



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 September 2022
EMA/709939/2022
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): octenidine dihydrochloride / phenoxyethanol

Procedure No. PSUSA/00002199/202201



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
octenisept-Lösung zur Wund- und Schleimhautdesinfektion	not available	1-20402	SCHÜLKE & MAYR GESMBH	AT
Linoseptic 1 mg/g + 10 mg/g Gel	DE/H/3491/002	136065	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	AT
Linoseptic 1 mg/g + 20 mg/g Spray zur Anwendung auf der Haut, Lösung	DE/H/3491/001/DC	136066	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	AT
Linoseptic 1 mg/g + 20 mg/g Spray zur Anwendung auf der Haut, Lösung	DE/H/3491/001/DC	136066	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	AT
ΟΚΤΕΚΕΪΡ 1 mg/ml + 20 mg/ml σπρέι για το δέρμα, διάλυμα	PL/H/0401/001	20170004	BAUSCH HEALTH IRELAND LIMITED	BG
Octiset, κολλικό διάλυμα	not available	022084	T.C.CHRISTOFOROU LTD.	CY
Octiset Προϊόν συνδυασμού: 0,1 g διυδροχλωρικής οκτενιδίνης/2,0 g φαينوξαιθανόλης ανά 100 g Δερματικό διάλυμα	not available	022083	T.C.CHRISTOFOROU LTD.	CY
Octenisept Kožní roztok	not available	32/558/08-C	SCHÜLKE & MAYR GMBH	CZ
Octenisept 1 mg/g + 20 mg/g kožní sprej, roztok	not available	32/462/12-C	SCHÜLKE & MAYR GMBH	CZ
Linoseptic 1 mg/g + 10 mg/g Gel	DE/H/3491/002	32/401/14-C	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	CZ
Linoseptic 1 mg/g + 20 mg/g Kožní sprej, roztok	DE/H/3491/001/DC	32/402/14-C	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	CZ
Linoseptic 1 mg/g + 20 mg/g Kožní sprej, roztok	DE/H/3491/001/DC	32/402/14-C	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	CZ
Octicide 1 mg/g + 20 mg/g kožní sprej, roztok	CZ/H/0883/001	32/077/19-C	NEOFYT SPOL. S R.O.	CZ
Wolffisept 1 mg/g + 20 mg/g Spray zur Anwendung auf der Haut, Lösung	not available	95060.00.00	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	DE
Ophenic 1 mg/ml + 20 mg/ml Spray zur Anwendung auf der Haut, Lösung	DE/H/3849/001	89796.00.00	SCHÜLKE & MAYR GMBH	DE

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Ophenic 1 mg/ml + 20 mg/ml Spray zur Anwendung auf der Haut, Lösung	not available	7001089.00.00	SCHÜLKE & MAYR GMBH	DE
Ophenic 1 mg/ml + 20 mg/ml Spray zur Anwendung auf der Haut, Lösung	not available	7001092.00.00	SCHÜLKE & MAYR GMBH	DE
OCTENISEPT® WUND-DESINFEKTION	not available	46428.00.00	SCHÜLKE & MAYR GMBH	DE
octenisept® liquid	not available	46425.00.00	SCHÜLKE & MAYR GMBH	DE
Septi-Wolff 1 mg/g + 10 mg/g Gel	not available	95063.00.00	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	DE
OCTENISEPT® ANTISEPTIKUM VOR KATHETERISIERUNG DER HARNBLASE	not available	46433.00.00	SCHÜLKE & MAYR GMBH	DE
Ophenic 1 mg/ml + 20 mg/ml Spray zur Anwendung auf der Haut, Lösung	not available	7001091.00.00	SCHÜLKE & MAYR GMBH	DE
Ophenic 1 mg/ml + 20 mg/ml Spray zur Anwendung auf der Haut, Lösung	not available	7001177.00.00	SCHÜLKE & MAYR GMBH	DE
octenisept®	not available	32834.00.00	SCHÜLKE & MAYR GMBH	DE
Octenisept® WD Lösung zur Anwendung auf der Haut	not available	63739.00.00	SCHÜLKE & MAYR GMBH	DE
Linola sept Wundgel mit Octenidin und Phenoxyethanol 1 mg/g + 10 mg/g Gel	DE/H/3491/002	86409.00.00	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	DE
Linola sept Wundspray mit Octenidin und Phenoxyethanol 1 mg/g + 20 mg/g Spray zur Anwendung auf der Haut, Lösung	DE/H/3491/001	86408.00.00	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	DE
Wolffisept 1 mg/g + 10 mg/g Gel	not available	95061.00.00	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	DE
octenisept® farblos	not available	46427.00.00	SCHÜLKE & MAYR GMBH	DE
Septi-Wolff 1 mg/g + 20 mg/g Spray zur Anwendung auf der Haut, Lösung	not available	95062.00.00	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	DE
Ophenic 1 mg/ml + 20 mg/ml Spray zur Anwendung auf der	not available	7001178.00.00	SCHÜLKE & MAYR GMBH	DE

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Haut, Lösung				
octenisept® Vaginaltherapeutikum	not available	48447.00.00	SCHÜLKE & MAYR GMBH	DE
octeniphen® Vaginaltherapeutikum	not available	48448.00.00	SCHÜLKE & MAYR GMBH	DE
Linola sept Wundspray mit Octenidin und Phenoxyethanol 1 mg/g + 20 mg/g Spray zur Anwendung auf der Haut, Lösung	DE/H/3491/001	86408.00.00	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	DE
Ophenic 1 mg/ml + 20 mg/ml Spray zur Anwendung auf der Haut, Lösung	not available	7001090.00.00	SCHÜLKE & MAYR GMBH	DE
Octenisept 1 mg/20 mg/ml, nahalahus	not available	882515	SURGITECH AS	EE
Linoseptic 1 mg/10 mg/g geel	DE/H/3491/002	857514	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	EE
Linoseptic 1 mg/20 mg/g Nahasprei, Lahus	DE/H/3491/001/DC	857414	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	EE
Linoseptic 1 mg/20 mg/g Nahasprei, Lahus	DE/H/3491/001/DC	857414	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	EE
Octicide 1 mg/20 mg/g nahasprei, lahus	CZ/H/0883/001	1020221	NEOFYT SPOL. S R.O.	EE
OCTENISEPT 0,1% (w/w) octenidine hydrochloride / 2,0% (w/w) phenoxyethanol	not available	43890/07/12-6-2008	PHARMEX S.A.	GR
Octenisept otopina za sluznicu i kožu	not available	HR-H-068837892-01	SCHÜLKE & MAYR GMBH	HR
Octenisept otopina za sluznicu i kožu	not available	HR-H-068837892-02	SCHÜLKE & MAYR GMBH	HR
Octenisept otopina za sluznicu i kožu	not available	HR-H-068837892-03	SCHÜLKE & MAYR GMBH	HR
Ophenic 1 mg/ml + 20 mg/ml külsóleges oldatos spray	DE/H/3849/001	OGYI-T-22900/01	SCHÜLKE & MAYR GMBH	HU
Ophenic 1 mg/ml + 20 mg/ml külsóleges oldatos spray	DE/H/3849/001	OGYI-T-22900/02	SCHÜLKE & MAYR GMBH	HU
Octenisept 1 mg/ml + 20 mg/ml külsóleges oldat	not available	OGYI-T-22688/01	ALLEGRO KFT	HU
Octenisept 1 mg/ml + 20	not available	OGYI-T-22688/02	ALLEGRO KFT	HU

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mg/ml külsőleges oldat				
Octenisept 1 mg/ml + 20 mg/ml külsőleges oldat	not available	OGYI-T-22688/03	ALLEGRO KFT	HU
Octenisept 1 mg/ml + 20 mg/ml külsőleges oldat	not available	OGYI-T-22688/04	ALLEGRO KFT	HU
Octenisept 1 mg/ml + 20 mg/ml külsőleges oldat	not available	OGYI-T-22688/05	ALLEGRO KFT	HU
Linoseptic 1 mg/g + 10 mg/g Gél	DE/H/3491/002	OGYI-T-22734/03	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	HU
Linoseptic 1 mg/g + 20 mg/g Külsőleges oldatos spray	DE/H/3491/001/DC	OGYI-T-22734/02	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	HU
Linoseptic 1 mg/g + 20 mg/g Külsőleges oldatos spray	DE/H/3491/001/DC	OGYI-T-22734/01	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	HU
Linoseptic 1 mg/g + 20 mg/g Külsőleges oldatos spray	DE/H/3491/001/DC	OGYI-T-22734/02	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	HU
Linoseptic 1 mg/g + 20 mg/g Külsőleges oldatos spray	DE/H/3491/001/DC	OGYI-T-22734/01	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	HU
Linoseptic 1 mg/g + 20 mg/g Külsőleges oldatos spray	DE/H/3491/001/DC	OGYI-T-22734/04	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	HU
Octicide 1 mg/g + 20 mg/g külsőleges oldatos spray	CZ/H/0883/001	OGYI-T-23809/01	NEOFYT SPOL. S R.O.	HU
Octicide 1 mg/g + 20 mg/g külsőleges oldatos spray	CZ/H/0883/001	OGYI-T-23809/02	NEOFYT SPOL. S R.O.	HU
Duoseptic 1 mg/20 mg/ml odos purškalas (tirpalas)	PL/H/0401/001	LT/1/17/4024/001	BAUSCH HEALTH IRELAND LIMITED	LT
Duoseptic 1 mg/20 mg/ml odos purškalas (tirpalas)	PL/H/0401/001	LT/1/17/4024/002	BAUSCH HEALTH IRELAND LIMITED	LT
Linoseptic 1 mg/10 mg/g Gelis	DE/H/3491/002	LT/1/14/3646/001	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	LT
Linoseptic 1 mg/20 mg/g Odos purškalas (tirpalas)	DE/H/3491/001	LT/1/14/3646/003	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	LT
Linoseptic 1 mg/20 mg/g Odos purškalas (tirpalas)	DE/H/3491/001	LT/1/14/3646/002	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	LT
Linoseptic 1 mg/20 mg/g Odos purškalas (tirpalas)	DE/H/3491/001	LT/1/14/3646/003	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	LT
Linoseptic 1 mg/20 mg/g Odos purškalas (tirpalas)	DE/H/3491/001	LT/1/14/3646/002	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	LT
Linoseptic 1 mg/20 mg/g Odos purškalas (tirpalas)	DE/H/3491/001	LT/1/14/3646/004	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	LT

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oktiseptas 1 mg/20 mg/ml odos tirpalas	not available	LT/1/14/3640/001	UAB APITERAPIJA	LT
oktiseptas 1 mg/20 mg/ml odos tirpalas	not available	LT/1/14/3640/002	UAB APITERAPIJA	LT
oktiseptas 1 mg/20 mg/ml odos tirpalas	not available	LT/1/14/3640/003	UAB APITERAPIJA	LT
oktiseptas 1 mg/20 mg/ml odos tirpalas	not available	LT/1/14/3640/004	UAB APITERAPIJA	LT
oktiseptas 1 mg/20 mg/ml odos tirpalas	not available	LT/1/14/3640/005	UAB APITERAPIJA	LT
octenisept®	not available	1997070007	SCHÜLKE & MAYR GMBH	LU
Linoseptic 1 mg/g + 10 mg/g Gels	DE/H/3491/002	14-0256	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	LV
Linoseptic 1 mg/g + 20 mg/g Uz ādas izsmidzināms aerosols, šķīdums	DE/H/3491/001/DC	14-0257	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	LV
octenisept 1mg/20mg/ml uz ādas lietojams šķīdums	not available	15-0171	INTERLUX , SIA	LV
Linoseptic 1 mg/g + 20 mg/g Uz ādas izsmidzināms aerosols, šķīdums	DE/H/3491/001/DC	14-0257	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	LV
OKTASEPTAL, (0,10 g + 2,00 g)/100 g, aerosol na skórę, roztwór	not available	24804	"UNIA" SPÓLDZIELNIA PRACY	PL
OKTASEPTAL, (0,10 g + 2,00 g)/100 g, roztwór na skórę	not available	26290	"UNIA" SPÓLDZIELNIA PRACY	PL
Maxiseptic, 1 mg/ml + 20 mg/ml, roztwór na skórę	PL/H/0403/001	23613	BAUSCH HEALTH IRELAND LIMITED	PL
Septisse, (0,10 g + 2,00 g)/100 g, aerosol na skórę, roztwór	not available	25786	ADAMED PHARMA S.A.	PL
OKTASEPTAL, (0,10 g + 2,00 g)/100 g, aerosol na skórę, roztwór	not available	24804	"UNIA" SPÓLDZIELNIA PRACY	PL
OKTASEPTAL, (0,10 g + 2,00 g)/100 g, roztwór na skórę	not available	26290	"UNIA" SPÓLDZIELNIA PRACY	PL
Maxiseptic, 1 mg/ml + 20 mg/ml, aerosol na skórę, roztwór	PL/H/0401/001	23659	BAUSCH HEALTH IRELAND LIMITED	PL

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Linoseptic	DE/H/3491/002	22639	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	PL
Linoseptic, 1 mg/g + 20 mg/g, aerosol na skóre, roztwór	DE/H/3491/001	22640	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	PL
OKTASEPTAL, (0,10 g + 2,00 g)/100 g, aerosol na skóre, roztwór	not available	24804	"UNIA" SPÓLDZIELNIA PRACY	PL
OKTASEPTAL, (0,10 g + 2,00 g)/100 g, roztwór na skóre	not available	26290	"UNIA" SPÓLDZIELNIA PRACY	PL
Linoseptic, 1 mg/g + 20 mg/g, aerosol na skóre, roztwór	DE/H/3491/001	22640	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	PL
OCTENISEPT (0,10 g + 2,00 g)/100g, plyn	not available	13036	SCHÜLKE & MAYR GMBH	PL
Octiset, 1 mg/ml + 20 mg/ml, Solução cutânea	not available	5282256	BSG PHARMACEUTICALS-PRODUTOS FARMACÊUTICOS INOVADORES, S.A.	PT
Octiset, 1 mg/ml + 20 mg/ml, Solução cutânea	not available	5282207	BSG PHARMACEUTICALS-PRODUTOS FARMACÊUTICOS INOVADORES, S.A.	PT
Octiset, 1 mg/ml + 20 mg/ml, Solução cutânea	not available	5282231	BSG PHARMACEUTICALS-PRODUTOS FARMACÊUTICOS INOVADORES, S.A.	PT
Octiset, 1 mg/ml + 20 mg/ml, Solução cutânea	not available	5282215	BSG PHARMACEUTICALS-PRODUTOS FARMACÊUTICOS INOVADORES, S.A.	PT
Octiset, 1 mg/ml + 20 mg/ml, Solução cutânea	not available	5282249	BSG PHARMACEUTICALS-PRODUTOS FARMACÊUTICOS INOVADORES, S.A.	PT
Octiset, 1 mg/ml + 20 mg/ml, Solução cutânea	not available	5282223	BSG PHARMACEUTICALS-PRODUTOS FARMACÊUTICOS INOVADORES, S.A.	PT
OCTENISEPT 1 mg/ml+20 mg/ml soluție cutanată	not available	13346/2020/01	SCHÜLKE & MAYR GESMBH	RO

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OCTENISEPT 1 mg/ml+20 mg/ml soluție cutanată	not available	13346/2020/02	SCHÜLKE & MAYR GESMBH	RO
OCTENISEPT 1 mg/ml+20 mg/ml soluție cutanată	not available	13346/2020/03	SCHÜLKE & MAYR GESMBH	RO
Octicide 1 mg/g + 20 mg/g spray cutanat, solutie	CZ/H/0883/001	13722/2021/01-02	NEOFYT SPOL. S R.O.	RO
Ofenosept 1 mg/20 mg v 1 ml dermalno pršilo, raztopina	not available	H/16/02241/001	SCHÜLKE & MAYR GMBH	SI
Ofenosept 1 mg/20 mg v 1 ml dermalno pršilo, raztopina	not available	H/16/02241/002	SCHÜLKE & MAYR GMBH	SI
Ofenosept 1 mg/20 mg v 1 ml dermalna raztopina	not available	H/16/02241/003	SCHÜLKE & MAYR GMBH	SI
Ofenosept 1 mg/20 mg v 1 ml dermalna raztopina	not available	H/16/02241/004	SCHÜLKE & MAYR GMBH	SI
Octenisept 1 mg/ml + 20 mg/ml Dermalna roztoková aerodisperzia	DE/H/3849/001/DC	32/0049/16-S	SCHÜLKE & MAYR GMBH	SK
Octicide 1 mg/g + 20 mg/g dermalný roztokový sprej	CZ/H/0883/001	32/0001/21-S	NEOFYT SPOL. S R.O.	SK