



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2024
EMA/CHMP/544052/2024
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): amiodarone

Procedure No. PSUSA/00000166/202312



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
Cordarone, 200 mg, comprimidos	not available	8287623	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Cordarone, 200 mg, comprimidos	not available	8287607	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Cordarone, 200 mg, comprimidos	not available	4590584	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Cordarone 150 mg/3 ml solução injetável	not available	8468009	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Cordarone, 200 mg, comprimidos	not available	5723150	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Cordarone 50 mg/ml injektionsvätska, lösning	not available	10572	SANOFI AB	SE
Cordarone 100 mg tablett	not available	11032	SANOFI AB	SE
Cordarone 200 mg tablett	not available	10656	SANOFI AB	SE
Cordarone 50 mg/ml injektionsvätska, lösning	not available	10572	SANOFI AB	SE
Cordarone 200 mg, tabletid	not available	311400	SANOFI WINTHROP INDUSTRIE	EE
CORDARONE 150 mg/3 ml solution injectable	not available	0025030	SANOFI BELGIUM	LU
CORDARONE 200 mg comprimés	not available	0024999	SANOFI BELGIUM	LU
CORDARONE 200 mg comprimés	not available	0025013	SANOFI BELGIUM	LU
CORDARONE 150 mg/3 ml solution injectable	not available	0571805	SANOFI BELGIUM	LU
CORDARONE 200 mg comprimés	not available	0025027	SANOFI BELGIUM	LU
CORDARONE 200 mg comprimés	not available	0893082	SANOFI BELGIUM	LU
Cordarone 200 mg comprimato	not available	11070/2018/02	SANOFI ROMANIA SRL	RO
Cordarone 200 mg comprimato	not available	11070/2018/01	SANOFI ROMANIA SRL	RO
Amiodarone hydrochloride 200 mg tablets	not available	PL 17780/0587	ZENTIVA PHARMA UK LIMITED	XI
Cordarone X 200 mg tablets	not available	PL	ZENTIVA PHARMA UK 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
		17780/0587		
Amiodarone Hydrochloride 20 mg/ml solution for infusion	NL/H/4955/001/DC	PL 01502/0113	HAMELN PHARMA LTD	XI
Amiodaron hameln 20 mg/ml oldatos infúzió	NL/H/4955/001/DC	OGYI-T-23345/03	HAMELN PHARMA GMBH	HU
Amiodaron hameln 20 mg/ml oldatos infúzió	NL/H/4955/001/DC	OGYI-T-23345/04	HAMELN PHARMA GMBH	HU
Amiodaron HCl hameln 20 mg/ml, oplossing voor infusie	NL/H/4955/001	RVG 125827	HAMELN PHARMA GMBH	NL
Amiodaronklorid hameln 20 mg/ml otopina za infuziju	NL/H/4955/001/DC	HR-H-475814519-01	HAMELN PHARMA GMBH	HR
Amiodaronklorid hameln 20 mg/ml otopina za infuziju	NL/H/4955/001/DC	HR-H-475814519-02	HAMELN PHARMA GMBH	HR
Amiodaronklorid hameln 20 mg/ml otopina za infuziju	NL/H/4955/001/DC	HR-H-475814519-03	HAMELN PHARMA GMBH	HR
Amiodaron hameln 20 mg/ml infuzní roztok	NL/H/4955/001/DC	13/389/19-C	HAMELN PHARMA GMBH	CZ
Amiodaron hameln 20 mg/ml Infusionslösung	NL/H/4955/001	2205306.00.00	HAMELN PHARMA GMBH	DE
Amiodaron hameln 20 mg/ml Infusionslösung	NL/H/4955/001/DC	140913	HAMELN PHARMA GMBH	AT
Amjodaron hameln 20 mg/ml raztopina za infundiranje	NL/H/4955/001/DC	H/21/02809/001	HAMELN PHARMA GMBH	SI
Amjodaron hameln 20 mg/ml raztopina za infundiranje	NL/H/4955/001/DC	H/21/02809/002	HAMELN PHARMA GMBH	SI
Amjodaron hameln 20 mg/ml raztopina za infundiranje	NL/H/4955/001/DC	H/21/02809/003	HAMELN PHARMA GMBH	SI
Amiodarone hameln 20 mg/ml	NL/H/4955/001/	049159015	HAMELN PHARMA GMBH	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
soluzione per infusione	DC			
Amiodarone hameln 20 mg/ml soluzione per infusione	NL/H/4955/001/DC	049159039	HAMELN PHARMA GMBH	IT
Amiodarone hameln 20 mg/ml soluzione per infusione	NL/H/4955/001/DC	049159027	HAMELN PHARMA GMBH	IT
Кордарон 150 mg/3 ml, инжекционен разтвор	not available	20000427	SANOFI WINTHROP INDUSTRIE	BG
КОРДАРОН 200 mg таблетки	not available	9800028	SANOFI WINTHROP INDUSTRIE	BG
Angoron 200 mg δισκία	not available	Γ9A 5895/6045/07-06-1972	SANOFI-AVENTIS MONOPROSOPH A.E.B.E	GR
Angoron 200 mg δισκία	not available	Γ9A 5895/6045/07-06-1972	SANOFI-AVENTIS MONOPROSOPH A.E.B.E	GR
Angoron 150 mg/3 ml amp ενέσιμο διάλυμα	not available	A6A/3174/604 5/22-03-79	SANOFI-AVENTIS MONOPROSOPH A.E.B.E	GR
Angoron 200 mg δισκία	not available	Γ9A 5895/6045/07-06-1972	SANOFI-AVENTIS MONOPROSOPH A.E.B.E	GR
CORDARONE 200 mg tabletten	not available	BE048885	SANOFI BELGIUM	BE
CORDARONE 200 mg tabletten	not available	BE048885	SANOFI BELGIUM	BE
CORDARONE 200 mg comprimés	not available	BE048885	SANOFI BELGIUM	BE
CORDARONE 200 mg tabletten	not available	BE048885	SANOFI BELGIUM	BE
CORDARONE 150 mg/3 ml solution injectable	not available	BE110634	SANOFI BELGIUM	BE
CORDARONE 150 mg/3 ml oplossing voor injectie	not available	BE110634	SANOFI BELGIUM	BE
CORDARONE 200 mg comprimés	not available	BE048885	SANOFI BELGIUM	BE
CORDARONE 200 mg comprimés	not available	BE048885	SANOFI BELGIUM	BE
CORDARONE 150 mg/3 ml solution injectable	not available	BE110634	SANOFI BELGIUM	BE

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CORDARONE 200 mg tabletten	not available	BE048885	SANOFI BELGIUM	BE
CORDARONE 150 mg/3 ml oplossing voor injectie	not available	BE110634	SANOFI BELGIUM	BE
CORDARONE 200 mg comprimés	not available	BE048885	SANOFI BELGIUM	BE
CORDARONE 200 mg Tabletten	not available	BE048885	SANOFI BELGIUM	BE
CORDARONE 200 mg Tabletten	not available	BE048885	SANOFI BELGIUM	BE
CORDARONE 200 mg Tabletten	not available	BE048885	SANOFI BELGIUM	BE
CORDARONE 200 mg Tabletten	not available	BE048885	SANOFI BELGIUM	BE
CORDARONE 150 mg/3 ml Injektionslösung	not available	BE110634	SANOFI BELGIUM	BE
CORDARONE 150 mg/3 ml Injektionslösung	not available	BE110634	SANOFI BELGIUM	BE
Cordarone	not available	7617	SANOFI-AVENTIS NORGE AS	NO
Cordarone	not available	7416	SANOFI-AVENTIS NORGE AS	NO
Cordarone 150 mg/3 ml injekčný roztok	not available	13/0134/82-CS	SANOFI WINTHROP INDUSTRIE	SK
Cordarone 200 mg tablety	not available	13/0135/82-CS	SANOFI WINTHROP INDUSTRIE	SK
Cordarone 200 mg tablety	not available	13/0135/82-CS	SANOFI WINTHROP INDUSTRIE	SK
Amiodaronă Accord 30 mg/ml concentrat pentru soluție injectabilă/perfuzabilă	ES/H/0626/001	13617/2020/01	ACCORD HEALTHCARE POLSKA SP. Z O.O.	RO
Amiodarone Accord 30 mg/ml concentrato per soluzione iniettabile/per infusione	ES/H/0626/001	047964010	ACCORD HEALTHCARE S.L.U.	IT
Amiodarona Accord 30mg/ml concentrado para solución inyectable y para perfusión	ES/H/0626/001	85739	ACCORD HEALTHCARE S.L.U.	ES
Amiodarona Accord 30 mg/ml concentrado para solução injetável ou	ES/H/0626/001	5806526	ACCORD HEALTHCARE S.L.U.	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
para perfusão				
Trangorex 150 mg/3ml solución inyectable.	not available	54723	SANOFI-AVENTIS, S.A.	ES
Trangorex 150 mg/3ml solución inyectable.	not available	54723	SANOFI-AVENTIS, S.A.	ES
CORDARONE 150 mg/3 ml soluzione iniettabile per uso endovenoso	not available	025035039	SANOFI S.R.L.	IT
CORDARONE 150 mg/3 ml soluzione iniettabile per uso endovenoso	not available	025035027	SANOFI S.R.L.	IT
CORDARONE 200 mg compresse	not available	025035015	SANOFI S.R.L.	IT
Cordarone X 150 mg/3 ml Solution for Injection	not available	PL 04425/0643	AVENTIS PHARMA LTD	XI
Cordarone X 150 mg/3 ml Solution for Injection	not available	PL 04425/0643	AVENTIS PHARMA LTD	XI
Amiodaron Winthrop 200 mg Tabletten	not available	37702.00.01	WINTHROP ARZNEIMITTEL GMBH	DE
Cordarone® 100 mg tabletit	not available	10522	SANOFI OY	FI
Cordarone® 200 mg tabletit	not available	9368	SANOFI OY	FI
Cordarone® 200 mg tabletter	not available	9368	SANOFI OY	FI
Cordarone® 100 mg tabletter	not available	10522	SANOFI OY	FI
Sedacoron 200 mg – Tabletten	not available	1-18028	EBEWE PHARMA	AT
Cordarone X 200mg Tablets.	not available	PA 540/142/2	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	IE
Cordarone X Intravenous, 150mg/3ml, Concentrate for solution for infusion or slow injection.	not available	PA 540/142/3	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	IE
Cordarone X 100mg Tablets.	not available	PA 540/142/1	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	IE
Cordarone X 200mg Tablets.	not available	PA540/142/2	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	IE
Cordarone X 100mg Tablets.	not available	PA 540/142/1	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	IE
Cordarone X Intravenous,	not available	PA 540/142/3	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	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
150mg/3ml, Concentrate for solution for infusion or slow injection				
AMIODAR 150 mg/3 ml soluzione iniettabile per uso endovenoso	not available	022033029	ALFASIGMA S.P.A.	IT
AMIODAR 200 mg compresse	not available	022033031	ALFASIGMA S.P.A.	IT
Trangorex 200 mg comprimidos	not available	48048	SANOFI-AVENTIS, S.A.	ES
AMIODARONE ZENTIVA 200 mg, comprimé sécable	not available	34009 367 360 4 7	ZENTIVA FRANCE	FR
Cordarone 200 mg tablete	not available	H/99/00421/0 02	SANOFI WINTHROP INDUSTRIE	SI
Cordarone 200 mg tablete	not available	H/99/00421/0 01	SANOFI WINTHROP INDUSTRIE	SI
CORDARONE; 200 mg, tabletki	not available	R/1637	SANOFI WINTHROP INDUSTRIE	PL
CORDARONE; 50 mg/ml, roztwór do wstrzykiwań	not available	R/1636	SANOFI WINTHROP INDUSTRIE	PL
Cordarone, tabletter	not available	13084	SANOFI A/S	DK
Cordarone, tabletter	not available	11776	SANOFI A/S	DK
Cordarone, injektionsvæske, opløsning	not available	11775	SANOFI A/S	DK
Cordarone, injektionsvæske, opløsning	not available	11775	SANOFI A/S	DK
Cordarone 50 mg/ml oldatos injekció	not available	OGYI-T-1166/04	SANOFI-AVENTIS ZRT	HU
Cordarone 50 mg/ml oldatos injekció	not available	OGYI-T-1166/03	SANOFI-AVENTIS ZRT	HU
Cordarone 200 mg tabletta	not available	OGYI-T-1166/01	SANOFI-AVENTIS ZRT	HU
Cordarone 200 mg tabletta	not available	OGYI-T-1166/02	SANOFI-AVENTIS ZRT	HU
Amiodarone 200 mg Tablets	not available	PL 44041/0001	NOUMED LIFE SCIENCES	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
Amiodarone hydrochloride 100mg tablets	not available	PL 17780/0586	ZENTIVA PHARMA UK LIMITED	XI
Cordarone X 100 mg tablets	not available	PL 17780/0586	ZENTIVA PHARMA UK LIMITED	XI
Amiodaron-ratiopharm 150 mg/3 ml Injektionslösung	not available	46221.00.00	RATIOPHARM GMBH	DE
CORDARONE 200 mg tablety	not available	13/135/82-C	SANOFI S.R.O.	CZ
CORDARONE 200 mg tablety	not available	13/135/82-C	SANOFI S.R.O.	CZ
CORDARONE 150 mg/3 ml injekční roztok	not available	13/134/82-C	SANOFI S.R.O.	CZ
CORDARONE 150 mg/3 ml injekční roztok	not available	13/134/82-C	SANOFI S.R.O.	CZ
Amiodarone 30 mg/ml solution for injection/infusion in pre-filled syringe	not available	PL 0142/1267	ACCORD-UK LIMITED	XI
Amiodarone 30 mg/ml solution for injection/infusion in pre-filled syringe	not available	PL 0142/1267	ACCORD-UK LIMITED	XI
Cordarex Injektionslösung 150 mg/3 ml	not available	41452.00.01	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Cordarex Injektionslösung 150 mg/3 ml	not available	41452.00.01	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Cordarex Injektionslösung 150 mg/3 ml	not available	41452.00.01	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Cordarex 200 mg Tabletten	not available	1617.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Cordarex 200 mg Tabletten	not available	1617.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Cordarex 200 mg Tabletten	not available	1617.00.00	SANOFI-AVENTIS DEUTSCHLAND 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
Cordarex 200 mg Tabletten	not available	1617.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Cordarex 200 mg Tabletten	not available	1617.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Cordarex 200 mg Tabletten	not available	1617.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Cordarex 200 mg Tabletten	not available	1617.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Cordarex 200 mg Tabletten	not available	1617.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
CORDARONE 150 mg/3 ml, solution injectable en ampoule (IV)	not available	34009 319 997 6 8	SANOFI WINTHROP INDUSTRIE	FR
CORDARONE 200 mg, comprimé sécable	not available	34009 559 001 2 2	SANOFI WINTHROP INDUSTRIE	FR
CORDARONE 200 mg, comprimé sécable	not available	34009 330 537 8 9	SANOFI WINTHROP INDUSTRIE	FR
CORDARONE 200 mg, comprimé sécable	not available	34009 302 565 0 3	SANOFI WINTHROP INDUSTRIE	FR
Cordarone 150 mg/3 ml koncentrat za otopinu za injekciju/infuziju	not available	HR-H-204962082-01	SANOFI WINTHROP INDUSTRIE	HR
Cordarone 200 mg tablete	not available	HR-H-451337551-01	SANOFI WINTHROP INDUSTRIE	HR
Cordarone 150 mg/3 mL solution for (IV) injection in ampoules	not available	MA1359/01401	SANOFI S.R.L.	MT

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
Cordarone 200 mg töflur	not available	853697	SANOFI-AVENTIS NORGE AS	IS
Cordarone 100 mg töflur	not available	890017	SANOFI-AVENTIS NORGE AS	IS
CORDARONE 200 mg, comprimé sécable	not available	34009 559 001 2 2	SANOFI WINTHROP INDUSTRIE	FR
CORDARONE 200 mg, comprimé sécable	not available	34009 330 537 8 9	SANOFI WINTHROP INDUSTRIE	FR
CORDARONE 200 mg, comprimé sécable	not available	34009 302 565 0 3	SANOFI WINTHROP INDUSTRIE	FR
Cordarone 200 mg tabletės	not available	LT/1/96/1502 /001	SANOFI WINTHROP INDUSTRIE	LT