



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 September 2021
EMA/606309/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: amiodarone

Procedure no.: PSUSA/00000166/202012



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
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
Amiodaron Accord 30 mg/ml Konzentrat zur Herstellung einer Injektions-/Infusionslösung	ES/H/0626/001	140415	ACCORD HEALTHCARE B.V.	AT
Amiodaron Accord 30 mg/ml Konzentrat zur Herstellung einer Injektions-/Infusionslösung	ES/H/0626/001	2203435.00.00	ACCORD HEALTHCARE B.V.	DE
Amiodaron HCl Hameln 20 mg/ml, oplossing voor infusie	NL/H/4955/001	RVG 125827	HAMELN PHARMA GMBH	NL
Amiodaron Winthrop 200 mg Tabletten	not available	37702.00.01	WINTHROP ARZNEIMITTEL GMBH	DE
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 30 mg/ml solution for	not available	PL 0142/1267	ACCORD-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
injection/infusion in pre-filled syringe				
Amiodarone 30 mg/ml solution for injection/infusion in pre-filled syringe	not available	PL 0142/1267	ACCORD-UK LIMITED	XI
Amiodarone Accord 30 mg/ml koncentrát pro injekční/infuzní roztok	ES/H/0626/001	13/037/19-C	ACCORD HEALTHCARE POLSKA SP. Z O.O.	CZ
Amiodarone Accord 30 mg/ml koncentrat till injektions-/infusionsvätska, lösning	ES/H/0626/001	58862	ACCORD HEALTHCARE B.V.	SE
Amiodarone Accord 30 mg/ml konsentrat til injeksjons-/infusjonsvæske, oppløsning	ES/H/0626/001	19-12732	ACCORD HEALTHCARE B.V.	NO
Amiodarone Hydrochloride 20 mg/ml solution for infusion	NL/H/4955/001	PL 01502/0113	HAMELN PHARMA LTD	XI
AMIODARONE ZENTIVA 200 mg, comprimé sécable	not available	34009 367 360 4 7	ZENTIVA FRANCE	FR
Amiodaron-ratiopharm 150 mg/3 ml Injektionslösung	not available	46221.00.00	RATIOPHARM GMBH	DE

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ANGORON	not available	Γ9A 5895/6045/07-06-1972	SANOFI-AVENTIS AEBE	GR
ANGORON	not available	Γ9A 5895/6045/07-06-1972	SANOFI-AVENTIS AEBE	GR
ANGORON	not available	A6A/3174/6045/22-03-79	SANOFI-AVENTIS AEBE	GR
ANGORON	not available	Γ9A 5895/6045/07-06-1972	SANOFI-AVENTIS AEBE	GR
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

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 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
Cordarone	not available	11775	SANOFI A/S	DK
Cordarone	not available	11775	SANOFI A/S	DK
CORDARONE	not available	025035039	SANOFI 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
CORDARONE	not available	025035027	SANOFI S.R.L.	IT
CORDARONE	not available	025035015	SANOFI S.R.L.	IT
CORDARONE	not available	7617	SANOFI-AVENTIS NORGE AS	NO
CORDARONE	not available	7416	SANOFI-AVENTIS NORGE AS	NO
Cordarone 100 mg tablett	not available	11032	SANOFI AB	SE
CORDARONE 100 MG TABLETTI	not available	10522	SANOFI OY	FI
Cordarone 100 mg töflur	not available	890017(IS)	SANOFI-AVENTIS NORGE AS	IS
CORDARONE 150 mg/3 ml injekční roztok	not available	13/134/82-C	SANOFI-AVENTIS SRO	CZ
CORDARONE 150 mg/3 ml injekční roztok	not available	13/134/82-C	SANOFI-AVENTIS SRO	CZ

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 150 mg/3 ml Injektionslösung	not available	NAT/H/1007/02	SANOFI BELGIUM	BE
CORDARONE 150 mg/3 ml Injektionslösung	not available	NAT/H/1007/02	SANOFI BELGIUM	BE
CORDARONE 150 mg/3 ml oplossing voor injectie	not available	NAT/H/1007/02	SANOFI BELGIUM	BE
CORDARONE 150 mg/3 ml oplossing voor injectie	not available	NAT/H/1007/02	SANOFI BELGIUM	BE
Cordarone 150 mg/3 ml solução injetável	not available	8468009	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
CORDARONE 150 mg/3 ml solution injectable	not available	NAT/H/1007/02	SANOFI BELGIUM	BE
CORDARONE 150 mg/3 ml solution injectable	not available	NAT/H/1007/02	SANOFI BELGIUM	BE
Cordarone 150 mg/3 ml injekčný roztok	not available	13/0134/82-CS	SANOFI-AVENTIS SLOVAKIA SRO	SK
CORDARONE 150 mg/3 ml, solution injectable en ampoule (IV)	not available	34009 319 997 6 8	SANOFI-AVENTIS 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
CORDARONE 150 MG/3 ML, SOLUTION INJECTABLE IV EN AMPOULES	not available	MA1359/01401	SANOFI S.P.A	MT
Cordarone 150 mg/3ml koncentrat za otopinu za injekciju/infuziju	not available	HR-H-204962082-01	SANOFI-AVENTIS CROATIA D.O.O.	HR
CORDARONE 200 MG	not available	MA1359/01402	SANOFI S.P.A	MT
CORDARONE 200 MG	not available	11070/2018/02	SANOFI ROMANIA SRL	RO
CORDARONE 200 MG	not available	11070/2018/01	SANOFI ROMANIA SRL	RO
CORDARONE 200 mg comprimés	not available	NAT/H/1007/01	SANOFI BELGIUM	BE
CORDARONE 200 mg comprimés	not available	NAT/H/1007/01	SANOFI BELGIUM	BE
CORDARONE 200 mg comprimés	not available	NAT/H/1007/01	SANOFI BELGIUM	BE
CORDARONE 200 mg comprimés	not available	NAT/H/1007/01	SANOFI BELGIUM	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
CORDARONE 200 mg comprimés	not available	0893082	SANOFI BELGIUM	LU
CORDARONE 200 MG TABLETE	not available	HR-H-451337551-01	SANOFI-AVENTIS CROATIA D.O.O.	HR
CORDARONE 200 MG TABLETE	not available	H/99/00421/002	SANOFI-AVENTIS D.O.O.	SI
CORDARONE 200 MG TABLETE	not available	H/99/00421/001	SANOFI-AVENTIS D.O.O.	SI
CORDARONE 200 MG TABLETS	not available	97-0599	SANOFI-AVENTIS LATVIA SIA	LV
Cordarone 200 mg tablett	not available	10656	SANOFI AB	SE
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
CORDARONE 200 mg tabletten	not available	NAT/H/1007/01	SANOFI BELGIUM	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
CORDARONE 200 mg tabletten	not available	NAT/H/1007/01	SANOFI BELGIUM	BE
CORDARONE 200 mg tabletten	not available	NAT/H/1007/01	SANOFI BELGIUM	BE
CORDARONE 200 mg tabletten	not available	NAT/H/1007/01	SANOFI BELGIUM	BE
CORDARONE 200 mg Tabletten	not available	NAT/H/1007/01	SANOFI BELGIUM	BE
CORDARONE 200 mg Tabletten	not available	NAT/H/1007/01	SANOFI BELGIUM	BE
CORDARONE 200 mg Tabletten	not available	NAT/H/1007/01	SANOFI BELGIUM	BE
CORDARONE 200 mg Tabletten	not available	NAT/H/1007/01	SANOFI BELGIUM	BE
CORDARONE 200 MG TABLETTI	not available	9368	SANOFI OY	FI
CORDARONE 200 mg tablety	not available	13/135/82-C	SANOFI-AVENTIS SRO	CZ

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 tablety	not available	13/135/82-C	SANOFI-AVENTIS SRO	CZ
Cordarone 200 mg töflur	not available	853697(IS)	SANOFI-AVENTIS NORGE AS	IS
Cordarone 200 mg tablety	not available	13/0135/82-CS	SANOFI-AVENTIS SLOVAKIA SRO	SK
Cordarone 200 mg tablety	not available	13/0135/82-CS	SANOFI-AVENTIS SLOVAKIA SRO	SK
CORDARONE 200 mg, comprimé sécable	not available	34009 330 537 8 9	SANOFI-AVENTIS FRANCE	FR
CORDARONE 200 mg, comprimé sécable	not available	34009 302 565 0 3	SANOFI-AVENTIS FRANCE	FR
CORDARONE 200 MG, tabletid	not available	311400	SANOFI-AVENTIS ESTONIA OÜ	EE
Cordarone 200 mg tabletės	not available	LT/1/96/1502/001	UAB SANOFI-AVENTIS LIETUVA	LT
Cordarone 50 mg/ml injeksjonsvæske, oppløsning	not available	7415	SANOFI-AVENTIS NORGE AS	NO

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 50 mg/ml injeksjonsvæske, oppløsning	not available	7415	SANOFI-AVENTIS NORGE AS	NO
Cordarone 50 mg/ml injektionsvätska, lösning	not available	10572	SANOFI AB	SE
Cordarone 50 mg/ml injektionsvätska, lösning	not available	10572	SANOFI AB	SE
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 50 MG/ML RAZTOPINA ZA INJICIRANJE ALI INFUNDIRANJE	not available	H/99/00421/003	SANOFI-AVENTIS D.O.O.	SI
Cordarone 50 mg/ml stungulyf, lausn	not available	853696(IS)	SANOFI-AVENTIS NORGE AS	IS
Cordarone 50 mg/ml stungulyf, lausn	not available	853696(IS)	SANOFI-AVENTIS NORGE AS	IS
Cordarone I.V. 150 mg/3 ml, oplossing voor injectie	not available	RVG 10937	GENZYME EUROPE B.V.	NL

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 I.V. 150 mg/3 ml, oplossing voor injectie	not available	RVG 10937	GENZYME EUROPE B.V.	NL
Cordarone X 100	not available	PL 17780/0586	ZENTIVA PHARMA UK LIMITED	XI
CORDARONE X 100MG TABLETS	not available	PA 540/142/1	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 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
Cordarone X 200	not available	PL 17780/0587	ZENTIVA PHARMA UK LIMITED	XI
CORDARONE X 200MG TABLETS	not available	PA 540/142/2	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	IE
CORDARONE X 200MG TABLETS	not available	PA 540/142/2	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
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 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, 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, 200 mg, comprimidos	not available	5723150	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Cordarone, tabletter	not available	13084	SANOFI A/S	DK
Cordarone, tabletter	not available	11776	SANOFI A/S	DK

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, tabletki	not available	R/1637	SANOFI-AVENTIS FRANCE	PL
CORDARONE; 50 mg/ml, roztwór do wstrzykiwań	not available	R/1636	SANOFI-AVENTIS FRANCE	PL
CORDARONE® 100 mg tabletter	not available	10522	SANOFI OY	FI
CORDARONE® 200 mg tabletter	not available	9368	SANOFI OY	FI
Sedacoron 200 mg – Tabletten	not available	1-18028	EBEWE PHARMA	AT
TRANGOREX 150 MG / 3 ML SOLUCION INYECTABLE	not available	54723	SANOFI-AVENTIS, S.A.	ES
TRANGOREX 150 MG / 3 ML SOLUCION INYECTABLE	not available	54723	SANOFI-AVENTIS, S.A.	ES
TRANGOREX 200 MG COMPRIMIDOS	not available	48048	SANOFI-AVENTIS, S.A.	ES
Кордарон 150 mg/3 ml, инжекционен разтвор	not available	20000427	SANOFI BULGARIA EOOD	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
КОРДАРОН 200 mg таблетки	not available	9800028	SANOFI BULGARIA EOOD	BG