



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

08 June 2023
EMA/74537/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): atovaquone / proguanil

Procedure No. PSUSA/00000266/202210



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 Filmtabletten	DE/H/6220/001	1-21997	GLAXOSMITHKLINE PHARMA GMBH.	AT
Malarone Junior 62,5 mg/25 mg comprimés pelliculés.	UK/H/170/002	BE 248473	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
MALARONE 250 mg/100 mg filmomhulde tabletten	DE/H/6220/001	BE 186821	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Malarone 250 mg/100 mg Filmtabletten	DE/H/6220/001	BE 186821	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Malarone Junior 62,5 mg/25 mg filmomhulde tabletten	DE/H/6220/002	BE248473	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Malarone Junior 62,5 mg/25 mg Filmtabletten	UK/H/0170/002	BE 248473	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
MALARONE 250 mg/100 mg comprimés pelliculés	DE/H/6220/001	BE 186821	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Malarone 250 mg/100 mg potahované tablety	DE/H/6220/001	25/547/05-C	GLAXOSMITHKLINE (IRELAND) LIMITED	CZ
Malarone? Junior Filmtabletten 62,5 mg/25 mg Filmtabletten	DE/H/6220/002	40274.01.00	GLAXOSMITHKLINE GMBH & CO. KG	DE
Malarone Filmtabletten 250 mg/100 mg Filmtabletten	DE/H/6220/001	40274.00.00	GLAXOSMITHKLINE GMBH & CO. KG	DE
Malarone	not available	19361	GLAXOSMITHKLINE PHARMA A/S	DK
Malarone	not available	33576	GLAXOSMITHKLINE PHARMA A/S	DK
Malarone Paediatric, 62,5 mg/25 mg õhukese polümeerikattega tabletid	not available	425603	GLAXOSMITHKLINE (IRELAND) LIMITED	EE
Malarone, 250 mg/100 mg õhukese	not available	425503	GLAXOSMITHKLINE (IRELAND) LIMITED	EE

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polümeerikattega tabletid				
Malarone Pediátrico 62,5 mg/25 mg comprimidos recubiertos con película	DE/H/6220/002	65.257	GLAXOSMITHKLINE S.A.	ES
Malarone 250 mg/100 mg comprimidos recubiertos con película	DE/H/6220/001	63452	GLAXOSMITHKLINE S.A.	ES
Malarone 250 mg/100 mg filmdragerade tabletter	DE/H/6220/001	21375	GLAXOSMITHKLINE OY	FI
Malarone 250 mg/100 mg tabletti, kalvopäällysteinen	DE/H/6220/001	21375	GLAXOSMITHKLINE OY	FI
ATOVAQUONE/PROGUAN IL ZENTIVA 62,5 mg/25 mg ENFANTS, comprimé pelliculé	not available	NL42884	LABORATOIRE GLAXOSMITHKLINE	FR
ATOVAQUONE/PROGUAN IL ZENTIVA 250 mg/100 mg, comprimé pelliculé	not available	NL42885	LABORATOIRE GLAXOSMITHKLINE	FR
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/PROGUAN ILBIOGARAN 250 mg / 100 mg, comprimé pelliculé	not available	NL42822	LABORATOIRE GLAXOSMITHKLINE	FR
ATOVAQUONE/PROGUAN ILBIOGARAN 62,5 mg / 25 mg ENFANTS, comprimé pelliculé	not available	NL42821	LABORATOIRE GLAXOSMITHKLINE	FR
Malarone Παιδιατρικό Δισκίο	DE/H/6220/002	2487502	GLAXOSMITHKLINE SINGLE MEMBER A.E.B.E.	GR
Malarone επικαλυμμένα με λεπτό υμένιο δισκία	DE/H/6220/001	2487501	GLAXOSMITHKLINE SINGLE MEMBER A.E.B.E.	GR

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250 mg/100 mg				
Malarone 250 mg/100 mg filmtabletta	DE/H/6220/001	OGYI-T-20107/01	GLAXOSMITHKLINE TRADING SERVICES LIMITED	HU
Malarone 250 mg/100 mg film-coated tablets	DE/H/6220/001	PA 1077/111/1	GLAXOSMITHKLINE (IRELAND) LIMITED	IE
Malarone 250 mg/100 mg filmuhúðaðar töflur	DE/H/6220/001	IS/1/05/054/01	GLAXOSMITHKLINE PHARMA A/S	IS
MALARONE Bambini 62,5 mg/25 mg compresse rivestite con film	DE/H/6220/002	033299037	GLAXOSMITHKLINE S.P.A.	IT
MALARONE 250 mg/100 mg compresse rivestite con film	DE/H/6220/001	033299013	GLAXOSMITHKLINE S.P.A.	IT
Malarone 250 mg/100 mg plevele dengtos tabletės	DE/H/6220/001	LT/1/06/0441/001	GLAXOSMITHKLINE TRADING SERVICES LIMITED	LT
Malarone Junior 62,5 mg/25 mg comprimés pelliculés.	UK/H/170/002	0260/09/04/0395	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Malarone Junior 62,5 mg/25 mg Filmtabletten	UK/H/170/002	0260/09/04/0395	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Malarone 250 mg/100 mg Filmtabletten	UK/H/170/001	2009 04 0394	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
MALARONE 250 mg/100 mg comprimés pelliculés	DE/H/6220/001	2009 04 0394	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Malarone 250 mg/100 mg apvalkotās tabletēs	DE/H/6220/001	06-0013	GLAXOSMITHKLINE TRADING SERVICES LIMITED	LV
Malarone 250 mg/100 mg film-coated tablets	DE/H/6220/001	MA192/04401	GLAXOSMITHKLINE (IRELAND) LIMITED	MT
Malarone Junior 62,5/25 mg filmomhulde tabletten	DE/H/6220/002	RVG 28319	GLAXOSMITHKLINE B.V.	NL
Malarone 250/100 mg filmomhulde tabletten	DE/H/6220/001	RVG 25386	GLAXOSMITHKLINE B.V.	NL
Malarone Junior 62,5 mg/25 mg filmdrasjerte	DE/H/6220/002	02-1376	GLAXOSMITHKLINE AS	NO

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tabletter				
Malarone 250 mg/100 mg filmdrasjerte tabletter	DE/H/6220/001	00-1938	GLAXOSMITHKLINE AS	NO
Malarone, 250 mg + 100 mg, tabletki powlekane	DE/H/6220/001	12142	GLAXOSMITHKLINE (IRELAND) LIMITED	PL
Malarone 250 mg/100 mg comprimidos revestidos por película	DE/H/6220/001	5692587	GLAXOSMITHKLINE - PRODUTOS FARMACEUTICOS, LDA	PT
Malarone Junior 62,5/25 mg filmdragerade tabletter	DE/H/6220/002	18805	GLAXOSMITHKLINE AB	SE
MALARONE 250 mg/100 mg filmsko obložene tablete	DE/H/6220/001	H/06/00962/001	GLAXOSMITHKLINE TRADING SERVICES LIMITED	SI
Malarone 250 mg/100 mg filmom obalené tablety	DE/H/6220/001	25/0127/06-S	GLAXOSMITHKLINE (IRELAND) LIMITED	SK