



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 March 2025
EMA/96425/2025
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): montelukast

Procedure No. PSUSA/00002087/202407



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
Montelukast Sandoz 4 mg - Granulat	AT/H/0823/001	1-30200	SANDOZ GMBH	AT
Singulair 10 mg Filmtabletten	FI/H/0104/001	1-22766	ORGANONHEALTHCARE GMBH	AT
Singulair 4 mg Kautabletten	FI/H/0104/003	1-23982	ORGANONHEALTHCARE GMBH	AT
Singulair 5 mg Kautabletten	FI/H/0104/002	1-22765	ORGANONHEALTHCARE GMBH	AT
Singulair 10 mg comprimés pelliculés	FI/H/0104/001	BE191913	ORGANONBELGIUM	BE
Singulair 10 mg filmomhulde tabletten	FI/H/0104/001	BE191913	ORGANONBELGIUM	BE
SINGULAIR 10 mg Filmtabletten	FI/H/0104/001	BE191913	ORGANONBELGIUM	BE
Singulair 4 mg comprimés à croquer	FI/H/0104/003	BE225285	ORGANONBELGIUM	BE
Singulair 4 mg granulaat	FI/H/0104/004	BE333672	ORGANONBELGIUM	BE
Singulair 4 mg Granulat	FI/H/0104/004	BE333672	ORGANONBELGIUM	BE
Singulair 4 mg granulés	FI/H/0104/004	BE333672	ORGANONBELGIUM	BE
Singulair 4 mg Kautabletten	FI/H/0104/003	BE225285	ORGANONBELGIUM	BE
Singulair 4 mg kauwtabletten	FI/H/0104/003	BE225285	ORGANONBELGIUM	BE
Singulair 5 mg comprimés à croquer	FI/H/0104/002	BE191904	ORGANONBELGIUM	BE
Singulair 5 mg Kautabletten	FI/H/0104/002	BE191904	ORGANONBELGIUM	BE
Singulair 5 mg kauwtabletten	FI/H/0104/002	BE191904	ORGANONBELGIUM	BE
СИНГУЛАР 10 mg филмирани таблетки	not available	9800292	N.V. ORGANON	BG
Сингулар 4 mg гранули	FI/H/0104/004	20030631	N.V. ORGANON	BG
Сингулар 4 mg таблетки за дъвчене	FI/H/0104/003	20010585	N.V. ORGANON	BG
СИНГУЛАР 5 mg	not available	9800291	N.V. ORGANON	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
таблетки за дъвчене				
Singulair 10 mg film-coated tablets	not available	19611	N.V. ORGANON	CY
Singulair 4 mg κοκκία	FI/H/0104/004	19676	N.V. ORGANON	CY
Singulair 4 mg μασώμενα δισκία	FI/H/0104/003	19291	N.V. ORGANON	CY
Singulair 5 mg chewable tablets	not available	19610	N.V. ORGANON	CY
SINGULAIR 10 mg potahované tablety	not available	14/351/99-C	N.V. ORGANON	CZ
Singulair 4 mg granule	FI/H/0104/004	14/259/09-C	N.V. ORGANON	CZ
SINGULAIR Junior 5 mg žvýkácí tablety	not available	14/350/99-C	N.V. ORGANON	CZ
Singulair Mini 4 mg žvýkácí tablety	FI/H/0104/003	14/190/01-C	N.V. ORGANON	CZ
Singulair junior® 5 mg Kautabletten	FI/H/0104/002	42011.00.00	ORGANONHEALTHCARE GMBH	DE
Singulair® 10 mg Filmtabletten	FI/H/0104/001	42011.00.01	ORGANONHEALTHCARE GMBH	DE
Singulair® mini 4 mg Granulat	FI/H/0104/004	42011.00.02	ORGANONHEALTHCARE GMBH	DE
Singulair® mini 4 mg Kautabletten	FI/H/0104/003	42011.01.00	ORGANONHEALTHCARE GMBH	DE
Singulair, filmovertrukne tabletter	FI/H/0104/001	19198	N.V. ORGANON	DK
Singulair, tyggetabletter 4 mg	FI/H/0104/003	31761	N.V. ORGANON	DK
Singulair, tyggetabletter 5 mg	FI/H/0104/002	19197	N.V. ORGANON	DK
Singulair 10 mg comprimidos recubiertos con película	FI/H/0104/001	61980	ORGANONSALUD, S.L.	ES
Singulair 4 mg comprimidos masticables	FI/H/0104/003	63673	ORGANONSALUD, S.L.	ES
Singulair 4 mg granulado	FI/H/0104/004	65429	ORGANONSALUD, S.L.	ES
Singulair 5 mg comprimidos masticables	FI/H/0104/002	61979	ORGANONSALUD, S.L.	ES
Montelukast Organon 10	FI/H/0735/	27198	N.V. ORGANON	FI

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
mg filmdragerad tablett				
Montelukast Organon 10 mg tabletti, kalvopäällysteinen	FI/H/0735/	27198	N.V. ORGANON	FI
Montelukast Organon 4 mg granulat	FI/H/0735/	28141	N.V. ORGANON	FI
Montelukast Organon 4 mg purutabletti	FI/H/0735/	28140	N.V. ORGANON	FI
Montelukast Organon 4 mg rakeet	FI/H/0735/	28141	N.V. ORGANON	FI
Montelukast Organon 4 mg tuggtablett	FI/H/0735/	28140	N.V. ORGANON	FI
Montelukast Organon 5 mg purutabletti	FI/H/0735/	27199	N.V. ORGANON	FI
Montelukast Organon 5 mg tuggtablett	FI/H/0735/	27199	N.V. ORGANON	FI
Singulair 10 mg filmdragerad tablett	FI/H/0104/001	12766	N.V. ORGANON	FI
Singulair 10 mg tabletti, kalvopäällysteinen	FI/H/0104/001	12766	N.V. ORGANON	FI
Singulair 4 mg granulat	FI/H/0104/004	17099	N.V. ORGANON	FI
Singulair 4 mg purutabletti	FI/H/0104/003	15621	N.V. ORGANON	FI
Singulair 4 mg rakeet	FI/H/0104/004	17099	N.V. ORGANON	FI
Singulair 4 mg tuggtablett	FI/H/0104/003	15621	N.V. ORGANON	FI
Singulair 5 mg purutabletti	FI/H/0104/002	12767	N.V. ORGANON	FI
Singulair 5 mg tuggtablett	FI/H/0104/002	12767	N.V. ORGANON	FI
SINGULAIR 10 mg, comprimé pelliculé	FI/H/0104/001	34009 346 140 5 7	ORGANON_FRANCE	FR
SINGULAIR 10 mg, comprimé pelliculé	FI/H/0104/001	34009 346 141 1 8	ORGANON_FRANCE	FR
SINGULAIR 10 mg, comprimé pelliculé	FI/H/0104/001	34009 346 142 8 6	ORGANON_FRANCE	FR
SINGULAIR 10 mg, comprimé pelliculé	FI/H/0104/001	34009 346 143 4 7	ORGANON_FRANCE	FR

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
SINGULAIR 10 mg, comprimé pelliculé	FI/H/0104/001	34009 346 144 0 8	ORGANON_FRANCE	FR
SINGULAIR 10 mg, comprimé pelliculé	FI/H/0104/001	34009 346 145 7 6	ORGANON_FRANCE	FR
SINGULAIR 10 mg, comprimé pelliculé	FI/H/0104/001	34009 346 146 3 7	ORGANON_FRANCE	FR
SINGULAIR 10 mg, comprimé pelliculé	FI/H/0104/001	34009 346 148 6 6	ORGANON_FRANCE	FR
SINGULAIR 10 mg, comprimé pelliculé	FI/H/0104/001	34009 346 150 0 9	ORGANON_FRANCE	FR
SINGULAIR 10 mg, comprimé pelliculé	FI/H/0104/001	34009 346 151 7 7	ORGANON_FRANCE	FR
SINGULAIR 10 mg, comprimé pelliculé	FI/H/0104/001	34009 375 745 9 4	ORGANON_FRANCE	FR
SINGULAIR 10 mg, comprimé pelliculé	FI/H/0104/001	34009 375 747 1 6	ORGANON_FRANCE	FR
SINGULAIR 10 mg, comprimé pelliculé	FI/H/0104/001	34009 561 166 5 2	ORGANON_FRANCE	FR
SINGULAIR 10 mg, comprimé pelliculé	FI/H/0104/001	34009 561 310 9 9	ORGANON_FRANCE	FR
SINGULAIR 4 mg, comprimé à croquer	FI/H/0104/003	34009 393 108 7 9	ORGANON_FRANCE	FR
SINGULAIR 4 mg, comprimé à croquer	FI/H/0104/003	34009 393 109 3 0	ORGANON_FRANCE	FR
SINGULAIR 4 mg, comprimé à croquer	FI/H/0104/003	34009 393 110 1 2	ORGANON_FRANCE	FR
SINGULAIR 4 mg, comprimé à croquer	FI/H/0104/003	34009 393 111 8 0	ORGANON_FRANCE	FR
SINGULAIR 4 mg, comprimé à croquer	FI/H/0104/003	34009 393 112 4 1	ORGANON_FRANCE	FR
SINGULAIR 4 mg, comprimé à croquer	FI/H/0104/003	34009 393 113 0 2	ORGANON_FRANCE	FR
SINGULAIR 4 mg, comprimé à croquer	FI/H/0104/003	34009 393 114 7 0	ORGANON_FRANCE	FR
SINGULAIR 4 mg, comprimé à croquer	FI/H/0104/003	34009 393 115 3 1	ORGANON_FRANCE	FR
SINGULAIR 4 mg, comprimé à croquer	FI/H/0104/003	34009 393 117 6 0	ORGANON_FRANCE	FR

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SINGULAIR 4 mg, comprimé à croquer	FI/H/0104/003	34009 393 118 2 1	ORGANON_FRANCE	FR
SINGULAIR 4 mg, comprimé à croquer	FI/H/0104/003	34009 393 119 9 9	ORGANON_FRANCE	FR
SINGULAIR 4 mg, comprimé à croquer	FI/H/0104/003	34009 574 789 6 4	ORGANON_FRANCE	FR
SINGULAIR 4 mg, comprimé à croquer	FI/H/0104/003	34009 574 790 4 6	ORGANON_FRANCE	FR
SINGULAIR 4 mg, comprimé à croquer	FI/H/0104/003	34009 574 791 0 7	ORGANON_FRANCE	FR
SINGULAIR 4 mg, comprimé à croquer	FI/H/0104/003	34009 574 792 7 5	ORGANON_FRANCE	FR
SINGULAIR 4 mg, granulés	FI/H/0104/004	34009 393 120 7 1	ORGANON_FRANCE	FR
SINGULAIR 4 mg, granulés	FI/H/0104/004	34009 393 121 3 2	ORGANON_FRANCE	FR
SINGULAIR 4 mg, granulés	FI/H/0104/004	34009 393 123 6 1	ORGANON_FRANCE	FR
SINGULAIR 4 mg, granulés	FI/H/0104/004	34009 393 124 2 2	ORGANON_FRANCE	FR
SINGULAIR 5 mg, comprimé à croquer	FI/H/0104/002	34009 346 127 9 4	ORGANON_FRANCE	FR
SINGULAIR 5 mg, comprimé à croquer	FI/H/0104/002	34009 346 128 5 5	ORGANON_FRANCE	FR
SINGULAIR 5 mg, comprimé à croquer	FI/H/0104/002	34009 346 129 1 6	ORGANON_FRANCE	FR
SINGULAIR 5 mg, comprimé à croquer	FI/H/0104/002	34009 346 131 6 6	ORGANON_FRANCE	FR
SINGULAIR 5 mg, comprimé à croquer	FI/H/0104/002	34009 346 132 2 7	ORGANON_FRANCE	FR
SINGULAIR 5 mg, comprimé à croquer	FI/H/0104/002	34009 346 133 9 5	ORGANON_FRANCE	FR
SINGULAIR 5 mg, comprimé à croquer	FI/H/0104/002	34009 346 134 5 6	ORGANON_FRANCE	FR
SINGULAIR 5 mg, comprimé à croquer	FI/H/0104/002	34009 346 135 1 7	ORGANON_FRANCE	FR
SINGULAIR 5 mg, comprimé à croquer	FI/H/0104/002	34009 346 137 4 6	ORGANON_FRANCE	FR

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
SINGULAIR 5 mg, comprimé à croquer	FI/H/0104/002	34009 346 138 0 7	ORGANON_FRANCE	FR
SINGULAIR 5 mg, comprimé à croquer	FI/H/0104/002	34009 375 746 5 5	ORGANON_FRANCE	FR
SINGULAIR 5 mg, comprimé à croquer	FI/H/0104/002	34009 375 748 8 4	ORGANON_FRANCE	FR
SINGULAIR 5 mg, comprimé à croquer	FI/H/0104/002	34009 561 165 9 1	ORGANON_FRANCE	FR
SINGULAIR 5 mg, comprimé à croquer	FI/H/0104/002	34009 561 943 1 5	ORGANON_FRANCE	FR
Singulair 10 mg επικαλυμμένα με λεπτό υμένιο δισκία	FI/H/0104/001	47334/01-07-2011	VIANEX S.A.	GR
Singulair 4 mg μασώμενα δισκία	FI/H/0104/003	18586/17-02-2014	VIANEX S.A.	GR
Singulair 5 mg μασώμενα δισκία	FI/H/0104/002	47333/01-07-2011	VIANEX S.A.	GR
Singulair 10 mg filmom obložene tablete	not available	HR-H-556066749	ORGANON PHARMA DRUŠTVO S OGRANI?ENOM ODGOVORNOŠ?U ZA TRGOVINU I USLUGE	HR
Singulair junior 5 mg tablete za žvakanje	not available	HR-H-436317310	ORGANON PHARMA DRUŠTVO S OGRANI?ENOM ODGOVORNOŠ?U ZA TRGOVINU I USLUGE	HR
Singulair mini 4 mg oralne granule	not available	HR-H-490892692	ORGANON PHARMA DRUŠTVO S OGRANI?ENOM ODGOVORNOŠ?U ZA TRGOVINU I USLUGE	HR
Singulair mini 4 mg tablete za žvakanje	not available	HR-H-559814832	ORGANON PHARMA DRUŠTVO S OGRANI?ENOM ODGOVORNOŠ?U ZA TRGOVINU I USLUGE	HR
Singulair 10 mg filmtabletta	not available	OGYI-T-6680/01	ORGANON HUNGARY KFT.	HU
Singulair 4 mg granulátum	FI/H/0104/004	OGYI-T-6680/02	ORGANON HUNGARY KFT.	HU
Singulair Junior 5 mg	not available	OGYI-T-6680/06	ORGANON HUNGARY KFT.	HU

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rágótabletta				
Singulair Mini 4 mg rágótabletta	FI/H/0104/003	OGYI-T-6680/03	ORGANON HUNGARY KFT.	HU
Singulair Mini 4 mg rágótabletta	FI/H/0104/003	OGYI-T-6680/04	ORGANON HUNGARY KFT.	HU
Singulair Mini 4 mg rágótabletta	FI/H/0104/003	OGYI-T-6680/05	ORGANON HUNGARY KFT.	HU
SINGULAIR 10 mg film-coated tablets	FI/H/0104/001	PA23198/014/004	ORGANON PHARMA (IRELAND) LIMITED	IE
Singulair Paediatric 4 mg chewable tablets	FI/H/0104/003	PA23198/014/001	ORGANON PHARMA (IRELAND) LIMITED	IE
Singulair Paediatric 4 mg granules	FI/H/0104/004	PA23198/014/002	ORGANON PHARMA (IRELAND) LIMITED	IE
Singulair Paediatric 5 mg chewable tablets	FI/H/0104/002	PA 23198/014/003	ORGANON PHARMA (IRELAND) LIMITED	IE
Singulair 10 mg filmuhúðaðar töflur	not available	970103	N.V. ORGANON	IS
Singulair 4 mg tuggutöflur.	FI/H/0104/003	IS/1/02/102/01	N.V. ORGANON	IS
Singulair 5 mg tuggutöflur	not available	970102	N.V. ORGANON	IS
Lukasm 10 mg compresse rivestite con film	not available	034004010	ORGANON ITALIA S.R.L.	IT
Lukasm 4 mg compresse masticabili	not available	034004034	ORGANON ITALIA S.R.L.	IT
Lukasm 4 mg compresse masticabili	not available	034004046	ORGANON ITALIA S.R.L.	IT
Lukasm 4 mg compresse masticabili	not available	034004059	ORGANON ITALIA S.R.L.	IT
Lukasm 4 mg compresse masticabili	not available	034004061	ORGANON ITALIA S.R.L.	IT
Lukasm 4 mg compresse masticabili	not available	034004073	ORGANON ITALIA S.R.L.	IT
Lukasm 4 mg compresse masticabili	not available	034004085	ORGANON ITALIA S.R.L.	IT
Lukasm 4 mg compresse masticabili	not available	034004097	ORGANON ITALIA S.R.L.	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
Lukasm 4 mg compresse masticabili	not available	034004109	ORGANON ITALIA S.R.L.	IT
Lukasm 4 mg compresse masticabili	not available	034004111	ORGANON ITALIA S.R.L.	IT
Lukasm 4 mg compresse masticabili	not available	034004123	ORGANON ITALIA S.R.L.	IT
Lukasm 4 mg compresse masticabili	not available	034004135	ORGANON ITALIA S.R.L.	IT
Lukasm 4 mg compresse masticabili	not available	034004147	ORGANON ITALIA S.R.L.	IT
Lukasm 4 mg compresse masticabili	not available	034004150	ORGANON ITALIA S.R.L.	IT
Lukasm 4 mg compresse masticabili	not available	034004162	ORGANON ITALIA S.R.L.	IT
Lukasm 4 mg compresse masticabili	not available	034004174	ORGANON ITALIA S.R.L.	IT
Lukasm 4 mg compresse masticabili	not available	034004186	ORGANON ITALIA S.R.L.	IT
Lukasm 4 mg granulato	not available	034004198	ORGANON ITALIA S.R.L.	IT
Lukasm 4 mg granulato	not available	034004200	ORGANON ITALIA S.R.L.	IT
Lukasm 4 mg granulato	not available	034004212	ORGANON ITALIA S.R.L.	IT
Lukasm 4 mg granulato	not available	034004224	ORGANON ITALIA S.R.L.	IT
Lukasm 5 mg compresse masticabili	not available	034004022	ORGANON ITALIA S.R.L.	IT
Montegen 10 mg compresse rivestite con film.	not available	034003018	NEOPHARMED GENTILI SPA	IT
Montegen 4 mg compresse masticabili	not available	034003184	NEOPHARMED GENTILI SPA	IT
Montegen 4 mg compresse masticabili	not available	034003172	NEOPHARMED GENTILI SPA	IT
Montegen 4 mg compresse masticabili	not available	034003160	NEOPHARMED GENTILI SPA	IT
Montegen 4 mg compresse masticabili	not available	034003158	NEOPHARMED GENTILI SPA	IT
Montegen 4 mg compresse masticabili	not available	034003145	NEOPHARMED GENTILI SPA	IT
Montegen 4 mg	not available	034003133	NEOPHARMED GENTILI SPA	IT

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compresse masticabili				
Montegen 4 mg compresse masticabili	not available	034003121	NEOPHARMED GENTILI SPA	IT
Montegen 4 mg compresse masticabili	not available	034003119	NEOPHARMED GENTILI SPA	IT
Montegen 4 mg compresse masticabili	not available	034003107	NEOPHARMED GENTILI SPA	IT
Montegen 4 mg compresse masticabili	not available	034003057	NEOPHARMED GENTILI SPA	IT
Montegen 4 mg compresse masticabili	not available	034003095	NEOPHARMED GENTILI SPA	IT
Montegen 4 mg compresse masticabili	not available	034003083	NEOPHARMED GENTILI SPA	IT
Montegen 4 mg compresse masticabili	not available	034003071	NEOPHARMED GENTILI SPA	IT
Montegen 4 mg compresse masticabili	not available	034003069	NEOPHARMED GENTILI SPA	IT
Montegen 4 mg compresse masticabili	not available	034003044	NEOPHARMED GENTILI SPA	IT
Montegen 4 mg compresse masticabili	not available	034003032	NEOPHARMED GENTILI SPA	IT
Montegen 4 mg granulato	not available	034003210	NEOPHARMED GENTILI SPA	IT
Montegen 4 mg granulato	not available	034003222	NEOPHARMED GENTILI SPA	IT
Montegen 4 mg granulato	not available	034003208	NEOPHARMED GENTILI SPA	IT
Montegen 4 mg granulato	not available	034003196	NEOPHARMED GENTILI SPA	IT
Montegen 5 mg compresse masticabili	not available	034003020	NEOPHARMED GENTILI SPA	IT
Singulair 10 mg compresse rivestite con film	FI/H/0104/001	034001014	ORGANON ITALIA S.R.L.	IT
SINGULAIR 4 mg compresse masticabili	FI/H/0104/003	034001038	ORGANON ITALIA S.R.L.	IT
SINGULAIR 4 mg compresse masticabili	FI/H/0104/003	034001040	ORGANON ITALIA S.R.L.	IT

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SINGULAIR 4 mg compresse masticabili	FI/H/0104/003	034001053	ORGANON ITALIA S.R.L.	IT
SINGULAIR 4 mg compresse masticabili	FI/H/0104/003	034001065	ORGANON ITALIA S.R.L.	IT
SINGULAIR 4 mg compresse masticabili	FI/H/0104/003	034001077	ORGANON ITALIA S.R.L.	IT
SINGULAIR 4 mg compresse masticabili	FI/H/0104/003	034001089	ORGANON ITALIA S.R.L.	IT
SINGULAIR 4 mg compresse masticabili	FI/H/0104/003	034001091	ORGANON ITALIA S.R.L.	IT
SINGULAIR 4 mg compresse masticabili	FI/H/0104/003	034001103	ORGANON ITALIA S.R.L.	IT
SINGULAIR 4 mg compresse masticabili	FI/H/0104/003	034001115	ORGANON ITALIA S.R.L.	IT
SINGULAIR 4 mg compresse masticabili	FI/H/0104/003	034001127	ORGANON ITALIA S.R.L.	IT
SINGULAIR 4 mg compresse masticabili	FI/H/0104/003	034001139	ORGANON ITALIA S.R.L.	IT
SINGULAIR 4 mg compresse masticabili	FI/H/0104/003	034001141	ORGANON ITALIA S.R.L.	IT
SINGULAIR 4 mg compresse masticabili	FI/H/0104/003	034001154	ORGANON ITALIA S.R.L.	IT
SINGULAIR 4 mg compresse masticabili	FI/H/0104/003	034001166	ORGANON ITALIA S.R.L.	IT
SINGULAIR 4 mg compresse masticabili	FI/H/0104/003	034001178	ORGANON ITALIA S.R.L.	IT
SINGULAIR 4 mg compresse masticabili	FI/H/0104/003	034001180	ORGANON ITALIA S.R.L.	IT
SINGULAIR 4 mg granulato	FI/H/0104/004	034001192	ORGANON ITALIA S.R.L.	IT
SINGULAIR 4 mg granulato	FI/H/0104/004	034001204	ORGANON ITALIA S.R.L.	IT
SINGULAIR 4 mg granulato	FI/H/0104/004	034001216	ORGANON ITALIA S.R.L.	IT
SINGULAIR 4 mg granulato	FI/H/0104/004	034001228	ORGANON ITALIA S.R.L.	IT
Singulair 5 mg compresse masticabili	FI/H/0104/002	034001026	ORGANON ITALIA S.R.L.	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
Singulair 10 mg comprimés pelliculés	FI/H/0104/001	2008099927	ORGANONBELGIUM	LU
Singulair 4 mg comprimés à croquer	FI/H/0104/003	2008099925	ORGANONBELGIUM	LU
Singulair 4 mg granulés	FI/H/0104/004	2008099928	ORGANONBELGIUM	LU
Singulair 5 mg comprimés à croquer	FI/H/0104/002	2008099926	ORGANONBELGIUM	LU
Singulair mini 4 mg granulas	FI/H/0104/004	02-0351	N.V. ORGANON	LV
Singulair 10 mg filmomhulde tabletten	FI/H/0104/001	RVG 23164	N.V. ORGANON	NL
Singulair 4 mg granulaat	FI/H/0104/004	RVG 104604	N.V. ORGANON	NL
Singulair 4 mg kauwtabletten	FI/H/0104/003	RVG 25800	N.V. ORGANON	NL
Singulair 5 mg kauwtabletten	FI/H/0104/002	RVG 23165	N.V. ORGANON	NL
Singulair 10 mg tabletter, filmdrasjerte	not available	97-1192	N.V. ORGANON	NO
Singulair 4 mg granulát	FI/H/0104/004	02-1421	N.V. ORGANON	NO
Singulair 4 mg tyggetabletter	FI/H/0104/003	00-6225	N.V. ORGANON	NO
Singulair 5 mg tyggetabletter	not available	97-1193	N.V. ORGANON	NO
Singulair 10, 10 mg, tabletki powlekane	not available	7957	ORGANON POLSKA SP. Z O.O.	PL
Singulair 4, 4 mg, tabletki do rozgryzania i żucia	FI/H/0104/003	8780	ORGANON POLSKA SP. Z O.O.	PL
Singulair 5, 5 mg, tabletki do rozgryzania i żucia	not available	7956	ORGANON POLSKA SP. Z O.O.	PL
Singulair 10 mg comprimidos revestidos por película	FI/H/0104/001	2639680	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
Singulair 10 mg comprimidos revestidos por película	FI/H/0104/001	2639789	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
Singulair 10 mg	FI/H/0104/001	2639888	ORGANONPORTUGAL,	PT

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
comprimidos revestidos por película			SOCIEDADE UNIPESSOAL LDA.	
Singulair 10 mg comprimidos revestidos por película	FI/H/0104/001	3628989	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
Singulair 10 mg comprimidos revestidos por película	FI/H/0104/001	3629086	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
Singulair 10 mg comprimidos revestidos por película	FI/H/0104/001	3629185	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
Singulair 10 mg comprimidos revestidos por película	FI/H/0104/001	3629284	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
Singulair 10 mg comprimidos revestidos por película	FI/H/0104/001	3629383	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
Singulair 10 mg comprimidos revestidos por película	FI/H/0104/001	3629482	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
Singulair 10 mg comprimidos revestidos por película	FI/H/0104/001	3629581	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
Singulair 10 mg comprimidos revestidos por película	FI/H/0104/001	3629680	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
Singulair 10 mg comprimidos revestidos por película	FI/H/0104/001	3629789	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
Singulair 10 mg comprimidos revestidos por película	FI/H/0104/001	3629888	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
Singulair 10 mg comprimidos revestidos por película	FI/H/0104/001	3629987	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
Singulair 10 mg comprimidos revestidos por película	FI/H/0104/001	3630084	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
Singulair 10 mg	FI/H/0104/001	3630183	ORGANONPORTUGAL,	PT

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
comprimidos revestidos por película			SOCIEDADE UNIPESSOAL LDA.	
SINGULAIR 4 mg comprimidos para mastigar	FI/H/0104/003	3502283	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 4 mg comprimidos para mastigar	FI/H/0104/003	3502382	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 4 mg comprimidos para mastigar	FI/H/0104/003	3502481	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 4 mg comprimidos para mastigar	FI/H/0104/003	3502580	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 4 mg comprimidos para mastigar	FI/H/0104/003	3502689	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 4 mg comprimidos para mastigar	FI/H/0104/003	3502788	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 4 mg comprimidos para mastigar	FI/H/0104/003	3502887	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 4 mg comprimidos para mastigar	FI/H/0104/003	3502986	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 4 mg comprimidos para mastigar	FI/H/0104/003	3503083	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 4 mg comprimidos para mastigar	FI/H/0104/003	3503182	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 4 mg comprimidos para mastigar	FI/H/0104/003	3503281	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 4 mg comprimidos para mastigar	FI/H/0104/003	3503380	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 4 mg	FI/H/0104/003	3503489	ORGANONPORTUGAL,	PT

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
comprimidos para mastigar			SOCIEDADE UNIPESSOAL LDA.	
SINGULAIR 4 mg comprimidos para mastigar	FI/H/0104/003	3503588	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 4 mg comprimidos para mastigar	FI/H/0104/003	3503687	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 4 mg comprimidos para mastigar	FI/H/0104/003	3503786	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 4 mg granulado	FI/H/0104/004	4314589	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 4 mg granulado	FI/H/0104/004	4314688	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 4 mg granulado	FI/H/0104/004	4314787	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 4 mg granulado	FI/H/0104/004	4314886	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 5 mg comprimidos para mastigar	FI/H/0104/002	2639987	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 5 mg comprimidos para mastigar	FI/H/0104/002	2640084	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 5 mg comprimidos para mastigar	FI/H/0104/002	2640183	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 5 mg comprimidos para mastigar	FI/H/0104/002	3630282	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 5 mg comprimidos para mastigar	FI/H/0104/002	3630381	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 5 mg	FI/H/0104/002	3630480	ORGANONPORTUGAL,	PT

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
comprimidos para mastigar			SOCIEDADE UNIPESSOAL LDA.	
SINGULAIR 5 mg comprimidos para mastigar	FI/H/0104/002	3630589	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 5 mg comprimidos para mastigar	FI/H/0104/002	3630688	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 5 mg comprimidos para mastigar	FI/H/0104/002	3630787	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 5 mg comprimidos para mastigar	FI/H/0104/002	3630886	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 5 mg comprimidos para mastigar	FI/H/0104/002	3630985	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 5 mg comprimidos para mastigar	FI/H/0104/002	3631082	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 5 mg comprimidos para mastigar	FI/H/0104/002	3631181	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 5 mg comprimidos para mastigar	FI/H/0104/002	3631280	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 5 mg comprimidos para mastigar	FI/H/0104/002	3631389	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
SINGULAIR 5 mg comprimidos para mastigar	FI/H/0104/002	3631488	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
Singulair 10 mg comprimate filmate	not available	10455/2017/01	ORGANON BIOSCIENCES S.R.L.	RO
Singulair 10 mg comprimate filmate	not available	10455/2017/02	ORGANON BIOSCIENCES S.R.L.	RO
Singulair 4 mg comprimate masticabile	FI/H/0104/003	4718/2012/01	ORGANON BIOSCIENCES S.R.L.	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
Singulair 4 mg comprimate masticabile	FI/H/0104/003	4718/2012/02	ORGANON BIOSCIENCES S.R.L.	RO
Singulair 4 mg comprimate masticabile	FI/H/0104/003	4718/2012/03	ORGANON BIOSCIENCES S.R.L.	RO
Singulair 4 mg comprimate masticabile	FI/H/0104/003	4718/2012/04	ORGANON BIOSCIENCES S.R.L.	RO
Singulair 4 mg comprimate masticabile	FI/H/0104/003	4718/2012/05	ORGANON BIOSCIENCES S.R.L.	RO
Singulair 4 mg comprimate masticabile	FI/H/0104/003	4718/2012/06	ORGANON BIOSCIENCES S.R.L.	RO
Singulair 4 mg comprimate masticabile	FI/H/0104/003	4718/2012/07	ORGANON BIOSCIENCES S.R.L.	RO
Singulair 4 mg comprimate masticabile	FI/H/0104/003	4718/2012/08	ORGANON BIOSCIENCES S.R.L.	RO
Singulair 4 mg comprimate masticabile	FI/H/0104/003	4718/2012/09	ORGANON BIOSCIENCES S.R.L.	RO
Singulair 4 mg comprimate masticabile	FI/H/0104/003	4718/2012/10	ORGANON BIOSCIENCES S.R.L.	RO
Singulair 4 mg comprimate masticabile	FI/H/0104/003	4718/2012/11	ORGANON BIOSCIENCES S.R.L.	RO
Singulair 4 mg comprimate masticabile	FI/H/0104/003	4718/2012/12	ORGANON BIOSCIENCES S.R.L.	RO
Singulair 4 mg comprimate masticabile	FI/H/0104/003	4718/2012/13	ORGANON BIOSCIENCES S.R.L.	RO
Singulair 4 mg comprimate masticabile	FI/H/0104/003	4718/2012/14	ORGANON BIOSCIENCES S.R.L.	RO
Singulair 4 mg comprimate masticabile	FI/H/0104/003	4718/2012/15	ORGANON BIOSCIENCES S.R.L.	RO
Singulair 4 mg granule	FI/H/0104/004	7309/2015/01	ORGANON BIOSCIENCES S.R.L.	RO
Singulair 4 mg granule	FI/H/0104/004	7309/2015/02	ORGANON BIOSCIENCES S.R.L.	RO
Singulair 4 mg granule	FI/H/0104/004	7309/2015/03	ORGANON BIOSCIENCES S.R.L.	RO
Singulair 4 mg granule	FI/H/0104/004	7309/2015/04	ORGANON BIOSCIENCES S.R.L.	RO
Singulair 5 mg comprimate masticabile	not available	10454/2017/01	ORGANON BIOSCIENCES S.R.L.	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
Singulair 5 mg comprimate masticabile	not available	10454/2017/02	ORGANON BIOSCIENCES S.R.L.	RO
Singulair 10 mg filmdragerade tabletter	FI/H/0104/001	13945	N.V. ORGANON	SE
Singulair 4 mg granulater	FI/H/0104/004	18853	N.V. ORGANON	SE
Singulair 4 mg tuggtabletter	FI/H/0104/003	16596	N.V. ORGANON	SE
Singulair 5 mg tuggtabletter	FI/H/0104/002	13944	N.V. ORGANON	SE
Singulair 10 mg filmsko obložene tablete	not available	H/99/02277/003	N.V. ORGANON	SI
Singulair 10 mg filmsko obložene tablete	not available	H/99/02277/004	N.V. ORGANON	SI
Singulair 4 mg zrnca	FI/H/0104/004	H/03/01424/001	N.V. ORGANON	SI
Singulair 4 mg zrnca	FI/H/0104/004	H/03/01424/002	N.V. ORGANON	SI
Singulair 4 mg zrnca	FI/H/0104/004	H/03/01424/003	N.V. ORGANON	SI
Singulair 4 mg zrnca	FI/H/0104/004	H/03/01424/004	N.V. ORGANON	SI
Singulair 4 mg žvečljive tablete	FI/H/0104/003	H/03/01424/005	N.V. ORGANON	SI
Singulair 4 mg žvečljive tablete	FI/H/0104/003	H/03/01424/006	N.V. ORGANON	SI
Singulair 4 mg žvečljive tablete	FI/H/0104/003	H/03/01424/007	N.V. ORGANON	SI
Singulair 4 mg žvečljive tablete	FI/H/0104/003	H/03/01424/008	N.V. ORGANON	SI
Singulair 4 mg žvečljive tablete	FI/H/0104/003	H/03/01424/009	N.V. ORGANON	SI
Singulair 4 mg žvečljive tablete	FI/H/0104/003	H/03/01424/010	N.V. ORGANON	SI
Singulair 4 mg žvečljive tablete	FI/H/0104/003	H/03/01424/011	N.V. ORGANON	SI
Singulair 4 mg žvečljive tablete	FI/H/0104/003	H/03/01424/012	N.V. ORGANON	SI
Singulair 4 mg žvečljive tablete	FI/H/0104/003	H/03/01424/013	N.V. ORGANON	SI
Singulair 4 mg žvečljive tablete	FI/H/0104/003	H/03/01424/014	N.V. ORGANON	SI
Singulair 4 mg žvečljive tablete	FI/H/0104/003	H/03/01424/015	N.V. ORGANON	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
tablete				
Singulair 4 mg žvečljive tablete	FI/H/0104/003	H/03/01424/016	N.V. ORGANON	SI
Singulair 4 mg žvečljive tablete	FI/H/0104/003	H/03/01424/017	N.V. ORGANON	SI
Singulair 4 mg žvečljive tablete	FI/H/0104/003	H/03/01424/018	N.V. ORGANON	SI
Singulair 4 mg žvečljive tablete	FI/H/0104/003	H/03/01424/019	N.V. ORGANON	SI
Singulair 4 mg žvečljive tablete	FI/H/0104/003	H/03/01424/020	N.V. ORGANON	SI
Singulair 5 mg žvečljive tablete	not available	H/99/02277/001	N.V. ORGANON	SI
Singulair 5 mg žvečljive tablete	not available	H/99/02277/002	N.V. ORGANON	SI
Montelukast Organon 10 mg filmom obalené tablet	not available	14/0175/11-S	N.V. ORGANON	SK
Montelukast Organon 4 mg žuvacie tablety	FI/H/0735/	14/0662/10-S	N.V. ORGANON	SK
Montelukast Organon 5 mg žuvacie tablet	not available	14/0174/11-S	N.V. ORGANON	SK
Singulair 4 mg granulát	FI/H/0104/004	14/0039/09-S	N.V. ORGANON	SK
Almus Pharmaceuticals Montelukast 4mg Chewable Tablets	not available	PL 17907 / 0475	BRISTOL LABORATORIES LIMITED	XI
Almus Pharmaceuticals Montelukast 5mg Chewable Tablets	not available	PL 17907/0476	BRISTOL LABORATORIES LIMITED	XI
Montelukast 10mg film-coated tablets	not available	PL 17907/0474	BRISTOL LABORATORIES LIMITED	XI
Montelukast 10mg film-coated tablets	not available	PL 20416/0547	CRESCENT PHARMA LIMITED	XI
Montelukast Paediatric 4mg Chewable Tablets	not available	PL 17907 / 0475	BRISTOL LABORATORIES LIMITED	XI
Montelukast Paediatric 5mg Chewable Tablets	not available	PL 17907/0476	BRISTOL LABORATORIES LIMITED	XI

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
SINGULAIR® 10 mg Film-coated Tablets	not available	PL 00025/0358	ORGANON PHARMA (UK) LIMITED	XI
SINGULAIR® Paediatric 4 mg Chewable Tablets	not available	PL 00025/0412	ORGANON PHARMA (UK) LIMITED	XI
SINGULAIR® Paediatric 4 mg Granules	not available	PL 00025/0440	ORGANON PHARMA (UK) LIMITED	XI
SINGULAIR® Paediatric 5 mg Chewable Tablets	not available	PL 00025/0357	ORGANON PHARMA (UK) LIMITED	XI