



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 February 2023
EMA/66152/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): Apis mellifera (801) (with or without adjuvant), Apis mellifera venom

Procedure No. PSUSA/00010722/202207



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
ALUTARD SQ Bienengift 100.000 SQ-E/ml Injektionssuspension (Fortsetzungsbehandlung)	SE/H/1637/001	238173	ALK-ABELLO A/S	AT
ALUTARD SQ Bienengift Injektionssuspension (Anfangsbehandlung) (100 SQ E/ml, 1.000 SQ E/ml, 10.000 SQ E/ml und 100.000 SQ E/ml)	SE/H/1637/002	238174	ALK-ABELLO A/S	AT
Alutard SQ Bee 100 000 SQ-U/ml Injektionssuspension	SE/H/1637/001	BE521973	ALK-ABELLO A/S	BE
Alutard SQ Bee 100 000 SQ-U/ml, suspensie voor injectie	SE/H/1637/001	BE521973	ALK-ABELLO A/S	BE
Alutard SQ Bee 100 000 SQ-U/ml, suspension injectable	SE/H/1637/001	BE521973	ALK-ABELLO A/S	BE
Alutard SQ Bee Starter Pack 100 + 1000 + 10 000 + 100 000 SQ-U/ml Injektionssuspension	SE/H/1637/002	BE521982	ALK-ABELLO A/S	BE
Alutard SQ Bee Starter Pack 100 + 1000 + 10 000 + 100 000 SQ-U/ml, suspensie voor injectie	SE/H/1637/002	BE521982	ALK-ABELLO A/S	BE
Alutard SQ Bee Starter Pack 100 + 1000 + 10 000 + 100 000 SQ-U/ml, suspension injectable	SE/H/1637/002	BE521982	ALK-ABELLO A/S	BE
Pharmalgen® Bee, 120 microgram, poeder en oplosmiddel voor oplossing voor injectie.	not available	BE 125991	ALK-ABELLO BV	BE

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
Pharmalgen® Bee, 120 microgrammes, poudre et solvant pour solution injectable	not available	BE 125991	ALK-ABELLO BV	BE
Alutard SQ hmyzí alergený injekční suspenze	not available	59/526/92-B/C	ALK-ABELLO A/S	CZ
Alutard SQ hmyzí alergený injekční suspenze	not available	59/526/92-B/C	ALK-ABELLO A/S	CZ
Soluprick SQ kožní roztok	not available	59/500/92-S/C	ALK-ABELLO A/S	CZ
Soluprick SQ kožní roztok	not available	59/500/92-S/C	ALK-ABELLO A/S	CZ
ALK-depot SQ® 801 Bienengift, 100, 1.000, 10.000 und 100.000 SQ-E/ml, Injektionssuspension zur subkutanen Anwendung	not available	112A/91A-D	ALK-ABELLO ARZNEIMITTEL GMBH	DE
ALK-depot SQ® 801 Bienengift, 100.000 SQ-E/ml, Injektionssuspension zur subkutanen Anwendung	not available	112A/91D	ALK-ABELLO ARZNEIMITTEL GMBH	DE
ALK-lyophilisiert SQ® 801 Bienengift , 100.000 SQ-Einheiten/ml (100 Mikrogramm/ml), Pulver und Lösungsmittel zur Herstellung einer Injektions- und Hauttestlösung	not available	62A/82E	ALK-ABELLO ARZNEIMITTEL GMBH	DE
ALK-prick SQ Insektengifte - 801 Bienengift - 1 µg/ml - Lösung für den Pricktest	not available	222A/85D	ALK-ABELLO ARZNEIMITTEL GMBH	DE

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ALK-prick SQ Insektengifte - 801 Bienengift - 10 µg/ml - Lösung für den Pricktest	not available	222A/85C	ALK-ABELLÓ ARZNEIMITTEL GMBH	DE
ALK-prick SQ Insektengifte - 801 Bienengift - 100 µg/ml - Lösung für den Pricktest	not available	222A/85B	ALK-ABELLÓ ARZNEIMITTEL GMBH	DE
ALK-prick SQ Insektengifte - 801 Bienengift - 300 µg/ml - Lösung für den Pricktest	not available	222A/85A	ALK-ABELLÓ ARZNEIMITTEL GMBH	DE
Reless®-Bienengift Allergengehalt: 100 Mikrogramm/ml Pulver und Lösungsmittel zur Herstellung einer Injektions- und Hauttestlösung	not available	208A/89A	ALK-ABELLÓ ARZNEIMITTEL GMBH	DE
Reless®-Bienengift Allergengehalt: 100 Mikrogramm/ml Pulver und Lösungsmittel zur Herstellung einer Injektions- und Hauttestlösung	not available	208A/89	ALK-ABELLÓ ARZNEIMITTEL GMBH	DE
Venomil® Biene Diagnostikpackung: 120 Mikrogramm, Einleitungstherapie: 550 Mikrogramm, Erhaltungstherapie: 120 Mikrogramm; Pulver und Lösungsmittel zur Herstellung einer Injektionslösung und Pricktestlösung	not available	120A/80	BENCARD ALLERGIE GMBH	DE

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
Venomil® Biene Erhaltungstherapie: 120 Mikrogramm; Pulver und Lösungsmittel zur Herstellung einer Injektionslösung - Fertigspritze	not available	120A/80	BENCARD ALLERGIE GMBH	DE
ALK 801 Bigift Apis mellifera Opløsning til priktest (Soluprick SQ) Venomallergen	not available	12656	ALK-ABELLO A/S	DK
ALK 801 Bigift Apis mellifera, Opløsning til priktest (Soluprick SQ) Venomallergen	not available	12655	ALK-ABELLO A/S	DK
ALK 801 Bigift, Apis mellifera, Injektionsvæske, suspension, s.c. (Alutard SQ), Initial- og vedligeholdelsespakning, Venomallergen	not available	12492	ALK-ABELLO A/S	DK
ALK 801 Bigift, Apis mellifera, Injektionsvæske, suspension, s.c. (Alutard SQ), Initial- og vedligeholdelsespakning, Venomallergen	not available	12491	ALK-ABELLO A/S	DK
ALK 801 Bigift, Apis mellifera, Pulver og solvens til injektionsvæske, opløsning (Aquagen SQ), Vedligeholdelsespakning, Venomallergen	not available	12493	ALK-ABELLO A/S	DK

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Pharmalgen Bi Pulver og solvens til injektionsvæske, opløsning	not available	10283	ALK-ABELLO A/S	DK
Alutard SQ Apis mellifera, 100 000 SQ-U/ml suspensi3n inyactable	SE/H/1637/001	82857	ALK-ABELLO A/S	ES
Alutard SQ Apis mellifera, envase de inicio (100 SQ-U/ml, 1 000 SQ-U/ml, 10 000 SQ-U/ml y 100 000 SQ-U/ml), suspensi3n inyactable	SE/H/1637/002	82856	ALK-ABELLO A/S	ES
ALUTARD SQ hy3nteismyrkyt, injektioneste, suspensio - 801 Mehil3isen myrkky (Apis mellifera)	not available	10407	ALK-ABELLO A/S	FI
ALUTARD SQ hy3nteismyrkyt, injektioneste, suspensio - 801 Mehil3isen myrkky (Apis mellifera)	not available	10407	ALK-ABELLO A/S	FI
SOLUPRICK® SQ hy3nteismyrkyt, liuos ihopistotestiin - 801 Mehil3isen myrkky (Apis mellifera)	not available	10310	ALK-ABELLO A/S	FI
SOLUPRICK® SQ hy3nteismyrkyt, liuos ihopistotestiin - 801 Mehil3isen myrkky (Apis mellifera)	not available	10310	ALK-ABELLO 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
SOLUPRICK® SQ hyönteismyrkyt, liuos ihopistotestiin - 801 Mehiläisen myrkky (Apis mellifera)	not available	10310	ALK-ABELLO A/S	FI
ALBEY VENIN D'ABEILLE Apis mellifera 120 microgrammes, poudre et solvant pour solution injectable	not available	3400932855698	STALLERGENES	FR
ALBEY VENIN D'ABEILLE Apis mellifera 120 microgrammes, poudre et solvant pour solution injectable	not available	3400932855759	STALLERGENES	FR
ALBEY VENIN D'ABEILLE Apis mellifera 120 microgrammes, poudre et solvant pour solution injectable	not available	3400935966483	STALLERGENES	FR
ALBEY VENIN D'ABEILLE Apis mellifera 550 microgrammes, poudre et solvant pour solution injectable	not available	3400932707058	STALLERGENES	FR
ALBEY VENIN D'ABEILLE Apis mellifera 550 microgrammes, poudre et solvant pour solution injectable	not available	3400932707119	STALLERGENES	FR
ALBEY VENIN D'ABEILLE Apis mellifera 550 microgrammes, poudre et solvant pour solution injectable	not available	3400932707348	STALLERGENES	FR

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ALUTARD VENIN D'ABEILLE APIS MELLIFERA 100 000 SQ-U/mL, suspension injectable	SE/H/1637/001	34009 301 746 0 9	ALK-ABELLO A/S	FR
ALUTARD VENIN D'ABEILLE APIS MELLIFERA kit d'initiation (100 SQ-U/mL, 1 000 SQ-U/mL, 10 000 SQ-U/mL et 100 000 SQ-U/mL), suspension injectable	SE/H/1637/002	34009 301 746 2 3	ALK-ABELLO A/S	FR
ALYOSTAL VENIN D'ABEILLE APIS MELLIFERA 110 microgrammes, poudre et solvant pour solution injectable	not available	3400933282677	STALLERGENES	FR
ALYOSTAL VENIN D'ABEILLE APIS MELLIFERA 110 microgrammes, poudre et solvant pour solution injectable	not available	3400933282677	STALLERGENES	FR
ALYOSTAL VENIN D'ABEILLE APIS MELLIFERA 550 microgrammes, poudre et solvant pour solution injectable.	not available	332 829-6 / 3400933282967	STALLERGENES	FR
ALYOSTAL VENIN D'ABEILLE APIS MELLIFERA 550 microgrammes, poudre et solvant pour solution injectable.	not available	332 829-6 / 3400933282967	STALLERGENES	FR

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Alutard SQ Méh 100 000 SQ U/ml szuszpenziós injekció	SE/H/1637/001	OGYI-T-23334/02	ALK-ABELLO A/S	HU
Alutard SQ Méh dózisbeállító csomag (100 SQ U/ml, 1000 SQ U/ml, 10 000 SQ U/ml és 100 000 SQ U/ml) szuszpenziós injekció	SE/H/1637/002	OGYI-T-23334/01	ALK-ABELLO A/S	HU
ALUTARD SQ Bee 100 000 SQ-U/ml suspension for injection	SE/H/1637/001	PA1255/008/001	ALK-ABELLO A/S	IE
ALUTARD SQ Bee Initial Pack (100 SQ-U/ml, 1 000 SQ-U/ml, 10 000 SQ-U/ml and 100 000 SQ-U/ml) suspension for injection	SE/H/1637/002	PA 1255/008/002	ALK-ABELLO A/S	IE
ALUTARD Apis mellifera 100 SQ-U/ml, 1.000 SQ-U/ml, 10.000 SQ-U/ml e 100.000 SQ-U/ml, sospensione iniettabile Confezione di inizio	SE/H/1637/002	045902020	ALK-ABELLO A/S	IT
ALUTARD Apis mellifera 100.000 SQ-U/ml, sospensione iniettabile	SE/H/1637/001	045902018	ALK-ABELLO A/S	IT
Alutard SQ Bee 100 000 SQ-U/ml, Injektionssuspension	SE/H/1637/001	2018060146	ALK-ABELLO A/S	LU
Alutard SQ Bee 100 000 SQ-U/ml, suspension injectable	SE/H/1637/001	2018060146	ALK-ABELLO A/S	LU
Alutard SQ Bee Starter Pack 100 + 1000 + 10 000 + 100 000 SQ-U/ml, Injektionssuspension	SE/H/1637/002	2018060145	ALK-ABELLO A/S	LU

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
Alutard SQ Bee Starter Pack 100 + 1000 + 10 000 + 100 000 SQ-U/ml, suspension injectable	SE/H/1637/002	2018060145	ALK-ABELLO A/S	LU
Alutard SQ Bijengif 100.000 SQ-E/ml, suspensie voor injectie	not available	RVG 121480	ALK-ABELLO BV	NL
Alutard SQ Bijengif 100-100.000 SQ-E/ml, suspensie voor injectie	not available	RVG 121479	ALK-ABELLO BV	NL
Pharmalgen Bijengif 120 microgram, poeder en oplosmiddel voor oplossing voor injectie	not available	RVG 121483	ALK-ABELLO BV	NL
Soluprick SQ Bijengif 10, 100 en 300 microgram/ml, oplossing voor huidpriktest	not available	RVG 127678	ALK-ABELLO BV	NL
Alutard SQ Bigift 100 000 SQ-U/ml injeksjonsvæske, suspensjon	SE/H/1637/001	17-11864	ALK-ABELLO A/S	NO
Alutard SQ Bigift startpakning (100 SQ-U/ml, 1000 SQ-U/ml, 10 000 SQ-U/ml, 100 000 SQ-U/ml) injeksjonsvæske, suspensjon	SE/H/1637/002	17-11863	ALK-ABELLO A/S	NO
ALUTARD SQ Wyciagi alergenowe jądów owadów blonkoskrzydłych (osy i pszczoły) Zawiesina do wstrzykiwań Leczenie podtrzymujące: 100 000 SQ-U/ml	not available	R/ 3595	ALK-ABELLO A/S	PL

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
ALUTARD SQ Wyciągi alergenowe jadów owadów błonkoskrzydłych (osy i pszczoły) zawiesina do wstrzykiwań Leczenie podstawowe: 100 SQ-U/ml, 1000 SQ-U/ml, 10 000 SQ-U/ml, 100 000 SQ-U/ml	not available	R/ 3595	ALK-ABELLO A/S	PL
Pharmalgen Hymenoptera venoms Wyciągi alergenowe jadów owadów błonkoskrzydłych (osy, pszczoły) Proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwań	not available	R/0104	ALK-ABELLO A/S	PL
Alutard SQ Apis mellifera, 100 000 SQ-U/ml suspensão injetável	SE/H/1637/001	5753462	ALK-ABELLO A/S	PT
Alutard SQ Apis mellifera, embalagem para tratamento inicial (100 SQ-U/ml, 1 000 SQ-U/ml, 10 000 SQ-U/ml e 100 000 SQ-U/ml), suspensão injetável	SE/H/1637/002	5753454	ALK-ABELLO A/S	PT
Alutard SQ venin de albină 100000 SQ-U/ml suspensie injectabilă	SE/H/1637/001	13237/2020/01	ALK-ABELLO A/S	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
Alutard SQ venin de albina cutie pentru initierea si cresterea dozei (100 SQ-U/ml, 1000 SQ-U/ml, 10000 SQ-U/ml si 100000 SQ-U/ml) suspensie injectabila	SE/H/1637/002	13238/2020/01	ALK-ABELLO A/S	RO
Alutard SQ Bigift, 100 000 SQ-E/ml injektionsvätska suspension	SE/H/1637/001	90155	ALK-ABELLO A/S	SE
Alutard SQ Bigift, Styrkeserie (100 SQ-E/ml, 1 000 SQ-E/ml, 10 000 SQ-E/ml och 100 000 SQ-E/ml), injektionsvätska suspension	SE/H/1637/002	90156	ALK-ABELLO A/S	SE
Aquagen SQ Bigift, 100 000 SQ-E/ml, pulver och vätska till injektionsvätska, lösning	not available	90157	ALK-ABELLO A/S	SE
Soluprick SQ Bigift, lösning för pricktest	not available	90159	ALK-ABELLO A/S	SE
Soluprick SQ Bigift, lösning för pricktest	not available	90160	ALK-ABELLO A/S	SE
Cebelji strup Alutard SQ 100 000 SQ-U/ml suspenzija za injiciranje	SE/H/1637/001	H/18/02441/002	ALK-ABELLO A/S	SI
Čebelji strup Alutard SQ suspenzija za injiciranje (začetno pakiranje)	SE/H/1637/002	H/18/02441/001	ALK-ABELLO A/S	SI
Alutard SQ jedy hmyzu injekčná suspenzia	not available	59/0111/16-S	ALK-ABELLO A/S	SK
Alutard SQ jedy hmyzu injekčná suspenzia	not available	59/0111/16-S	ALK-ABELLO A/S	SK

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
Soluprick Injekčný roztok na kožný prick test	not available	59/0500/92-S	ALK-ABELLO A/S	SK
Soluprick Injekčný roztok na kožný prick test	not available	59/0500/92-S	ALK-ABELLO A/S	SK
Soluprick Injekčný roztok na kožný prick test	not available	59/0500/92-S	ALK-ABELLO A/S	SK
ALUTARD SQ Bee 100 000 SQ U/ml, suspension for injection.	SE/H/1637/001	PL 10085/0054	ALK-ABELLO A/S	XI
ALUTARD SQ Bee Initial Pack (100 SQ U/ml, 1 000 SQ U/ml, 10 000 SQ U/ml and 100 000 SQ U/ml), suspension for injection.	SE/H/1637/002	PL 10085/0055	ALK-ABELLO A/S	XI