



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 January 2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: solifenacin

Procedure no.: PSUSA/00002769/202006



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
Vesicare 1 mg/ml Suspension zum Einnehmen	NL/H/0487/003	136800	ASTELLAS PHARMA GES.M.B.H.	AT
Vesicare 5 mg - Filmdabletten	NL/H/0487/001	1 – 25518	ASTELLAS PHARMA GES.M.B.H.	AT
Vesicare® 10 mg - Filmdabletten	NL/H/0487/002	1 - 25519	ASTELLAS PHARMA GES.M.B.H.	AT
Vesicare 1 mg/ml suspensie voor oraal gebruik	NL/H/0487/003	BE480284	ASTELLAS PHARMA B.V., OFFICE BE	BE
Vesicare 1 mg/ml, suspension buvable	NL/H/0487/003	BE480284	ASTELLAS PHARMA B.V., OFFICE BE	BE
Vesicare 1 mg/ml Suspension zum Einnehmen	NL/H/0487/003	BE480284	ASTELLAS PHARMA B.V., OFFICE BE	BE
Vesicare 5 mg Filmdabletten	NL/H/0487/001	BE265797	ASTELLAS PHARMA B.V., OFFICE BE	BE
Vesicare 5 mg Filmdabletten	NL/H/0487/001	BE404932	ASTELLAS PHARMA B.V., OFFICE BE	BE
Vesicare 10 mg Filmdabletten	NL/H/0487/002	BE404941	ASTELLAS PHARMA B.V., OFFICE BE	BE
Vesicare 10 mg Filmdabletten	NL/H/0487/002	BE265806	ASTELLAS PHARMA B.V., OFFICE BE	BE
Vesicare 5 mg, filmomhulde tablet	NL/H/0487/001	BE265797	ASTELLAS PHARMA B.V., OFFICE BE	BE
Vesicare 5 mg, comprimé pelliculé	NL/H/0487/001	BE265797	ASTELLAS PHARMA B.V., OFFICE BE	BE
Vesicare 10 mg, filmomhulde tablet	NL/H/0487/002	BE265806	ASTELLAS PHARMA B.V., OFFICE BE	BE
Vesicare 10 mg, comprimé pelliculé	NL/H/0487/002	BE265806	ASTELLAS PHARMA B.V., OFFICE BE	BE
Vesicare 5 mg, comprimé pelliculé	NL/H/0487/001	BE404932	ASTELLAS PHARMA B.V., OFFICE BE	BE
Vesicare 5 mg, filmomhulde tablet	NL/H/0487/001	BE404932	ASTELLAS PHARMA B.V., OFFICE BE	BE
Vesicare 10 mg, comprimé pelliculé	NL/H/0487/002	BE404941	ASTELLAS PHARMA B.V., OFFICE BE	BE
Vesicare 10 mg, filmomhulde tablet	NL/H/0487/002	BE404941	ASTELLAS PHARMA B.V., OFFICE BE	BE
Везикер 1 mg/ml перорална суспензия	NL/H/0487/003	20150345	ASTELLAS PHARMA D.O.O.	BG
ВЕЗИКЕР 5 mg филмирани таблетки	not available	20050192	ASTELLAS PHARMA D.O.O.	BG
Vesicare 1 mg/ml πόσιμο εναιώρημα	NL/H/0487/003	022366	ASTELLAS PHARMACEUTICALS A.E.B.E.	CY
Vesicare® 10 mg, επικαλυμμένο με λεπτό υμένιο δισκίο	NL/H/0487/002	19751	ASTELLAS PHARMACEUTICALS A.E.B.E.	CY
Vesicare® 5 mg, επικαλυμμένο με λεπτό υμένιο δισκίο	NL/H/0487/001	19727	ASTELLAS PHARMACEUTICALS A.E.B.E.	CY
Vesicare 1 mg/ml perorální suspenze	NL/H/0487/003	73/447/15-C	ASTELLAS PHARMA S.R.O.	CZ
Vesicare 10 mg potahované tablety	NL/H/0487/002	73/067/05-C	ASTELLAS PHARMA S.R.O.	CZ
Vesicare 5 mg potahované tablety	NL/H/0487/001	73/066/05-C	ASTELLAS PHARMA S.R.O.	CZ
Vesikur 1 mg/ml Suspension zum Einnehmen	NL/H/0487/003	93778.00.00	ASTELLAS PHARMA GMBH	DE
Vesikur 10 mg Filmdabletten	NL/H/0487/002	59808.01.00	ASTELLAS PHARMA GMBH	DE
Vesikur 5 mg Filmdabletten	NL/H/0487/001	59808.00.00	ASTELLAS PHARMA 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
Vesicare, oral suspension	NL/H/0487/003	55030	ASTELLAS PHARMA A/S	DK
Vesicare, filmovertukne tabletter	NL/H/0487/001	36386	ASTELLAS PHARMA A/S	DK
Vesicare, filmovertukne tabletter	NL/H/0487/002	36387	ASTELLAS PHARMA A/S	DK
Vesicare, 1 mg/ml suukaudne suspensioon	NL/H/0487/003	891315	ASTELLAS PHARMA D.O.O.	EE
Vesicare, 5 mg õhukese polümeerikattega tabletid	NL/H/0487/001	467505	ASTELLAS PHARMA D.O.O.	EE
Vesicare, 10 mg õhukese polümeerikattega tabletid	NL/H/0487/002	467605	ASTELLAS PHARMA D.O.O.	EE
Vesicare 1 mg/ml suspensión oral	NL/H/0487/003	80116	ASTELLAS PHARMA S.A.	ES
Vesicare 5 mg comprimidos recubiertos con película	NL/H/0487/001	66.258	ASTELLAS PHARMA S.A.	ES
Vesicare 10 mg comprimidos recubiertos con película	NL/H/0487/002	66.257	ASTELLAS PHARMA S.A.	ES
Vesicare 1 mg/ml oraalisuspensio	NL/H/0487/003	32848	ASTELLAS PHARMA A/S	FI
Vesicare 1 mg/ml oral suspension	NL/H/0487/003	32848	ASTELLAS PHARMA A/S	FI
Vesicare 5 mg filmdragerad tablett	NL/H/0487/001	19192	ASTELLAS PHARMA A/S	FI
Vesicare 10 mg filmdragerad tablett	NL/H/0487/002	19193	ASTELLAS PHARMA A/S	FI
Vesicare 5 mg, kalvopäällysteinen tabletti	NL/H/0487/001	19192	ASTELLAS PHARMA A/S	FI
Vesicare 10 mg, kalvopäällysteinen tabletti	NL/H/0487/002	19193	ASTELLAS PHARMA A/S	FI
VESICARE 1 mg/ml, suspension buvable	NL/H/0487/003	34009 300 366 4 8	ASTELLAS PHARMA SAS	FR
VESICARE 10 mg, comprimé pelliculé	NL/H/0487/002	378 128-0	ASTELLAS PHARMA SAS	FR
VESICARE 5 mg, comprimé pelliculé	NL/H/0487/001	378 127-4	ASTELLAS PHARMA SAS	FR
VESICARE 5 mg, comprimé pelliculé	NL/H/0487/001	365 515-0	ASTELLAS PHARMA SAS	FR
VESICARE 10 mg, comprimé pelliculé	NL/H/0487/002	365 516-7	ASTELLAS PHARMA SAS	FR
Vesicare 1 mg/ml πόσιμο εναιώρημα	NL/H/0487/003	951841/14/2-8-16	ASTELLAS PHARMACEUTICALS A.E.B.E.	GR
Vesicare® 10 mg, επικαλυμμένο με λεπτό υμένιο δισκίο	NL/H/0487/002	61104	ASTELLAS PHARMACEUTICALS A.E.B.E.	GR
Vesicare® 5 mg, επικαλυμμένο με λεπτό υμένιο δισκίο	NL/H/0487/001	61101/09-09-2010	ASTELLAS PHARMACEUTICALS A.E.B.E.	GR
Vesicare 5 mg filmom obložene tablete	not available	HR-H-748673544	ASTELLAS D.O.O.	HR
Vesicare 10 mg filmom obložene tablete	not available	HR-H-010904082	ASTELLAS D.O.O.	HR
Vesicare 1 mg/ml oralna suspenzija	NL/H/0487/003	HR-H-664354012	ASTELLAS D.O.O.	HR

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
Vesicare 1 mg/ml belsőleges szuszpenzió	NL/H/0487/003	OGYI-T-10052/04	ASTELLAS PHARMA KFT	HU
Vesicare 5 mg filmtabletta	NL/H/0487/001	OGYI-T-10051/03	ASTELLAS PHARMA KFT	HU
Vesicare 10 mg filmtabletta	NL/H/0487/002	OGYI-T-10052/01	ASTELLAS PHARMA KFT	HU
Vesicare 10 mg filmtabletta	NL/H/0487/002	OGYI-T-10052/03	ASTELLAS PHARMA KFT	HU
Vesicare 5 mg filmtabletta	NL/H/0487/001	OGYI-T-10051/02	ASTELLAS PHARMA KFT	HU
Vesicare 5 mg filmtabletta	NL/H/0487/001	OGYI-T-10051/01	ASTELLAS PHARMA KFT	HU
Vesicare 10 mg filmtabletta	NL/H/0487/002	OGYI-T-10052/02	ASTELLAS PHARMA KFT	HU
Vesitirim 1 mg/ml oral suspension	NL/H/0487/003	PA 1241/009/003	ASTELLAS PHARMA CO. LTD.	IE
Vesitirim® 5 mg, film-coated tablet	NL/H/0487/001	PA 1241/9/1	ASTELLAS PHARMA CO. LTD.	IE
Vesitirim® 10 mg, film-coated tablet	NL/H/0487/002	PA 1241/009/002	ASTELLAS PHARMA CO. LTD.	IE
Vesicare 1 mg/ml mixtúra, dreifa	NL/H/0487/003	IS/1/15/113/01	ASTELLAS PHARMA A/S	IS
Vesicare 5 mg filmuhúðaðar töflur	NL/H/0487/001	IS/1/04/013/01	ASTELLAS PHARMA A/S	IS
Vesicare 10 mg filmuhúðaðar töflur	NL/H/0487/002	IS/1/04/013/02	ASTELLAS PHARMA A/S	IS
Vesiker 1 mg/ml sospensione orale	NL/H/0487/003	036564235	ASTELLAS PHARMA S.P.A.	IT
Vesiker 5 mg, compresse rivestite con film	NL/H/0487/001	036564197	ASTELLAS PHARMA S.P.A.	IT
Vesiker 5 mg, compresse rivestite con film	NL/H/0487/001	036564211	ASTELLAS PHARMA S.P.A.	IT
Vesiker® 10 mg, compresse rivestite con film	NL/H/0487/002	036564209	ASTELLAS PHARMA S.P.A.	IT
Vesiker® 10 mg, compresse rivestite con film	NL/H/0487/002	036564223	ASTELLAS PHARMA S.P.A.	IT
Vesiker® 10 mg, compresse rivestite con film	NL/H/0487/002	036564096	ASTELLAS PHARMA S.P.A.	IT
Vesiker 5 mg, compresse rivestite con film	NL/H/0487/001	036564019	ASTELLAS PHARMA S.P.A.	IT
Vesiker® 10 mg, compresse rivestite con film	NL/H/0487/002	036564110	ASTELLAS PHARMA S.P.A.	IT
Vesiker® 10 mg, compresse rivestite con film	NL/H/0487/002	036564108	ASTELLAS PHARMA S.P.A.	IT
Vesiker® 10 mg, compresse rivestite con film	NL/H/0487/002	036564185	ASTELLAS PHARMA S.P.A.	IT
Vesiker® 10 mg, compresse rivestite con film	NL/H/0487/002	036564122	ASTELLAS PHARMA S.P.A.	IT
Vesiker® 10 mg, compresse rivestite con film	NL/H/0487/002	036564134	ASTELLAS PHARMA S.P.A.	IT
Vesiker® 10 mg, compresse rivestite con film	NL/H/0487/002	036564159	ASTELLAS PHARMA S.P.A.	IT
Vesiker® 10 mg, compresse rivestite con film	NL/H/0487/002	03656146	ASTELLAS PHARMA S.P.A.	IT
Vesiker 5 mg, compresse rivestite con film	NL/H/0487/001	036564033	ASTELLAS PHARMA S.P.A.	IT
Vesiker® 10 mg, compresse rivestite con film	NL/H/0487/002	036564161	ASTELLAS PHARMA S.P.A.	IT
Vesiker 5 mg, compresse rivestite con film	NL/H/0487/001	036564021	ASTELLAS PHARMA S.P.A.	IT
Vesiker 5 mg, compresse rivestite con film	NL/H/0487/001	036564058	ASTELLAS PHARMA S.P.A.	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
Vesiker 5 mg, compresse rivestite con film	NL/H/0487/001	036564173	ASTELLAS PHARMA S.P.A.	IT
Vesiker 5 mg, compresse rivestite con film	NL/H/0487/001	036564045	ASTELLAS PHARMA S.P.A.	IT
Vesiker 5 mg, compresse rivestite con film	NL/H/0487/001	036564084	ASTELLAS PHARMA S.P.A.	IT
Vesiker 5 mg, compresse rivestite con film	NL/H/0487/001	036564060	ASTELLAS PHARMA S.P.A.	IT
Vesiker 5 mg, compresse rivestite con film	NL/H/0487/001	036564072	ASTELLAS PHARMA S.P.A.	IT
Vesicare 1 mg/ml Suspension zum Einnehmen	NL/H/0487/003	136800	ASTELLAS PHARMA GES.M.B.H.	LI
Vesicare 5 mg - Filmtabletten	NL/H/0487/001	1 – 25518	ASTELLAS PHARMA EUROPE B.V.	LI
Vesicare® 10 mg - Filmtabletten	NL/H/0487/002	1 - 25519	ASTELLAS PHARMA EUROPE B.V.	LI
Vesicare 1 mg/ml geriamoji suspensija	NL/H/0487/003	LT/1/05/0465/021	ASTELLAS PHARMA D.O.O.	LT
Vesicare 5 mg plėvele dengtos tabletės	NL/H/0487/001	LT/1/05/0465/005	ASTELLAS PHARMA D.O.O.	LT
Vesicare 5 mg plėvele dengtos tabletės	NL/H/0487/001	LT/1/05/0465/019	ASTELLAS PHARMA D.O.O.	LT
Vesicare 5 mg plėvele dengtos tabletės	NL/H/0487/001	LT/1/05/0465/008	ASTELLAS PHARMA D.O.O.	LT
Vesicare 5 mg plėvele dengtos tabletės	NL/H/0487/001	LT/1/05/0465/006	ASTELLAS PHARMA D.O.O.	LT
Vesicare 5 mg plėvele dengtos tabletės	NL/H/0487/001	LT/1/05/0465/009	ASTELLAS PHARMA D.O.O.	LT
Vesicare 10 mg plėvele dengtos tabletės	NL/H/0487/002	LT/1/05/0465/010	ASTELLAS PHARMA D.O.O.	LT
Vesicare 10 mg plėvele dengtos tabletės	NL/H/0487/002	LT/1/05/0465/016	ASTELLAS PHARMA D.O.O.	LT
Vesicare 5 mg plėvele dengtos tabletės	NL/H/0487/001	LT/1/05/0465/003	ASTELLAS PHARMA D.O.O.	LT
Vesicare 5 mg plėvele dengtos tabletės	NL/H/0487/001	LT/1/05/0465/002	ASTELLAS PHARMA D.O.O.	LT
Vesicare 10 mg plėvele dengtos tabletės	NL/H/0487/002	LT/1/05/0465/017	ASTELLAS PHARMA D.O.O.	LT
Vesicare 5 mg plėvele dengtos tabletės	NL/H/0487/001	LT/1/05/0465/007	ASTELLAS PHARMA D.O.O.	LT
Vesicare 5 mg plėvele dengtos tabletės	NL/H/0487/001	LT/1/05/0465/001	ASTELLAS PHARMA D.O.O.	LT
Vesicare 10 mg plėvele dengtos tabletės	NL/H/0487/002	LT/1/05/0465/015	ASTELLAS PHARMA D.O.O.	LT
Vesicare 10 mg plėvele dengtos tabletės	NL/H/0487/002	LT/1/05/0465/018	ASTELLAS PHARMA D.O.O.	LT
Vesicare 10 mg plėvele dengtos tabletės	NL/H/0487/002	LT/1/05/0465/013	ASTELLAS PHARMA D.O.O.	LT
Vesicare 5 mg plėvele dengtos tabletės	NL/H/0487/001	LT/1/05/0465/004	ASTELLAS PHARMA D.O.O.	LT
Vesicare 10 mg plėvele dengtos tabletės	NL/H/0487/002	LT/1/05/0465/020	ASTELLAS PHARMA D.O.O.	LT
Vesicare 10 mg plėvele dengtos tabletės	NL/H/0487/002	LT/1/05/0465/014	ASTELLAS PHARMA D.O.O.	LT
Vesicare 10 mg plėvele dengtos tabletės	NL/H/0487/002	LT/1/05/0465/011	ASTELLAS PHARMA D.O.O.	LT
Vesicare 10 mg plėvele dengtos tabletės	NL/H/0487/002	LT/1/05/0465/012	ASTELLAS PHARMA D.O.O.	LT
Vesicare 1 mg/ml, suspension buvable	NL/H/0487/003	2016040100	ASTELLAS PHARMA B.V., OFFICE BE	LU
Vesicare 5 mg, comprimé pelliculé	NL/H/0487/001	0566/11031050	ASTELLAS PHARMA B.V., OFFICE BE	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
Vesicare 10 mg, comprimé pelliculé	NL/H/0487/002	0566/11031049	ASTELLAS PHARMA B.V., OFFICE BE	LU
Vesicare 1 mg/ml suspensija iekšķīgai lietošanai	NL/H/0487/003	15-0265	ASTELLAS PHARMA D.O.O.	LV
Vesicare 10 mg apvalkotās tabletes	NL/H/0487/002	05-0099	ASTELLAS PHARMA D.O.O.	LV
Vesicare 5 mg apvalkotās tabletes	NL/H/0487/001	05 - 0098	ASTELLAS PHARMA D.O.O.	LV
Vesicare 1 mg/mloral suspension	NL/H/0487/003	MA067/00803	ASTELLAS PHARMA EUROPE B.V.	MT
Vesicare® 5 mg, film-coated tablet	NL/H/0487/001	MA067/00801	ASTELLAS PHARMA EUROPE B.V.	MT
Vesicare® 10 mg, film-coated tablet	NL/H/0487/002	MA067/00802	ASTELLAS PHARMA EUROPE B.V.	MT
Vesicare 1 mg/ml, suspensie voor oraal gebruik	NL/H/0487/003	RVG116539	ASTELLAS PHARMA EUROPE B.V.	NL
Vesicare 5 mg, filmomhulde tabletten	NL/H/0487/001	RVG 29151	ASTELLAS PHARMA EUROPE B.V.	NL
Vesicare 10 mg, filmomhulde tabletten	NL/H/0487/002	RVG 29152	ASTELLAS PHARMA EUROPE B.V.	NL
Solifenacinesuccinaat LM I mg/m1 drank	UK/H/6356/001	RVG 119526	LM MANUFACTURING LTD	NL
Vesicare 1 mg/ml mikstur, suspensjon	NL/H/0487/003	14-10413	ASTELLAS PHARMA A/S	NO
Vesicare® 5 mg tablett, filmdrasjert	NL/H/0487/001	04-2481	ASTELLAS PHARMA A/S	NO
Vesicare 10 mg tablett, filmdrasjert	NL/H/0487/002	04-2482	ASTELLAS PHARMA A/S	NO
Vesicare, 1 mg/ml, zawiesina doustna	NL/H/0487/003	22927	ASTELLAS PHARMA SP.Z.O.O.	PL
Vesicare 10 mg tabletki powlekane	NL/H/0487/002	11372	ASTELLAS PHARMA SP.Z.O.O.	PL
VESICARE 5 MG TABLETKI POWLEKANE	NL/H/0487/001	11371	ASTELLAS PHARMA SP.Z.O.O.	PL
Vesicare 1 mg/ml suspensão oral	NL/H/0487/003	5661541	ASTELLAS FARMA LDA.	PT
Vesicare 5 mg, comprimido revestido por película	NL/H/0487/001	5247788	ASTELLAS FARMA LDA.	PT
Vesicare 5 mg, comprimido revestido por película	NL/H/0487/001	5247887	ASTELLAS FARMA LDA.	PT
Vesicare 10 mg, comprimido revestido por película	NL/H/0487/002	5247986	ASTELLAS FARMA LDA.	PT
Vesicare 10 mg, comprimido revestido por película	NL/H/0487/002	5248083	ASTELLAS FARMA LDA.	PT
Vesicare 1 mg/ml suspensie orală	NL/H/0487/003	8442/2015/01	ASTELLAS PHARMA EUROPE B.V.	RO
Vesicare 5 mg comprimate filmate	not available	5772/2005/01	ASTELLAS PHARMA EUROPE B.V.	RO
Vesicare 10 mg comprimate filmate	not available	5773/2005/01	ASTELLAS PHARMA EUROPE B.V.	RO
Vesicare 1 mg/ml oral suspension	NL/H/0487/003	52105	ASTELLAS PHARMA A/S	SE
Vesicare 5 mg filmdragerad tablett	NL/H/0487/001	20617	ASTELLAS PHARMA A/S	SE
Vesicare 10 mg filmdragerad tablett	NL/H/0487/002	20618	ASTELLAS PHARMA A/S	SE
Vesicare 1 mg/ml peroralna suspenzija	NL/H/0487/003	H/05/01634/021	ASTELLAS PHARMA D.O.O.	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
Vesicare 10 mg filmsko obložene tablete	NL/H/0487/002	H/05/01634/011	ASTELLAS PHARMA D.O.O.	SI
Vesicare 5 mg filmsko obložene tablete	NL/H/0487/001	H/05/01634/001	ASTELLAS PHARMA D.O.O.	SI
Vesicare 1 mg/ml perorálna suspenzia	NL/H/0487/003	73/0423/15-S	ASTELLAS PHARMA S.R.O.	SK
Vesicare 5 mg filmom obalené tablety	NL/H/0487/001	73/0063/05-S	ASTELLAS PHARMA S.R.O.	SK
Vesicare 10 mg filmom obalené tablety	NL/H/0487/002	73/0064/05-S	ASTELLAS PHARMA S.R.O.	SK
Solifenacín LM 1 mg/ml perorálny roztok solifenacíniumsukcinát	UK/H/6356/001	73/0349/18-S	LM MANUFACTURING LTD	SK
Solifenacin 1 mg/ml Oral Solution	not available	PL 40496/0004	BRILL PHARMA LIMITED	UK
Vesicare 1 mg/ml oral suspension	NL/H/0487/003	PL00166/0406	ASTELLAS PHARMA LTD.	UK
Vesicare® 5 mg, film-coated tablet	NL/H/0487/001	PL 00166/0197	ASTELLAS PHARMA LTD.	UK
Vesicare® 10 mg, film-coated tablet	NL/H/0487/002	PL 00166/0198	ASTELLAS PHARMA LTD.	UK