



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 September 2018
EMA/735443/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: aldesleukin

Procedure no.: PSUSA/00000076/201712



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
Proleukin® 18 Millionen IE Pulver zur Herstellung einer Injektions- oder Infusionslösung	NL/H/0005/001	BE150823	NOVARTIS PHARMA N.V.	BE
Proleukin 18 x 10 ⁶ UI, Poudre pour solution injectable ou pour perfusion	NL/H/0005/001	2000025656	NOVARTIS PHARMA N.V.	LU
Proleukin® 18 Millionen IE Pulver zur Herstellung einer Injektions- oder Infusionslösung Aldesleukin	NL/H/0005/001	2000025656	NOVARTIS PHARMA N.V.	LU
PROLEUKIN® 18 X 10 ⁶ IU Κόνις για ενέσιμο διάλυμα ή διάλυμα προς έγχυση	NL/H/0005/001	204400201	NOVARTIS (HELLAS) S.A.C.I.	GR
PROLEUKIN® 18 X 10 ⁶ IU Κόνις για ενέσιμο διάλυμα ή διάλυμα προς έγχυση	NL/H/0005/001	204400202	NOVARTIS (HELLAS) S.A.C.I.	GR
Proleukin 18 X 10 ⁶ UI Polvere per soluzione iniettabile o per infusione	NL/H/0005/001	027131010	NOVARTIS FARMA S.P.A.	IT
PROLEUKIN 18000000 UI Pó para solução injectável ou para perfusão	NL/H/0005/001	3974987	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
PROLEUKIN 18000000 UI Pó para solução injectável ou para perfusão	NL/H/0005/001	3975083	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Proleukin, pulver til injektions- og infusionsvæske, opløsning	NL/H/0005/001	13282	NOVARTIS HEALTHCARE A/S	DK
Proleukin 18 x 10 ⁶ IU injektio- tai infuusiokuiva-aine, liuosta varten	NL/H/0005/001	10757	NOVARTIS FINLAND OY	FI
Proleukin® 18 milj. IU pulver till injektions- eller infusionsvätska, lösning	NL/H/0005/001	10757	NOVARTIS FINLAND OY	FI
PROLEUKIN 18 x 10 ⁶ UI polvo para solución para perfusión intrevenosa	NL/H/0005/001	58.653	NOVARTIS FARMACÉUTICA S.A.	ES
PROLEUKIN 18 x 10 ⁶ UI polvo para solución inyectable	NL/H/0005/001	62.287	NOVARTIS FARMACÉUTICA S.A.	ES

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Proleukin 18 x 10 ⁶ NE por oldatos injekcióhoz vagy oldatos infúzióhoz	not available	OGYI-T-4172/01	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
Proleukin 18 x 10 ⁶ IE Poeder voor oplossing voor injectie of infusie	NL/H/0005/001	RVG 13354	NOVARTIS PHARMA B.V.	NL
PROLEUKIN® S 18 X 10 ⁶ IE Pulver zur Herstellung einer Injektionslösung oder Infusionslösung	NL/H/0005/001	17152.00.00	NOVARTIS PHARMA GMBH	DE
Proleukin 18 X 10 ⁶ IE, Poeder voor oplossing voor injectie of infusie	NL/H/0005/001	BE150823	NOVARTIS PHARMA N.V.	BE
PROLEUKIN 18 millions U.I., poudre pour solution pour perfusion	NL/H/0005/001	34009 562 155 7 7	NOVARTIS PHARMA S.A.S.	FR
PROLEUKIN 18 millions U.I., poudre pour solution pour perfusion	NL/H/0005/001	34009 562 156 3 8	NOVARTIS PHARMA S.A.S.	FR
PROLEUKIN 18 millions U.I., poudre pour solution injectable	NL/H/0005/002	34009 562 158 6 7	NOVARTIS PHARMA S.A.S.	FR
PROLEUKIN 18 millions U.I., poudre pour solution injectable	NL/H/0005/002	34009 562 159 2 8	NOVARTIS PHARMA S.A.S.	FR
Proleukin 18 x 10 ⁶ IE - Pulver zur Herstellung einer Injektions- oder Infusionslösung	NL/H/0005/001	1-22475	NOVARTIS PHARMA GMBH	AT
PROLEUKIN® 18 x 10 ⁶ IU Powder for solution for injection or infusion	NL/H/0005/001	PL 00101/0936	NOVARTIS PHARMACEUTICALS UK LIMITED	UK
Proleukin 18 X 10 ⁶ UI Poudre pour solution injectable ou pour perfusion	NL/H/0005/001	BE150823	NOVARTIS PHARMA N.V.	BE
PROLEUKIN 18 x 10 ⁶ a.e. Stungulyfs-/innrennsstofn, lausn	NL/H/0005/001	IS/1/13/058/01	NOVARTIS HEALTHCARE A/S	IS