHEPLAPHARM ARZNEIMITTEL GMBH | DE |
| EinsAlpha® 0,25 µg Kapseln | not available | 912.01.00 | CHEPLAPHARM ARZNEIMITTEL GMBH | DE |
| EinsAlpha® 0,5 µg Kapseln | not available | 912.02.00 | CHEPLAPHARM ARZNEIMITTEL GMBH | DE |
| EinsAlpha® 1 µg Kapseln | not available | 912.00.00 | CHEPLAPHARM ARZNEIMITTEL GMBH | DE |
| EinsAlpha® 2 µg/ml Tropfen | not available | 42729.00.00 | CHEPLAPHARM ARZNEIMITTEL GMBH | DE |

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|--|---------------|--------|-------------------------------------|----|
| Etalpha, bløde kapsler | not available | 09751 | CHEPLAPHARM ARZNEIMITTEL GMBH | DK |
| Etalpha, bløde kapsler | not available | 19078 | CHEPLAPHARM ARZNEIMITTEL GMBH | DK |
| Etalpha, bløde kapsler | not available | 09200 | CHEPLAPHARM ARZNEIMITTEL GMBH | DK |
| Etalpha, injektionsvæske, opløsning | not available | 13467 | CHEPLAPHARM ARZNEIMITTEL GMBH | DK |
| Etalpha, orale dråber, opløsning | not available | 12080 | CHEPLAPHARM ARZNEIMITTEL GMBH | DK |
| Etalpha 1 microgramo solución inyectable | not available | 61.022 | CHEPLAPHARM ARZNEIMITTEL GMBH | ES |
| Etalpha 2 microgramos solución inyectable | not available | 61.023 | CHEPLAPHARM ARZNEIMITTEL GMBH | ES |

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|--|---------------|--------|-------------------------------------|----|
| Etalpa 2 microgramos/ml gotas orales en solución | not available | 55.906 | CHEPLAPHARM ARZNEIMITTEL GMBH | ES |
| Etalpa 0,25 mikrog kapseli, pehmeä | not available | 7973 | CHEPLAPHARM ARZNEIMITTEL GMBH | FI |
| Etalpa 0,25 mikrog kapseli, pehmeä | not available | 7973 | CHEPLAPHARM ARZNEIMITTEL GMBH | FI |
| Etalpa 0,25 mikrogram kapslar, mjuka | not available | 7973 | CHEPLAPHARM ARZNEIMITTEL GMBH | FI |
| Etalpa 0,25 mikrogram kapslar, mjuka | not available | 7973 | CHEPLAPHARM ARZNEIMITTEL GMBH | FI |
| Etalpa 0,5 mikrog kapseli, pehmeä | not available | 13240 | CHEPLAPHARM ARZNEIMITTEL GMBH | FI |
| Etalpa 0,5 mikrog kapseli, pehmeä | not available | 13240 | CHEPLAPHARM ARZNEIMITTEL GMBH | FI |

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| Etalpa 0,5 mikrog kapseli, pehmeä | not available | 13240 | CHEPLAPHARM ARZNEIMITTEL GMBH | FI |
| Etalpa 0,5 mikrogram kapslar, mjuka | not available | 13240 | CHEPLAPHARM ARZNEIMITTEL GMBH | FI |
| Etalpa 0,5 mikrogram kapslar, mjuka | not available | 13240 | CHEPLAPHARM ARZNEIMITTEL GMBH | FI |
| Etalpa 0,5 mikrogram kapslar, mjuka | not available | 13240 | CHEPLAPHARM ARZNEIMITTEL GMBH | FI |
| UN-ALFA 0,10 microgramme, solution buvable en gouttes. | not available | 34009 326 084 2 3 | CHEPLAPHARM ARZNEIMITTEL GMBH | FR |
| UN-ALFA 0,10 microgramme, solution buvable en gouttes. | not available | 34009 554 217 7 1 | CHEPLAPHARM ARZNEIMITTEL GMBH | FR |
| UN-ALFA 0,25 microgramme, capsule orale | not available | 34009 323 242 6 2 | CHEPLAPHARM ARZNEIMITTEL GMBH | FR |

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| UN-ALFA 0,25 microgramme, capsule orale | not available | 34009 348 414 5 3 | CHEPLAPHARM ARZNEIMITTEL GMBH | FR |
| UN-ALFA 0,50 microgramme, capsule molle | not available | 34009 347 616 3 8 | CHEPLAPHARM ARZNEIMITTEL GMBH | FR |
| UN-ALFA 0,50 microgramme, capsule molle | not available | 34009 347 618 6 7 | CHEPLAPHARM ARZNEIMITTEL GMBH | FR |
| UN-ALFA 0,50 microgramme, capsule molle | not available | 34009 347 619 2 8 | CHEPLAPHARM ARZNEIMITTEL GMBH | FR |
| UN-ALFA 1 microgramme, capsule orale | not available | 34009 323 243 2 3 | CHEPLAPHARM ARZNEIMITTEL GMBH | FR |
| UN-ALFA 1 microgramme, capsule orale | not available | 34009 348 415 1 4 | CHEPLAPHARM ARZNEIMITTEL GMBH | FR |
| UN-ALFA 1 microgramme/0,5 ml, solution injectable IV en ampoule | not available | 34009 557 299 4 5 | CHEPLAPHARM ARZNEIMITTEL GMBH | FR |

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| UN-ALFA 2 microgrammes/1 ml, solution injectable IV en ampoule | not available | 34009 557 298 8 4 | CHEPLAPHARM ARZNEIMITTEL GMBH | FR |
| One-Alpha® 0,25 mcg καψάκιο μαλακό | not available | 64745/26-10-2021 | CHEPLAPHARM ARZNEIMITTEL GMBH | GR |
| One-Alpha® 0,50 mcg καψάκιο μαλακό | not available | 101122/26-10-2021 | CHEPLAPHARM ARZNEIMITTEL GMBH | GR |
| One-Alpha® 0,5ml Ενέσιμο διάλυμα | not available | 101121/26-10-2021 | CHEPLAPHARM ARZNEIMITTEL GMBH | GR |
| One-Alpha® 1 mcg καψάκιο μαλακό | not available | 99029/26-10-2021 | CHEPLAPHARM ARZNEIMITTEL GMBH | GR |
| One-Alpha® 1ml Ενέσιμο διάλυμα | not available | 101120/26-10-2021 | CHEPLAPHARM ARZNEIMITTEL GMBH | GR |
| One-Alpha 0.25 microgram soft capsules | not available | PA2239/017/002 | CHEPLAPHARM ARZNEIMITTEL GMBH | IE |

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|--|---------------|----------------|-------------------------------------|----|
| One-Alpha 1 microgram soft capsules | not available | PA2239/017/001 | CHEPLAPHARM ARZNEIMITTEL GMBH | IE |
| One-Alpha 2 micrograms/ml oral drops | not available | PA2239/017/003 | CHEPLAPHARM ARZNEIMITTEL GMBH | IE |
| Etalpa 0,25 míkrógrömm mjúk hylki | not available | 792367 | CHEPLAPHARM ARZNEIMITTEL GMBH | IS |
| Etalpa 1 míkrógramm mjúk hylki | not available | 799001 | CHEPLAPHARM ARZNEIMITTEL GMBH | IS |
| DEDIOL 0,25 mcg capsule molli | not available | 025487024 | CHEPLAPHARM ARZNEIMITTEL GMBH | IT |
| DEDIOL 2 mcg/ml gocce orali, soluzione | not available | 025487036 | CHEPLAPHARM ARZNEIMITTEL GMBH | IT |

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|---|---------------|------------------|---------------|----|
| Alfacalcidol Zentiva 0,25 mikrogramo minkštosios kapsulės | not available | LT/1/97/3477/006 | ZENTIVA, K.S. | LT |
| Alfacalcidol Zentiva 0,25 mikrogramo minkštosios kapsulės | not available | LT/1/97/3477/001 | ZENTIVA, K.S. | LT |
| Alfacalcidol Zentiva 0,25 mikrogramo minkštosios kapsulės | not available | LT/1/97/3477/002 | ZENTIVA, K.S. | LT |
| Alfacalcidol Zentiva 1 mikrogramas minkštosios kapsulės | not available | LT/1/97/3477/003 | ZENTIVA, K.S. | LT |
| Alfacalcidol Zentiva 1 mikrogramas minkštosios kapsulės | not available | LT/1/97/3477/007 | ZENTIVA, K.S. | LT |

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|---|---------------|------------------|-------------------------------------|----|
| Alfacalcidol Zentiva 1 mikrogramas minkštosios kapsulės | not available | LT/1/97/3477/004 | ZENTIVA, K.S. | LT |
| Alfacalcidol Zentiva 1 mikrogramas minkštosios kapsulės | not available | LT/1/97/3477/005 | ZENTIVA, K.S. | LT |
| Etalpa 0,25 microgramme capsules molles | not available | 2008099003 | CHEPLAPHARM ARZNEIMITTEL GMBH | LU |
| Etalpa 0,25 microgramme capsules molles | not available | 2008099003 | CHEPLAPHARM ARZNEIMITTEL GMBH | LU |
| Etalpa 0,25 Mikrogramm Weichkapseln | not available | 2008099003 | CHEPLAPHARM ARZNEIMITTEL GMBH | LU |
| Etalpa 0,25 Mikrogramm Weichkapseln | not available | 2008099003 | CHEPLAPHARM ARZNEIMITTEL GMBH | LU |

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|--|---------------|------------|-------------------------------------|----|
| Etalpha 1 microgramme capsules molles | not available | 2008099004 | CHEPLAPHARM ARZNEIMITTEL GMBH | LU |
| Etalpha 1 microgramme capsules molles | not available | 2008099004 | CHEPLAPHARM ARZNEIMITTEL GMBH | LU |
| Etalpha 1 microgramme capsules molles | not available | 2008099004 | CHEPLAPHARM ARZNEIMITTEL GMBH | LU |
| Etalpha 1 microgramme/0,5 ml solution injectable | not available | 2008099006 | CHEPLAPHARM ARZNEIMITTEL GMBH | LU |
| Etalpha 1 Mikrogramm Weichkapseln | not available | 2008099004 | CHEPLAPHARM ARZNEIMITTEL GMBH | LU |
| Etalpha 1 Mikrogramm Weichkapseln | not available | 2008099004 | CHEPLAPHARM ARZNEIMITTEL GMBH | LU |
| Etalpha 1 Mikrogramm Weichkapseln | not available | 2008099004 | CHEPLAPHARM ARZNEIMITTEL GMBH | LU |

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| Etalpa 1 Mikrogramm/0,5 ml Injektionslösung | not available | 2008099006 | CHEPLAPHARM ARZNEIMITTEL GMBH | LU |
| Etalpa 2 microgrammes/ml solution buvable en gouttes | not available | 2008090005 | CHEPLAPHARM ARZNEIMITTEL GMBH | LU |
| Etalpa 2 Mikrogramm/ml Tropfen zum Einnehmen, Lösung | not available | 2008090005 | CHEPLAPHARM ARZNEIMITTEL GMBH | LU |
| One-Alpha 1 microgram soft capsules | not available | MA1456/00202 | CHEPLAPHARM ARZNEIMITTEL GMBH | MT |
| One-Alpha Capsules 0.25 microgram | not available | MA1456/00201 | CHEPLAPHARM ARZNEIMITTEL GMBH | MT |
| Etalpa 0,25 microgram zachte capsules | NL/H/1928/001 | RVG 08318 | CHEPLAPHARM ARZNEIMITTEL GMBH | NL |
| Etalpa 0,5 microgram zachte capsules | NL/H/1928/002 | RVG 22263 | CHEPLAPHARM ARZNEIMITTEL GMBH | NL |

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|---|---------------|-----------|-------------------------------------|----|
| Etalpa 1 microgram zachte capsules | NL/H/1928/003 | RVG 07603 | CHEPLAPHARM ARZNEIMITTEL GMBH | NL |
| Etalpa 2 microgram/ml druppels voor oraal gebruik, oplossing | not available | RVG 09284 | CHEPLAPHARM ARZNEIMITTEL GMBH | NL |
| Etalpa i.v. 2 microgram/ml, oplossing voor injectie | NL/H/1929/001 | RVG 14698 | CHEPLAPHARM ARZNEIMITTEL GMBH | NL |
| Etalpa 0,25 mikrogram kapsel, myk | not available | 6466 | CHEPLAPHARM ARZNEIMITTEL GMBH | NO |
| Etalpa 0,5 mikrogram kapsel, myk | not available | 97-3611 | CHEPLAPHARM ARZNEIMITTEL GMBH | NO |
| Etalpa 2 mikrogram/ml dråper, oppløsning | not available | 97-4690 | CHEPLAPHARM ARZNEIMITTEL GMBH | NO |
| Etalpa 0,25 microgramas cápsulas | not available | 8532408 | CHEPLAPHARM ARZNEIMITTEL GMBH | PT |

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| Etalpa 0,25 microgramas cápsulas | not available | 8532499 | CHEPLAPHARM ARZNEIMITTEL GMBH | PT |
| Etalpa 0,25 microgramas cápsulas | not available | 8532481 | CHEPLAPHARM ARZNEIMITTEL GMBH | PT |
| Etalpa 0,5 microgramas cápsulas | not available | 3256385 | CHEPLAPHARM ARZNEIMITTEL GMBH | PT |
| Etalpa 1 micrograma cápsulas | not available | 8532473 | CHEPLAPHARM ARZNEIMITTEL GMBH | PT |
| Etalpa 1 micrograma cápsulas | not available | 8532465 | CHEPLAPHARM ARZNEIMITTEL GMBH | PT |
| Etalpa 1 micrograma cápsulas | not available | 8532416 | CHEPLAPHARM ARZNEIMITTEL GMBH | PT |
| Etalpa, 2 µg/ml, solução para perfusão | not available | 4189080 | CHEPLAPHARM ARZNEIMITTEL GMBH | PT |

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|--|---------------|--------------|-------------------------------------|----|
| Etalpa, 2 µg/ml, solução para perfusão | not available | 4188983 | CHEPLAPHARM ARZNEIMITTEL GMBH | PT |
| One-Alpha 2 micrograme/ml soluție injectabilă | NL/H/1929/001 | 8595/2016/02 | CHEPLAPHARM ARZNEIMITTEL GMBH | RO |
| One-Alpha 2 micrograme/ml soluție injectabilă | NL/H/1929/001 | 8595/2016/01 | CHEPLAPHARM ARZNEIMITTEL GMBH | RO |
| Etalpa 0,25 mikrogram kapslar, mjuka | not available | 9391 | CHEPLAPHARM ARZNEIMITTEL GMBH | SE |
| Etalpa 0,5 mikrogram kapslar, mjuka | not available | 13971 | CHEPLAPHARM ARZNEIMITTEL GMBH | SE |
| Etalpa 2 mikrogram/ml injektionsvätska, lösning | not available | 11367 | CHEPLAPHARM ARZNEIMITTEL GMBH | SE |
| Etalpa 2 mikrogram/ml orala droppar, lösning | not available | 14055 | CHEPLAPHARM ARZNEIMITTEL GMBH | SE |

