



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 September 2017
EMA/706786/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: Octenidine dihydrochloride / phenoxyethanol

Procedure no.: PSUSA/00002199/201701



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
octeniphen® Vaginaltherapeutikum	not available	48448.00.00	SCHÜLKE & MAYR GMBH	DE
octenisept	not available	UP/I-530-09/11-02/86	SCHÜLKE & MAYR GMBH	HR
octenisept	not available	UP/I-530-09/11-02/87	SCHÜLKE & MAYR GMBH	HR
octenisept	not available	UP/I-530-09/11-02/88	SCHÜLKE & MAYR GMBH	HR
Octenisept külsőleges oldat	not available	OGYI-T-22688/01	ALLEGRO KFT	HU
Octenisept külsőleges oldat	not available	OGYI-T-22688/02	ALLEGRO KFT	HU
Octenisept külsőleges oldat	not available	OGYI-T-22688/03	ALLEGRO KFT	HU
Octenisept külsőleges oldat	not available	OGYI-T-22688/04	ALLEGRO KFT	HU
Octenisept külsőleges oldat	not available	OGYI-T-22688/05	ALLEGRO KFT	HU
OCTENISEPT® WUND- DESINFEKTION	not available	46428.00.00	SCHÜLKE & MAYR GMBH	DE
octenisept 1 mg/20 mg/ml, nahalahas	not available	882515	SURGITECH AS	EE
Wolffisept 1 mg/g + 10 mg/g Gel	not available	95061.00.00	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	DE
Octenisept® WD	not available	63739.00.00	SCHÜLKE & MAYR GMBH	DE
Maxiseptic, 1 mg/ml + 20 mg/ml, roztwór na skórę	PL/H/0403/001	23613	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	PL
Octenisept Kožní roztok	not available	32/558/08-C	SCHÜLKE & MAYR GMBH	CZ
OCTENISEPT	not available	43890/07	PHARMEX S.A.	GR

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octenisept-Lösung zur Wund- und Schleimhautdesinfektion	not available	1-20402	SCHÜLKE & MAYR GESMBH	AT
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
Octiset Προϊόν συνδυασμού: 0,1 g διυδροχλωρικής οκτενιδίνης/2,0 g φαινοξαιθανόλης ανά 100 g Δερματικό διάλυμα	not available	022083	T.C.CHRISTOFOROU LTD.	CY
Octiset, κολπικό διάλυμα	not available	022084	T.C.CHRISTOFOROU LTD.	CY
Septi-Wolff 1 mg/g + 20 mg/g Spray	not available	95062.00.00	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	DE
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

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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 (0,10 g + 2,00 g)/100g, plyn	not available	13036	SCHÜLKE & MAYR GMBH	PL
Wolffisept 1 mg/g + 20 mg/g Spray	not available	95060.00.00	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	DE
octenisept®	not available	1997070007	SCHÜLKE & MAYR GMBH	LU
octenisept	not available	4645/2004/01	SCHÜLKE & MAYR GESMBH	RO
OCTENISEPT soluție cutanată	not available	4645/2004/02	SCHÜLKE & MAYR GESMBH	RO
OCTENISEPT soluție cutanată	not available	4645/2004/03	SCHÜLKE & MAYR GESMBH	RO
octenisept® farblös	not available	46427.00.00	SCHÜLKE & MAYR GMBH	DE
Octenisept® 0,1g/100g kožní sprej, roztok	not available	32/462/12-C	SCHÜLKE & MAYR GMBH	CZ

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
ОКТЕКЕЪР 1 mg/ml + 20 mg/ml спрей за кожа, разтвор	PL/H/0401/001	20170004	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	BG
Duoseptic 1 mg/20 mg/ml odos purškalas (tirpalas)	PL/H/0401/001	LT/1/17/4024/001	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LT
Duoseptic 1 mg/20 mg/ml odos purškalas (tirpalas)	PL/H/0401/001	LT/1/17/4024/002	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LT
Maxiseptic, 1 mg/ml + 20 mg/ml, aerosol na skóře, roztwór	PL/H/0401/001	23659	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	PL
Linoseptic 1 mg/g + 10 mg/g Gel	DE/H/3491/002	86409.00.00	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	DE
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/10 mg/g geel	DE/H/3491/002	857514	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	EE
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 + 10 mg/g Gels	DE/H/3491/002	14-0256	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	LV
Linoseptic 1 mg/g + 10 mg/g Gelīs	DE/H/3491/002	LT/1/14/3646/001	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	LT
Linoseptic 1 mg/g + 10 mg/g Gel	DE/H/3491/002	136065	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	AT
Linoseptic	DE/H/3491/002	22639	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	PL
octenisept® Vaginaltherapeutikum	not available	48447.00.00	SCHÜLKE & MAYR GMBH	DE

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octeniphen®	not available	46425.00.00	SCHÜLKE & MAYR GMBH	DE
octenisept 1mg/20mg/ml uz ādas lietojams šķīdums	not available	15-0171	INTERLUX , SIA	LV
Linoseptic 1 mg/g + 20 mg/g Spray zur Anwendung auf der Haut, Lösung	DE/H/3491/001/DC	86408.00.00	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	DE
Linoseptic 1 mg/g + 20 mg/g Kožní sprej, roztok	DE/H/3491/001	32/402/14-C	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	CZ
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/g + 20 mg/g Uz ādas izsmidzināms aerosols, šķīdums	DE/H/3491/001/DC	14-0257	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	LV
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	DE/H/3491/001/DC	22640	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	PL
Linoseptic 1 mg/g + 20 mg/g külsőleges oldatos spray	DE/H/3491/001	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	OGYI-T-22734/01	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	HU
Linoseptic 1 mg/20 mg/g Odos purškalas (tirpalas)	DE/H/3491/001/DC	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/DC	LT/1/14/3646/002	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	LT
Septi-Wolff 1 mg/g + 10 mg/g Gel	not available	95063.00.00	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	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
OCTENISEPT® ANTISEPTIKUM VOR KATHETERISIERUNG DER HARNBLASE	not available	46433.00.00	SCHÜLKE & MAYR GMBH	DE
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
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
Octenisept 1 mg/ml + 20 mg/ml cutaneous spray, solution	DE/H/3849/001	PL 05536/0001	SCHÜLKE & MAYR GMBH	UK
Ophenic 1 mg/ml + 20 mg/ml külsőleges oldatos spray	DE/H/3849/001	OGYI-T-22900/01	SCHÜLKE & MAYR GMBH	HU
Ophenic 1 mg/ml + 20 mg/ml külsőleges oldatos spray	DE/H/3849/001	OGYI-T-22900/02	SCHÜLKE & MAYR GMBH	HU
Ophenic 1 mg/ml + 20 mg/ml kutan spray, lösning	DE/H/3849/001	49126	SCHÜLKE & MAYR GMBH	SE
Octenisept 1 mg/ml + 20 mg/ml Dermálna roztoková aerodisperzia	DE/H/3849/001/DC	32/0049/16-S	SCHÜLKE & MAYR GMBH	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
Оцтенисерт 1 mg/ml + 20 mg/ml спрей за кожа, разтво	DE/H/3849/001	20150367	SCHÜLKE & MAYR GMBH	BG
Octenisept 1 mg/ml + 20 mg/ml spray cutaneo, soluzione	DE/H/3849/001	042703013	SCHÜLKE & MAYR GMBH	IT
Octenisept 1 mg/ml + 20 mg/ml spray cutaneo, soluzione	DE/H/3849/001	042703025	SCHÜLKE & MAYR GMBH	IT
Ophenic 1 mg/ml + 20 mg/ml uz ādas izsmidzināms aerosols, šķīdums	DE/H/3849/001	15-0267	SCHÜLKE & MAYR GMBH	LV
Ophenic, 1 mg/20 mg/ml nahasprei, lahus	DE/H/3849/001	910416	SCHÜLKE & MAYR GMBH	EE
Ophenic 1 mg/20 mg v 1 ml dermalno pršilo, raztopina	DE/H/3849/001	H/16/02181/001	SCHÜLKE & MAYR GMBH	SI
Ophenic 1 mg/20 mg v 1 ml dermalno pršilo, raztopina	DE/H/3849/001	H/16/02181/002	SCHÜLKE & MAYR GMBH	SI
Ophenic 1 mg / 20 mg / ml odos purškalas (tirpalas)	DE/H/3849/001	LT/1/15/3802/001	SCHÜLKE & MAYR GMBH	LT
Ophenic 1 mg / 20 mg / ml odos purškalas (tirpalas)	DE/H/3849/001	LT/1/15/3802/002	SCHÜLKE & MAYR GMBH	LT
octenisept®	not available	32834.00.00	SCHÜLKE & MAYR GMBH	DE