



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

05 September 2019
EMA/493351/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: benzydamine / cetylpyridine

Procedure no.: PSUSA/00000378/201901 PSUSA/00000378/201901

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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
Septolete duo 1,5 mg/5 mg u 1 ml sprej za usnu sluznicu, otopina	CZ/H/0508/001	HR-H-280375292	KRKA-FARMA D.O.O.	HR
Septabene 1.5 mg/ml + 5.0 mg/ml oromucosal spray, solution	CZ/H/0508/001	PA1347/049/001	KRKA, D.D., NOVO MESTO	IE
Septolete extra 1,5 mg/ml + 5 mg/ml orálna roztoková aerodisperzia	CZ/H/0508/001	69/0294/15-S	KRKA, D.D., NOVO MESTO	SK
Septolete extra 1,5 mg/ml + 5 mg/ml szájnyálkahártyán alkalmazott oldatos spray	CZ/H/508/ 001	OGYI-T-22871/06	KRKA, D.D., NOVO MESTO	HU
Septabene 1,5 mg/ml + 5,0 mg/ml orální sprej, roztok	CZ/H/0508/001	69/349/15-C	KRKA, D.D., NOVO MESTO	CZ
Septabene 1,5 mg/5,0 mg/ ml aerosols izsmidzinašanai mutes dobuma, škidums	CZ/H/0508/001	15-0183	KRKA, D.D., NOVO MESTO	LV
Septolete omni 1,5 mg + 5,0 mg/ml spray bucofaringian soluție	CZ/H/0508/001	8015/2015/01	KRKA, D.D., NOVO MESTO	RO
Septolete ultra, (1,5 mg + 5 mg)/ml, aerosol do stosowania w jamie ustnej, roztwór.	CZ/H/0508/001	22609	KRKA, D.D., NOVO MESTO	PL
Septabene 1,5 mg/5 mg/1 ml burnos gleivinės purškalas (tirpalas)	CZ/H/0508/001	LT/1/15/3784/001	KRKA, D.D., NOVO MESTO	LT

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
Septolete omni, 1,5 mg/5 mg/ml suuõõnesprei, lahus	CZ/H/508/ 001	884615	KRKA, D.D., NOVO MESTO	EE
Septabene 1,5 mg/5 mg v 1 ml oralno prõsilo, raztopina	CZ/H/0508/001	HN/15/01822/001	KRKA, D.D., NOVO MESTO	SI
Септолете тотал 1,5 mg/ml + 5,0 mg/ml спрей за устна лигавица, разтвор	CZ/H/0508/001	20150303	KRKA, D.D., NOVO MESTO	BG
Septafar 1,5 mg/ml + 5,0 mg/ml spray per mucosa orale, soluzione	CZ/H/0508/001	043452010	KRKA, D.D., NOVO MESTO	IT
Septolete Duo Spray 1,5 mg/ml + 5 mg/ml soluõõo para pulverizaõõo bucal	CZ/H/0508/001	5656145	KRKA FARMACÊUTICA, UNIPESSOAL LDA.	PT
GOLA ACTION 3 mg + 1 mg compresse orosolubili senza zucchero	not available	033501014	IODOSAN S.P.A.	IT
GOLA ACTION 150 mg/100 ml + 500 mg/100 ml spray per mucosa orale	not available	033501026	IODOSAN S.P.A.	IT
GOLA ACTION 150 mg/100 ml + 50 mg/100 ml collutorio	not available	033501038	IODOSAN S.P.A.	IT
Septabene 3 mg/1 mg lozenges	CZ/H/0667/001	PA 1347/063/001	KRKA, D.D., NOVO MESTO	IE

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
Septolete® 3 mg/1 mg Lutschtabletten	CZ/H/0667/001	96231.00.00	TAD PHARMA GMBH	DE
Benzydamin/Cetylpyridinium chlorid Krka 3 mg/1 mg pastilky	CZ/H/0667/ 001	69/780/15-C	KRKA, D.D., NOVO MESTO	CZ
Septolete extra s príchuťou citrónu a medu 3 mg/1 mg tvrdé pastilky	CZ/H/0507/002	69/0251/17-S	KRKA, D.D., NOVO MESTO	SK
Septolete extra s príchuťou citrónu a bazového kvetu 3 mg/1 mg tvrdé pastilky	CZ/H/0507/003	69/0252/17-S	KRKA, D.D., NOVO MESTO	SK
Septabene ar citronu un medu 3 mg/1 mg sūkājāmās tabletes	CZ/H/0507/003	17-0203	KRKA, D.D., NOVO MESTO	LV
Septabene ar citronu un plūškoku 3 mg/1 mg sūkājāmās tabletes	CZ/H/0507/002	17-0204	KRKA, D.D., NOVO MESTO	LV
Septolete duo limun i bazga 3 mg/1 mg pastile	CZ/H/0507/002	HR-H-111953709	KRKA-FARMA D.O.O.	HR
Septolete duo limun i med 3 mg/1 mg pastile	CZ/H/0507/003	HR-H-736729677	KRKA-FARMA D.O.O.	HR
Septolete omni lemon & elderflower, 3 mg/1 mg losengid	CZ/H/0507/ 003	952817	KRKA, D.D., NOVO MESTO	EE

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
Septotele omni lemon & honey, 3 mg/1 mg losengid	CZ/H/0507/ 003	952917	KRKA, D.D., NOVO MESTO	EE
Septabene z okusom limone in medu 3 mg/1 mg pastile	CZ/H/0507/ 003	HN/17/01832/001	KRKA, D.D., NOVO MESTO	SI
Septabene z okusom limone in medu 3 mg/1 mg pastile	CZ/H/0507/ 003	HN/17/01832/002	KRKA, D.D., NOVO MESTO	SI
Septabene z okusom limone in medu 3 mg/1 mg pastile	CZ/H/0507/ 003	HN/17/01832/003	KRKA, D.D., NOVO MESTO	SI
Septabene z okusom limone in medu 3 mg/1 mg pastile	CZ/H/0507/ 003	HN/17/01832/004	KRKA, D.D., NOVO MESTO	SI
Septabene z okusom limone in medu 3 mg/1 mg pastile	CZ/H/0507/ 003	HN/17/01832/005	KRKA, D.D., NOVO MESTO	SI
Septabene z okusom limone in bezga 3 mg/1 mg pastile	CZ/H/0507/ 003	HN/17/01833/001	KRKA, D.D., NOVO MESTO	SI
Septabene z okusom limone in bezga 3 mg/1 mg pastile	CZ/H/0507/ 003	HN/17/01833/002	KRKA, D.D., NOVO MESTO	SI
Septabene z okusom limone in bezga 3 mg/1 mg pastile	CZ/H/0507/ 003	HN/17/01833/003	KRKA, D.D., NOVO MESTO	SI

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
Septabene z okusom limone in bezga 3 mg/1 mg pastile	CZ/H/0507/ 003	HN/17/01833/004	KRKA, D.D., NOVO MESTO	SI
Septabene z okusom limone in bezga 3 mg/1 mg pastile	CZ/H/0507/ 003	HN/17/01833/005	KRKA, D.D., NOVO MESTO	SI
Septabene citron a med 3 mg/1 mg pastilky	CZ/H/0507/002	69/756/16-C	KRKA, D.D., NOVO MESTO	CZ
Septabene citron a bezový květ 3 mg/1 mg pastilky	CZ/H/0507/003	69/757/16-C	KRKA, D.D., NOVO MESTO	CZ
Septabene citrinų ir medaus skonio 3 mg/1 mg kietosios pastilės	CZ/H/0507/002	LT/1/17/4140/001	KRKA, D.D., NOVO MESTO	LT
Septabene citrinų ir medaus skonio 3 mg/1 mg kietosios pastilės	CZ/H/0507/002	LT/1/17/4140/002	KRKA, D.D., NOVO MESTO	LT
Septabene citrinų ir medaus skonio 3 mg/1 mg kietosios pastilės	CZ/H/0507/002	LT/1/17/4140/003	KRKA, D.D., NOVO MESTO	LT
Septabene citrinų ir medaus skonio 3 mg/1 mg kietosios pastilės	CZ/H/0507/002	LT/1/17/4140/004	KRKA, D.D., NOVO MESTO	LT
Septabene citrinų ir medaus skonio 3 mg/1 mg kietosios pastilės	CZ/H/0507/002	LT/1/17/4140/005	KRKA, D.D., NOVO MESTO	LT

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
Septabene citrinų ir šeivamedžio skonio 3 mg/1 mg kietosios pastilės	CZ/H/0507/003	LT/1/17/4141/001	KRKA, D.D., NOVO MESTO	LT
Septabene citrinų ir šeivamedžio skonio 3 mg/1 mg kietosios pastilės	CZ/H/0507/003	LT/1/17/4141/002	KRKA, D.D., NOVO MESTO	LT
Septabene citrinų ir šeivamedžio skonio 3 mg/1 mg kietosios pastilės	CZ/H/0507/003	LT/1/17/4141/003	KRKA, D.D., NOVO MESTO	LT
Septabene citrinų ir šeivamedžio skonio 3 mg/1 mg kietosios pastilės	CZ/H/0507/003	LT/1/17/4141/004	KRKA, D.D., NOVO MESTO	LT
Septabene citrinų ir šeivamedžio skonio 3 mg/1 mg kietosios pastilės	CZ/H/0507/003	LT/1/17/4141/005	KRKA, D.D., NOVO MESTO	LT
Septabene sitruuna & hunaja 3 mg/1 mg imeskelytabletti	CZ/H/0507/003	34369	KRKA SVERIGE AB	FI
Septabene sitruuna & seljankukka 3 mg/1 mg imeskelytabletti	CZ/H/0507/002	34370	KRKA SVERIGE AB	FI
Септолете тотал лимон и цвят от бяз 3 mg/1 mg таблетки за смучене	CZ/H/0507/003	20170331	KRKA, D.D., NOVO MESTO	BG
Септолете тотал лимон и мед 3 mg/1 mg таблетки за смучене	CZ/H/0507/002	20170332	KRKA, D.D., NOVO MESTO	BG

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
Septolete omni lămâie și miere 3 mg/1 mg pastile	CZ/H/0507/002	10388/2017/01	KRKA, D.D., NOVO MESTO	RO
Septolete omni lămâie și miere 3 mg/1 mg pastile	CZ/H/0507/002	10388/2017/02	KRKA, D.D., NOVO MESTO	RO
Septolete omni lămâie și miere 3 mg/1 mg pastile	CZ/H/0507/002	10388/2017/03	KRKA, D.D., NOVO MESTO	RO
Septolete omni lămâie și miere 3 mg/1 mg pastile	CZ/H/0507/002	10388/2017/04	KRKA, D.D., NOVO MESTO	RO
Septolete omni lămâie și miere 3 mg/1 mg pastile	CZ/H/0507/002	10388/2017/05	KRKA, D.D., NOVO MESTO	RO
Septolete omni lămâie și soc 3 mg/1 mg pastile	CZ/H/0507/003	10389/2017/01	KRKA, D.D., NOVO MESTO	RO
Septolete omni lămâie și soc 3 mg/1 mg pastile	CZ/H/0507/003	10389/2017/02	KRKA, D.D., NOVO MESTO	RO
Septolete omni lămâie și soc 3 mg/1 mg pastile	CZ/H/0507/003	10389/2017/03	KRKA, D.D., NOVO MESTO	RO
Septolete omni lămâie și soc 3 mg/1 mg pastile	CZ/H/0507/003	10389/2017/04	KRKA, D.D., NOVO MESTO	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
Septotele omni lămâie și soc 3 mg/1 mg pastile	CZ/H/0507/003	10389/2017/05	KRKA, D.D., NOVO MESTO	RO
Septotele Duo limão e mel 3 mg + 1 mg pastilhas	CZ/H/0507/002	5734777	KRKA FARMACÊUTICA, UNIPESOAL LDA.	PT
Septotele Duo limão e flor de sabugueiro 3 mg + 1 mg pastilhas	CZ/H/0507/003	5734801	KRKA FARMACÊUTICA, UNIPESOAL LDA.	PT
Septotele extra citrom-méz 3 mg/1 mg szopogató tableta	CZ/H/0507/ 003	OGYI-T-22871/07	KRKA, D.D., NOVO MESTO	HU
Septotele extra citrom-méz 3 mg/1 mg szopogató tableta	CZ/H/0507/ 003	OGYI-T-22871/08	KRKA, D.D., NOVO MESTO	HU
Septotele extra citrom-méz 3 mg/1 mg szopogató tableta	CZ/H/0507/ 003	OGYI-T-22871/09	KRKA, D.D., NOVO MESTO	HU
Septotele extra citrom-méz 3 mg/1 mg szopogató tableta	CZ/H/0507/ 003	OGYI-T-22871/10	KRKA, D.D., NOVO MESTO	HU
Septotele extra citrom-méz 3 mg/1 mg szopogató tableta	CZ/H/0507/ 003	OGYI-T-22871/11	KRKA, D.D., NOVO MESTO	HU
Septotele extra citrom-bodza 3 mg/1 mg szopogató tableta	CZ/H/0507/ 003	OGYI-T-22871/12	KRKA, D.D., NOVO MESTO	HU

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
Septolete extra citrom-bodza 3 mg/1 mg szopogató tableta	CZ/H/0507/ 003	OGYI-T-22871/13	KRKA, D.D., NOVO MESTO	HU
Septolete extra citrom-bodza 3 mg/1 mg szopogató tableta	CZ/H/0507/ 003	OGYI-T-22871/14	KRKA, D.D., NOVO MESTO	HU
Septolete extra citrom-bodza 3 mg/1 mg szopogató tableta	CZ/H/0507/ 003	OGYI-T-22871/15	KRKA, D.D., NOVO MESTO	HU
Septolete extra citrom-bodza 3 mg/1 mg szopogató tableta	CZ/H/0507/ 003	OGYI-T-22871/16	KRKA, D.D., NOVO MESTO	HU
Septolete ultra o smaku cytryny i miodu, 3 mg + 1 mg, pastylki twarde	CZ/H/0507/002	24561	KRKA, D.D., NOVO MESTO	PL
Septolete ultra o smaku cytryny i czarnego bzu, 3 mg + 1 mg, pastylki twarde	CZ/H/0507/003	24562	KRKA, D.D., NOVO MESTO	PL
Septolete aroma limone e miele 3 mg/1 mg pastiglie	CZ/H/0507/003	AIC N. 043735063	KRKA, D.D., NOVO MESTO	IT
Septolete aroma limone e miele 3 mg/1 mg pastiglie	CZ/H/0507/003	AIC N. 043735075	KRKA, D.D., NOVO MESTO	IT
Septolete aroma limone e miele 3 mg/1 mg pastiglie	CZ/H/0507/003	AIC N. 043735087	KRKA, D.D., NOVO MESTO	IT

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
Septolete aroma limone e miele 3 mg/1 mg pastiglie	CZ/H/0507/003	AIC N. 043735099	KRKA, D.D., NOVO MESTO	IT
Septolete aroma limone e miele 3 mg/1 mg pastiglie	CZ/H/0507/003	AIC N. 043735101	KRKA, D.D., NOVO MESTO	IT
Septolete aroma limone e fiori di sambuco 3 mg/1 mg pastiglie	CZ/H/0507/002	AIC N. 043735113	KRKA, D.D., NOVO MESTO	IT
Septolete aroma limone e fiori di sambuco 3 mg/1 mg pastiglie	CZ/H/0507/002	AIC N. 043735125	KRKA, D.D., NOVO MESTO	IT
Septolete aroma limone e fiori di sambuco 3 mg/1 mg pastiglie	CZ/H/0507/002	AIC N. 043735137	KRKA, D.D., NOVO MESTO	IT
Septolete aroma limone e fiori di sambuco 3 mg/1 mg pastiglie	CZ/H/0507/002	AIC N. 043735149	KRKA, D.D., NOVO MESTO	IT
Septolete aroma limone e fiori di sambuco 3 mg/1 mg pastiglie	CZ/H/0507/002	AIC N. 043735152	KRKA, D.D., NOVO MESTO	IT
Septolete duo 3 mg/1 mg pastile	CZ/H/0507/001	HR-H-327402766	KRKA-FARMA D.O.O.	HR
Septolete extra 3 mg/1 mg szopogató tabletta	CZ/H/0507/ 001	OGYI-T-22871/01	KRKA, D.D., NOVO MESTO	HU

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Septolete extra 3 mg/1 mg szopogató tableta	CZ/H/0507/ 001	OGYI-T-22871/02	KRKA, D.D., NOVO MESTO	HU
Septolete extra 3 mg/1 mg szopogató tableta	CZ/H/0507/ 001	OGYI-T-22871/03	KRKA, D.D., NOVO MESTO	HU
Septolete extra 3 mg/1 mg szopogató tableta	CZ/H/0507/ 001	OGYI-T-22871/04	KRKA, D.D., NOVO MESTO	HU
Septolete extra 3 mg/1 mg szopogató tableta	CZ/H/0507/ 001	OGYI-T-22871/05	KRKA, D.D., NOVO MESTO	HU
Септолете тотал 3 mg/1 mg таблатки за смучене	CZ/H/0507/001	20150283	KRKA, D.D., NOVO MESTO	BG
Septabene 3 mg/1 mg pastilky	CZ/H/0507/001	69/388/15-C	KRKA, D.D., NOVO MESTO	CZ
Septabene 3 mg/1 mg sūkājāmās tabletes	CZ/H/0507/001	15-0172	KRKA, D.D., NOVO MESTO	LV
Septolete extra 3 mg/1 mg tvrdé pastilky	CZ/H/0507/001	69/0311/15-S	KRKA, D.D., NOVO MESTO	SK
Septolete omni 3 mg/1 mg pastile	CZ/H/0507/001	8036/2015/01	KRKA, D.D., NOVO MESTO	RO

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Septotele omni 3 mg/1 mg pastile	CZ/H/0507/001	8036/2015/02	KRKA, D.D., NOVO MESTO	RO
Septotele omni 3 mg/1 mg pastile	CZ/H/0507/001	8036/2015/03	KRKA, D.D., NOVO MESTO	RO
Septotele omni 3 mg/1 mg pastile	CZ/H/0507/001	8036/2015/04	KRKA, D.D., NOVO MESTO	RO
Septotele omni 3 mg/1 mg pastile	CZ/H/0507/001	8036/2015/05	KRKA, D.D., NOVO MESTO	RO
Septotele ultra, 3 mg + 1 mg, pastylki twarde	CZ/H/0507/001	22606	KRKA, D.D., NOVO MESTO	PL
Septabene 3 mg/1 mg kietosios pastilės	CZ/H/0507/001	LT/1/15/3784/002	KRKA, D.D., NOVO MESTO	LT
Septabene 3 mg/1 mg kietosios pastilės	CZ/H/0507/001	LT/1/15/3784/003	KRKA, D.D., NOVO MESTO	LT
Septabene 3 mg/1 mg kietosios pastilės	CZ/H/0507/001	LT/1/15/3784/004	KRKA, D.D., NOVO MESTO	LT
Septabene 3 mg/1 mg kietosios pastilės	CZ/H/0507/001	LT/1/15/3784/005	KRKA, D.D., NOVO MESTO	LT

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Septabene 3 mg/1 mg kietosios pastilės	CZ/H/0507/001	LT/1/15/3784/006	KRKA, D.D., NOVO MESTO	LT
Septolete omni, 3 mg/1 mg losengid	CZ/H/0507/ 001	884715	KRKA, D.D., NOVO MESTO	EE
Septabene 3 mg/1 mg pastile	CZ/H/0507/001	HN/15/01823/001	KRKA, D.D., NOVO MESTO	SI
Septabene 3 mg/1 mg pastile	CZ/H/0507/001	HN/15/01823/002	KRKA, D.D., NOVO MESTO	SI
Septabene 3 mg/1 mg pastile	CZ/H/0507/001	HN/15/01823/003	KRKA, D.D., NOVO MESTO	SI
Septabene 3 mg/1 mg pastile	CZ/H/0507/001	HN/15/01823/004	KRKA, D.D., NOVO MESTO	SI
Septabene 3 mg/1 mg pastile	CZ/H/0507/001	HN/15/01823/005	KRKA, D.D., NOVO MESTO	SI
Septolete 3 mg/1mg pastiglie	CZ/H/0507/001	043735012	KRKA, D.D., NOVO MESTO	IT
Septolete 3 mg/1mg pastiglie	CZ/H/0507/001	043735024	KRKA, D.D., NOVO MESTO	IT

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Septolete 3 mg/1mg pastiglie	CZ/H/0507/001	043735036	KRKA, D.D., NOVO MESTO	IT
Septolete 3 mg/1mg pastiglie	CZ/H/0507/001	043735048	KRKA, D.D., NOVO MESTO	IT
Septolete 3 mg/1mg pastiglie	CZ/H/0507/001	043735051	KRKA, D.D., NOVO MESTO	IT
Septabene 3 mg/1 mg imeskelytabletit	CZ/H/0507/001	32304	KRKA SVERIGE AB	FI
Septolete Duo 3 mg + 1 mg pastilhas	CZ/H/0507/001	5658216	KRKA FARMACÉUTICA, UNIPESSOAL LDA.	PT