



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 January 2019
EMA/47773/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: pelargonium sidoides dc and/or pelargonium reniforme
curt. / radix

Procedure no.: PSUSA/00002329/201806



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
Pelargonium Granulat Schwabe 20 mg / 800 mg Granulat	not available	95998.00.00	DR. WILLMAR SCHWABE GMBH & CO. KG	DE
EPc-Liquidum Flüssigkeit Für Erwachsene und Kinder ab 1 Jahr	not available	65144.00.00	DR. WILLMAR SCHWABE GMBH & CO. KG	DE
Umckaloabo Saft für Kinder	not available	70150.00.00	ISO-ARZNEIMITTEL GMBH & CO. KG	DE
KALOBÄ 20 mg / 7,5 ml sirup	not available	94/143/15-C	DR. WILLMAR SCHWABE GMBH & CO. KG	CZ
BELIVAIR RHUME PELARGONIUM comprimé pelliculé	AT/H/0585/001	3400930031377	THERABEL LUCIEN PHARMA S.A.	FR
BELIVAIR RHUME PELARGONIUM comprimé pelliculé	AT/H/0585/001	3400930031384	THERABEL LUCIEN PHARMA S.A.	FR
BELIVAIR RHUME PELARGONIUM comprimé pelliculé	AT/H/0585/001	3400930031391	THERABEL LUCIEN PHARMA S.A.	FR
BELIVAIR PELARGONIUM comprimés pelliculés	AT/H/0585/001	BE-TU477137	THERABEL PHARMA S.A.	BE
BELIVAIR PELARGONIUM filmomhulde tabletten	AT/H/0585/001	BE-TU477137	THERABEL PHARMA S.A.	BE
Belivair Pelargonium Filmtabletten	AT/H/0585/001	736432	THERABEL PHARMA N.V.	AT
BELIVAIR PELARGONIUM Filmtabletten	AT/H/0585/001	BE-TU477137	THERABEL PHARMA S.A.	BE
Pelargonium DIREKT 20 mg / 800 mg Granulat	not available	95997.00.00	DR. WILLMAR SCHWABE GMBH & CO. KG	DE
Pelargonium-Schwabe Bronchialsaft für Kinder	not available	70151.00.00	DR. WILLMAR SCHWABE GMBH & CO. KG	DE

Umckaloabo 20 mg Filmtabletten	not available	67993.00.00	ISO-ARZNEIMITTEL GMBH & CO. KG	DE
DiaCold Tablets	not available	THR 42340/0017	DIAPHARM GMBH & CO. KG	UK
EPb-Liquidum Flüssigkeit Für Erwachsene und Kinder ab 1 Jahr	not available	65143.00.00	DR. WILLMAR SCHWABE GMBH & CO. KG	DE
Kaloba 20 mg potahované tablety	not available	94/137/15-C	DR. WILLMAR SCHWABE GMBH & CO. KG	CZ
PELARGONIUM ZENTIVA ERKÄLTUNGSLÖSUNG	not available	81733.00.00	ZENTIVA PHARMA GMBH	DE
PELARGONIUM ZENTIVA ERKÄLTUNGSLÖSUNG	not available	81733.00.00	ZENTIVA PHARMA GMBH	DE
PELARGONIUM ZENTIVA ERKÄLTUNGSLÖSUNG	not available	81733.00.00	ZENTIVA PHARMA GMBH	DE
PELARGONIUM ZENTIVA ERKÄLTUNGSLÖSUNG	not available	81733.00.00	ZENTIVA PHARMA GMBH	DE
BELIVAIR RHUME PELARGONIUM comprimé pelliculé	AT/H/0585/001	3400930031377	THERABEL LUCIEN PHARMA S.A.	FR
BELIVAIR RHUME PELARGONIUM comprimé pelliculé	AT/H/0585/001	3400930031384	THERABEL LUCIEN PHARMA S.A.	FR
BELIVAIR RHUME PELARGONIUM comprimé pelliculé	AT/H/0585/001	3400930031391	THERABEL LUCIEN PHARMA S.A.	FR
BELIVAIR PELARGONIUM comprimés pelliculés	AT/H/0585/001	BE-TU477137	THERABEL PHARMA S.A.	BE
BELIVAIR PELARGONIUM filmomhulde tabletten	AT/H/0585/001	BE-TU477137	THERABEL PHARMA S.A.	BE
Belivair Pelargonium Filmtabletten	AT/H/0585/001	736432	THERABEL PHARMA N.V.	AT

BELIVAIR PELARGONIUM Filmtabletten	AT/H/0585/001	BE-TU477137	THERABEL PHARMA S.A.	BE
DiaGonium Filmtabletten	not available	80530.00.00	CASSELLA-MED GMBH & CO. KG	DE
JUANOLCOLD RESFRIADOS Extracto seco de raíz de Pelargonium sidoides	not available	80.945	ANGELINI FARMACEUTICA, S.A.	ES
DiaPelargo Tablets	not available	THR 42340/0018	DIAPHARM GMBH & CO. KG	UK
Pelargonium Beutel Schwabe 20 mg / 800 mg Granulat	not available	95999.00.00	DR. WILLMAR SCHWABE GMBH & CO. KG	DE
DiaPelargo Filmtabletten	not available	HERB-00048	DIAPHARM GMBH & CO. KG	AT
DiaPelargo filmtabletta	not available	OGYI-TN-39/01	DIAPHARM GMBH & CO. KG	HU
DiaPelargo filmtabletta	not available	OGYI-TN-39/02	DIAPHARM GMBH & CO. KG	HU
DiaPelargo filmtabletta	not available	OGYI-TN-39/03	DIAPHARM GMBH & CO. KG	HU
DiaPelargo filmtabletta	not available	OGYI-TN-39/04	DIAPHARM GMBH & CO. KG	HU
DiaPelargo filmtabletta	not available	OGYI-TN-39/05	DIAPHARM GMBH & CO. KG	HU
PELARGONIUM COOPER, comprimé pelliculé	not available	EP00188-34009 301 282 3 7	COOPERATION PHARMACEUTIQUE FRANCAISE	FR
Kaloba - Tropfen zum Einnehmen	not available	HERB-00004	DR. WILLMAR SCHWABE GMBH & CO. KG	AT
Kaloba - Sirup	not available	736628	DR. WILLMAR SCHWABE GMBH & CO. KG	AT
Kaloba 20 mg Filmtabletten	not available	HERB-00011	DR. WILLMAR SCHWABE GMBH & CO. KG	AT
Kaloba 20 mg compresse rivestite con film	not available	038135012	DR. WILLMAR SCHWABE GMBH & CO. KG	IT

KALOPA 20 mg comprimido revestido por película	not available	5662606	DR. WILLMAR SCHWABE GMBH & CO. KG	PT
KALOPA 20 mg comprimido revestido por película	not available	5662614	DR. WILLMAR SCHWABE GMBH & CO. KG	PT
KALOPA 20 mg comprimido revestido por película	not available	5662572	DR. WILLMAR SCHWABE GMBH & CO. KG	PT
KALOPA 20 mg, comprimé pelliculé	not available	34009 300 075 3 2	DR. WILLMAR SCHWABE GMBH & CO. KG	FR
KALOPA 20 mg, comprimé pelliculé	not available	34009 300 075 4 9	DR. WILLMAR SCHWABE GMBH & CO. KG	FR
Kaloba 20 mg / 7,5 ml sciroppo	not available	038135075	DR. WILLMAR SCHWABE GMBH & CO. KG	IT
Kaloba 8 g / 9,75 ml gotas orais, solução	not available	5662549	DR. WILLMAR SCHWABE GMBH & CO. KG	PT
Kaloba 8 g / 9,75 ml gotas orais, solução	not available	5662556	DR. WILLMAR SCHWABE GMBH & CO. KG	PT
Kaloba 8 g / 9,75 ml gotas orais, solução	not available	5662564	DR. WILLMAR SCHWABE GMBH & CO. KG	PT
Kaloba 8g / 9,75 ml gocce orali, soluzione	not available	038135048	DR. WILLMAR SCHWABE GMBH & CO. KG	IT
Kaloba belsóleges oldatos cseppek	not available	OGYI-TN-1 / 01	DR. WILLMAR SCHWABE GMBH & CO. KG	HU
Kaloba belsóleges oldatos cseppek	not available	OGYI-TN-1 / 02	DR. WILLMAR SCHWABE GMBH & CO. KG	HU
KALOPA® comprimidos recubiertos con película Extracto de Pelargonium sidoides	not available	71.732	DR. WILLMAR SCHWABE GMBH & CO. KG	ES
Kaloba Pelargonium Cough & Cold Relief oral drops, solution	not available	THR 05332 / 0003	DR. WILLMAR SCHWABE GMBH & CO. KG	UK
Kaloba Pelargonium Cough & Cold Relief syrup	not available	THR 05332 / 0006	DR. WILLMAR SCHWABE GMBH & CO. KG	UK
Kaloba Pelargonium Cough & Cold Relief	not available	THR 05332 / 0006	DR. WILLMAR SCHWABE GMBH & CO. KG	UK

syrup				
Kaloba Pelargonium Cough & Cold Relief tablets	not available	THR 05332/0005	DR. WILLMAR SCHWABE GMBH & CO. KG	UK
Kaloba®, tablet	not available	RVG 100735	DR. WILLMAR SCHWABE GMBH & CO. KG	NL
Kaloba®, druppels voor oraal gebruik, oplossing	not available	RVG 34174	DR. WILLMAR SCHWABE GMBH & CO. KG	NL
KALOBA, solution buvable	not available	34009 300 074 8 8	DR. WILLMAR SCHWABE GMBH & CO. KG	FR
KALOBA, solution buvable	not available	34009 300 075 0 1	DR. WILLMAR SCHWABE GMBH & CO. KG	FR
KALOBA, solution buvable	not available	34009 300 074 9 5	DR. WILLMAR SCHWABE GMBH & CO. KG	FR
KALOBA® gotas orales Extracto de Pelargonium sidoides	not available	71.733	DR. WILLMAR SCHWABE GMBH & CO. KG	ES
Kaloban® druppels voor oraal gebruik, oplossing	not available	BE-TU356386	DR. WILLMAR SCHWABE GMBH & CO. KG	BE
Kaloban® filmomhulde tabletten	not available	BE-TU356404	DR. WILLMAR SCHWABE GMBH & CO. KG	BE
Kaloban® siroop	not available	BE-TU356395	DR. WILLMAR SCHWABE GMBH & CO. KG	BE
Umckalor 20 mg filmom obložene tablete	not available	UP/I-530-09/12-01/557	DR. WILLMAR SCHWABE GMBH & CO. KG	HR
Umckalor oralne kapi, otopina	not available	UP/I-530-09/12-01/556	DR. WILLMAR SCHWABE GMBH & CO. KG	HR
KALOBA 20 mg comprimido revestido por película	not available	5662630	DR. WILLMAR SCHWABE GMBH & CO. KG	PT
KALOBA 20 mg comprimido revestido por película	not available	5662622	DR. WILLMAR SCHWABE GMBH & CO. KG	PT
KALOBA 20 mg, comprimé pelliculé	not available	34009 300 076 0 0	DR. WILLMAR SCHWABE GMBH & CO. KG	FR

KALوبا 20 mg, comprimé pelliculé	not available	34009 300 075 9 4	DR. WILLMAR SCHWABE GMBH & CO. KG	FR
KALوبا 20 mg, comprimé pelliculé	not available	34009 300 075 8 7	DR. WILLMAR SCHWABE GMBH & CO. KG	FR
KALوبا 20 mg, comprimé pelliculé	not available	34009 300 075 7 0	DR. WILLMAR SCHWABE GMBH & CO. KG	FR
KALوبا 20 mg, comprimé pelliculé	not available	34009 300 075 5 6	DR. WILLMAR SCHWABE GMBH & CO. KG	FR
KALوبا 20 mg, comprimé pelliculé	not available	34009 300 075 2 5	DR. WILLMAR SCHWABE GMBH & CO. KG	FR
KALوبا 20 mg, comprimé pelliculé	not available	34009 300 075 1 8	DR. WILLMAR SCHWABE GMBH & CO. KG	FR
Peloide Tropfen	not available	HERB-00046	PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH	AT
Peloid belsőleges cseppek	not available	OGYI-TN-09/01	PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH	HU
Peloid belsőleges cseppek	not available	OGYI-TN-09/02	PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH	HU
Peloid belsőleges cseppek	not available	OGYI-TN-09/03	PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH	HU
DiaTussal Filmtabletten	not available	HERB-00047	PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH	AT
Peloide Tropfen	not available	HERB-00046	PHARMASELECT HANDELS GMBH	AT
Pelargonium	not available	67995.00.00	DR. WILLMAR SCHWABE GMBH & CO. KG	DE
Erkältungstropfen- Pelargonie	not available	81632.00.00	CASELLA-MED GMBH & CO. KG	DE
Pelafen, 20 mg, tabletki powlekane	not available	22988	PHYTOPHARM KŁĘKA SA	PL
ACTIVOX PELARGONIUM RHUME, solution buvable	not available	34009 300 161 3 8	ARKOPHARMA, S.A.	FR

Umckaloabo® 8 g/10 g Flüssigkeit Für Erwachsene und Kinder ab 1 Jahr	not available	6189629.00.00	ISO-ARZNEIMITTEL GMBH & CO. KG	DE
KALOPA 20 mg filmom obalené tablety	not available	94/0367/17-S	DR. WILLMAR SCHWABE GMBH & CO. KG	SK
EPd-Liquidum Flüssigkeit Für Erwachsene und Kinder ab 1 Jahr	not available	65145.00.00	DR. WILLMAR SCHWABE GMBH & CO. KG	DE
EPe-Liquidum Flüssigkeit Für Erwachsene und Kinder ab 1 Jahr	not available	65146.00.00	DR. WILLMAR SCHWABE GMBH & CO. KG	DE
Pelargonium-Schwabe	not available	67994.00.00	DR. WILLMAR SCHWABE GMBH & CO. KG	DE
Pelargonium- ratiopharm® Bronchialtropfen Flüssigkeit Für Erwachsene und Kinder ab 1 Jahr	not available	65142.00.00	BIOPLANTA ARZNEIMITTEL GMBH	DE
Умкатор 20 мг, филмирани таблетки	not available	20140148	DR. WILLMAR SCHWABE GMBH & CO. KG	BG
KALOPA perorálne kvapky	not available	94/0493/07-S	DR. WILLMAR SCHWABE GMBH & CO. KG	SK
Kaloba Perorální kapky, roztok	not available	94/098/08-C	DR. WILLMAR SCHWABE GMBH & CO. KG	CZ
Umckalor geriamieji lašai, tirpalas	not available	LT/1/97/1806	DEUTSCHE HOMÖOPATHIE-UNION DHU-ARZNEIMITTEL GMBH & CO. KG	LT
Умкатор капки перорални, разтвор	not available	20060755	DR. WILLMAR SCHWABE GMBH & CO. KG	BG
UMCKALOR pilieni iekšķīgai lietošanai, šķīdums	not available	00-0808	DEUTSCHE HOMÖOPATHIE-UNION DHU-ARZNEIMITTEL GMBH & CO. KG	LV

Umckalor 20 mg plèvele dengtos tabletės	not available	LT/1/97/1806/003	DEUTSCHE HOMÖOPATHIE-UNION DHU-ARZNEIMITTEL GMBH & CO. KG	LT
Umckalor 20 mg plèvele dengtos tabletės	not available	LT/1/97/1806/004	DEUTSCHE HOMÖOPATHIE-UNION DHU-ARZNEIMITTEL GMBH & CO. KG	LT
Umckalor 20 mg plèvele dengtos tabletės	not available	LT/1/97/1806/005	DEUTSCHE HOMÖOPATHIE-UNION DHU-ARZNEIMITTEL GMBH & CO. KG	LT
Umckalor 20 mg plèvele dengtos tabletės	not available	LT/1/97/1806/006	DEUTSCHE HOMÖOPATHIE-UNION DHU-ARZNEIMITTEL GMBH & CO. KG	LT
Pelargonium Sirup	not available	70149.00.00	DR. WILLMAR SCHWABE GMBH & CO. KG	DE
Kaloba sirup	not available	94/0396/17-S	DR. WILLMAR SCHWABE GMBH & CO. KG	SK

APPENDIX

DIVERGENT POSITION DATED 17 January 2019

DIVERGENT POSITION DATED 17 January 2019

Pelargonium sidoides dc and/or pelargonium reniforme curt. / radix
PSUSA/00002329/201806

The undersigned members of PRAC did not agree with the PRAC's opinion recommending that the terms of the Marketing Authorisation(s) should be maintained for the medicinal products containing the above referred active substance(s).

The reasons for divergent opinion were as follows:

Products manufactured from Pelargonium radix have been reported to exert toxic liver effects. Cases have been assessed to have at least a possible causal association to the product. The data presented in the current PSUSA procedure includes reports on serious liver reactions. Several companies state that the liver toxicity is an important identified risk. The safety information has been updated during the period to include warnings on liver toxicity symptoms. However, we are of the opinion that it does not exclude a clinically relevant risk to the patient, as symptoms usually occur at a stage of the liver disease when liver damage may be irreversible. Regular liver testing is not feasible as in Europe the products are marketed with OTC-status, which will make early detection of liver damage impossible.

Pelargonium radix is approved as a herbal medicine purely based on historical use. Although no new information is presented on the efficacy data in this PSUSA procedure, we are of the opinion that the proposed indication, i.e. symptomatic treatment of common cold, is a self-limiting, not a life-threatening disease, thus, any risk of severe adverse reactions is not regarded acceptable. Therefore, the benefit to risk ratio is deemed negative.

In view of the above considerations the delegates listed below consider the benefit risk of this PSUSA to be negative:

B. Grundmark

D. Bennee Olsen

M. Uuskula

K. Villikka