



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 June 2018
EMA/418958/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: atovaquone / proguanil

Procedure no.: PSUSA/00000266/201710



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
Malarone 250 mg/100 mg film-coated tablets	not available	AA167/01801	GLAXO WELLCOME UK LIMITED	MT
Malarone Paediatric, 62,5 mg/25 mg õhukese polümeerikattega tabletid	UK/H/0558/001	425603	GLAXO GROUP LIMITED	EE
Malarone, 250 mg/100 mg õhukese polümeerikattega tabletid	not available	425503	GLAXO GROUP LIMITED	EE
Malarone, filmovertrukne tabletter	not available	19361	GLAXOSMITHKLINE PHARMA A/S	DK
Malarone, filmovertrukne tabletter	not available	33576	GLAXOSMITHKLINE PHARMA A/S	DK
MALARONE 250 mg/100 mg, comprime pellicule	not available	NL22479	LABORATOIRE GLAXOSMITHKLINE	FR
MALARONE 62,5 mg/25 mg ENFANTS, comprimé pelliculé	not available	NL27585	LABORATOIRE GLAXOSMITHKLINE	FR
ATOVAQUONE/PROGUANIL ZENTIVA 62,5 mg/25 mg ENFANTS, comprimé pelliculé	not available	NL42884	LABORATOIRE GLAXOSMITHKLINE	FR
ATOVAQUONE/PROGUANIL BIOGARAN 250 mg / 100 mg, comprimé pelliculé	not available	NL42822	LABORATOIRE GLAXOSMITHKLINE	FR
ATOVAQUONE/PROGUANIL BIOGARAN 62,5 mg / 25 mg ENFANTS, comprimé pelliculé	not available	NL42821	LABORATOIRE GLAXOSMITHKLINE	FR
ATOVAQUONE/PROGUANIL ZENTIVA 250 mg/100 mg, comprimé pelliculé	not available	NL42885	LABORATOIRE GLAXOSMITHKLINE	FR
Malarone Junior 62,5 mg/25 mg comprimés pelliculés	UK/H/170/002	BE 248473	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE

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
Malarone 250 mg/100 mg film-coated tablets	not available	AA167/01801	GLAXO WELLCOME UK LIMITED	MT
Malarone Paediatric, 62,5 mg/25 mg õhukese polümeerikattega tabletid	UK/H/0558/001	425603	GLAXO GROUP LIMITED	EE
Malarone? Junior Filmtabletten 62,5 mg/25 mg Filmtabletten	UK/H/0170/002	40274.01.00	GLAXOSMITHKLINE GMBH & CO. KG	DE
Malarone Παιδιατρικό Δισκίο	UK/H/170/002	2487502	GLAXOSMITHKLINE AEBE	GR
MALARONE Bambini 62,5 mg/25 mg compresse rivestite con film	UK/H/170/002	033299037	GLAXOSMITHKLINE S.P.A.	IT
Malarone Junior 62,5 mg/25 mg comprimés pelliculés	UK/H/170/002	260/09 04 0395	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Malarone Junior 62,5/25 mg filmomhulde tabletten	UK/H/170/002	RVG 28319	GLAXOSMITHKLINE B.V.	NL
Malarone Junior 62,5 mg/25 mg filmdrasjerte tabletter	UK/H/0170/002	02-1376	GLAXOSMITHKLINE AS	NO
Malarone Pediátrico 62,5 mg/25 mg comprimidos recubiertos con película	UK/H/170/002	65.257	GLAXOSMITHKLINE S.A.	ES
Malarone Junior 62,5/25 mg filmdragerade tabletter	UK/H/0170/002	18805	GLAXOSMITHKLINE AB	SE
Malarone paediatric 62.5mg/25 mg film-coated tablets	UK/H/0170/002	PL 10949/0363	GLAXO WELLCOME UK LTD TRADING AS GLAXOSMITHKLINE UK	UK
Malarone 250 mg/100 mg filmdragerade tabletter	UK/H/170/001	21375	GLAXOSMITHKLINE OY	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
Malarone 250 mg/100 mg film-coated tablets	not available	AA167/01801	GLAXO WELLCOME UK LIMITED	MT
Malarone Paediatric, 62,5 mg/25 mg õhukese polümeerikattega tabletid	UK/H/0558/001	425603	GLAXO GROUP LIMITED	EE
MALARONE 250 mg/100 mg filmomhulde tabletten	UK/H/0170/001	BE 186821	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Malarone 250 mg/100 mg Filmtabletten	UK/H/170/001	BE 186821	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Malarone Junior 62,5 mg/25 mg filmomhulde tabletten	UK/H/170/002	BE248473	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Malarone Junior 62,5 mg/25 mg Filmtabletten	UK/H/0170/002	BE 248473	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Malarone Junior 62,5 mg/25 mg Filmtabletten	UK/H/170/002	260/09 04 0395	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Malarone 250 mg/100 mg Filmtabletten	UK/H/170/001	0260/09/04/0394	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
MALARONE 250 mg/100 mg filmsko obložene tablete	UK/H/170/001	H/06/00962/001	GLAXOSMITHKLINE D.O.O.	SI
Malarone 250 mg/100 mg Filmtabletten	UK/H/170/001	1-21997	GLAXOSMITHKLINE PHARMA GMBH.	AT
MALARONE 250 mg/100 mg comprimés pelliculés	UK/H/170/001	BE 186821	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Malarone, potahované tablety 250 mg/100 mg	UK/H/0170/001	25/547/05-C	GLAXO WELLCOME UK LTD	CZ
Malarone 250 mg/100 mg tabletti, kalvopäällysteinen	UK/H/170/001	21375	GLAXOSMITHKLINE OY	FI
Malarone® Filmtabletten 250 mg/100 mg Filmtabletten	UK/H/170/001	40274.00.00	GLAXOSMITHKLINE GMBH & CO. KG	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
Malarone 250 mg/100 mg film-coated tablets	not available	AA167/01801	GLAXO WELLCOME UK LIMITED	MT
Malarone Paediatric, 62,5 mg/25 mg ðhukese polümeerikattega tabletid	UK/H/0558/001	425603	GLAXO GROUP LIMITED	EE
Malarone επικαλυμμένα με λεπτό υμένιο δισκία 250 mg/100 mg	UK/H/170/001	2487501	GLAXOSMITHKLINE AEBE	GR
Malarone 250 mg/100 mg filmtabletta	UK/H/170/001	OGYI-T-20107/01	GLAXOSMITHKLINE KFT.	HU
Malarone 250 mg/100 mg filmuhúðaðar töflur	UK/H/0170/001	IS/1/05/054/01	GLAXOSMITHKLINE PHARMA A/S	IS
Malarone 250 mg/100 mg film-coated tablets	UK/H/0170/001	PA 1077/111/1	GLAXOSMITHKLINE (IRELAND) LIMITED	IE
MALARONE 250 mg/100 mg compresse rivestite con film	UK/H/170/001	033299013	GLAXOSMITHKLINE S.P.A.	IT
Malarone 250 mg/100 mg apvalkotās tabletes	UK/H/170/001	06-0013	GLAXOSMITHKLINE LATVIA SIA	LV
Malarone 250 mg/100 mg plėvele dengtos tabletės	UK/H/170/001	LT/1/06/0441/001	GLAXOSMITHKLINE LIETUVA UAB	LT
MALARONE 250 mg/100 mg comprimés pelliculés	UK/H/170/001	2009 04 0394	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Malarone 250/100 mg filmomhulde tabletten	UK/H/170/001	RVG 25386	GLAXOSMITHKLINE B.V.	NL
Malarone 250 mg/100 mg filmdrasjerte tabletter	UK/H/170/001	00-1938	GLAXOSMITHKLINE AS	NO
Malarone, 250 mg + 100 mg, tabletki powlekane	UK/H/0170/001	12142	GLAXOSMITHKLINE EXPORT LTD	PL
Malarone 250 mg/100 mg comprimidos revestidos por película	UK/H/0170/001	5692587	GLAXOSMITHKLINE - PRODUTOS FARMACEUTICOS, LDA	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
Malarone 250 mg/100 mg film-coated tablets	not available	AA167/01801	GLAXO WELLCOME UK LIMITED	MT
Malarone Paediatric, 62,5 mg/25 mg õhukese polümeerikattega tabletid	UK/H/0558/001	425603	GLAXO GROUP LIMITED	EE
Malarone 250 mg/100 mg filmom obalené tablety	UK/H/0170/001	25/0127/06-S	GLAXO GROUP LIMITED	SK
Malarone 250 mg/100 mg comprimidos recubiertos con película	UK/H/170/001	63452	GLAXOSMITHKLINE S.A.	ES
Malarone 250 mg/100 mg filmdragerade tabletter	UK/H/0170/001	13488	GLAXOSMITHKLINE AB	SE
Malarone 250 mg/100 mg film-coated tablets	UK/H/0170/001	PL 10949/0258	GLAXO WELLCOME UK LTD TRADING AS GLAXOSMITHKLINE UK	UK
Malarone 250 mg/100 mg film-coated tablets	not available	AA167/01801	GLAXO WELLCOME UK LIMITED	MT
Malarone Paediatric, 62,5 mg/25 mg õhukese polümeerikattega tabletid	UK/H/0558/001	425603	GLAXO GROUP LIMITED	EE
Malarone, 250 mg/100 mg õhukese polümeerikattega tabletid	not available	425503	GLAXO GROUP LIMITED	EE
Malarone, filmovertrukne tabletter	not available	19361	GLAXOSMITHKLINE PHARMA A/S	DK
Malarone, filmovertrukne tabletter	not available	33576	GLAXOSMITHKLINE PHARMA A/S	DK
MALARONE 250 mg/100 mg, comprime pellicule	not available	NL22479	LABORATOIRE GLAXOSMITHKLINE	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
Malarone 250 mg/100 mg film-coated tablets	not available	AA167/01801	GLAXO WELLCOME UK LIMITED	MT
Malarone Paediatric, 62,5 mg/25 mg õhukese polümeerikattega tabletid	UK/H/0558/001	425603	GLAXO GROUP LIMITED	EE
MALARONE 62,5 mg/25 mg ENFANTS, comprimé pelliculé	not available	NL27585	LABORATOIRE GLAXOSMITHKLINE	FR