



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

6 September 2018  
EMA/615607/2018  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: amiodarone

Procedure no.: PSUSA/00000166/201712

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An agency of the European Union



<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Amiodaron Ebewe 150 mg - Konzentrat zur Herstellung einer Infusionslösung	not available	1-18027	EBEWE PHARMA	AT
Sedacoron 200 mg – Tabletten	not available	1-18028	EBEWE PHARMA	AT
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 solution injectable	not available	BE110634	SANOFI BELGIUM	BE
CORDARONE 150 mg/3 ml oplossing voor injectie	not available	BE110634	SANOFI BELGIUM	BE
CORDARONE 150 mg/3 ml solution injectable	not available	BE110634	SANOFI BELGIUM	BE
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	not available	20000427	SANOFI BULGARIA EOOD	BG
CORDARONE	not available	019165	SANOFI-AVENTIS CYPRUS LTD	CY
CORDARONE	not available	019178	SANOFI-AVENTIS CYPRUS LTD	CY
CORDARONE	not available	13/135/82-C	SANOFI-AVENTIS SRO	CZ
CORDARONE	not available	13/135/82-C	SANOFI-AVENTIS SRO	CZ
CORDARONE	not available	13/134/82-C	SANOFI-AVENTIS SRO	CZ
CORDARONE	not available	13/134/82-C	SANOFI-AVENTIS SRO	CZ
CORDAREX INJEKTIONLOSUNG	not available	41452.00.01	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
CORDAREX INJEKTIONLOSUNG	not available	41452.00.01	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE

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CORDAREX INJEKTIONLOSUNG	not available	41452.00.01	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
CORDAREX	not available	1617.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
CORDAREX	not available	1617.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
AMIODARON WINTHROP 200 MG TABLETTEN	not available	37702.00.01	WINTHROP ARZNEIMITTEL GMBH	DE
CORDAREX	not available	1617.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
CORDAREX	not available	1617.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
CORDAREX	not available	1617.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
AMIODARON WINTHROP 200 MG TABLETTEN	not available	37702.00.01	WINTHROP ARZNEIMITTEL GMBH	DE
AMIODARON WINTHROP 200 MG TABLETTEN	not available	37702.00.01	WINTHROP ARZNEIMITTEL GMBH	DE
AMIODARON WINTHROP 200 MG TABLETTEN	not available	37702.00.01	WINTHROP ARZNEIMITTEL GMBH	DE
AMIODARON WINTHROP 200 MG TABLETTEN	not available	37702.00.01	WINTHROP ARZNEIMITTEL GMBH	DE
AMIODARON WINTHROP 200 MG TABLETTEN	not available	37702.00.01	WINTHROP ARZNEIMITTEL GMBH	DE
CORDAREX	not available	1617.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
AMIODARON WINTHROP 200 MG TABLETTEN	not available	37702.00.01	WINTHROP ARZNEIMITTEL GMBH	DE
CORDAREX	not available	1617.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
CORDAREX	not available	1617.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE

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Amiodaron-ratiopharm® 150 mg/3 ml Injektionslösung Wirkstoff: Amiodaronhydrochlorid	not available	46221.00.00	RATIOPHARM GMBH	DE
CORDARONE	not available	13084	SANOFI-AVENTIS DENMARK A/S	DK
CORDARONE	not available	11776	SANOFI-AVENTIS DENMARK A/S	DK
CORDARONE	not available	11775	SANOFI-AVENTIS DENMARK A/S	DK
CORDARONE 200 MG, tabletid	not available	311400	SANOFI-AVENTIS ESTONIA OÜ	EE
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
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
CORDARONE 50 MG/ML INJEKTIONESTE, LIUOS	not available	9367	SANOFI OY	FI
CORDARONE 100 MG TABLETTI	not available	10522	SANOFI OY	FI
CORDARONE 200 MG TABLETTI	not available	9368	SANOFI OY	FI
CORDARONE 50 MG/ML INJEKTIONESTE, LIUOS	not available	9367	SANOFI OY	FI
AMIODARONE ZENTIVA 200 MG, COMPRIME SECABLE	not available	367 360-4	SANOFI-AVENTIS FRANCE	FR

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CORDARONE 150 MG/3 ML, SOLUTION INJECTABLE IV EN AMPOULES	not available	34009 319 997 6 8	SANOFI-AVENTIS FRANCE	FR
CORDARONE 200 MG, COMPRIME SECABLE	not available	559 001-2	SANOFI-AVENTIS FRANCE	FR
CORDARONE 200 MG, COMPRIME SECABLE	not available	330 537-8	SANOFI-AVENTIS FRANCE	FR
CORDARONE 200 MG, COMPRIME SECABLE	not available	302 565-0	SANOFI-AVENTIS FRANCE	FR
ANGORON	not available	Г9А 5895/6045/07-06-72	SANOFI-AVENTIS AEBE	GR
ANGORON	not available	Г9А 5895/6045/07-06-72	SANOFI-AVENTIS AEBE	GR
ANGORON	not available	A6A/3174/6045/22-03-79	SANOFI-AVENTIS AEBE	GR
ANGORON	not available	Г9А 5895/6045/07-06-72	SANOFI-AVENTIS AEBE	GR
CORDARONE 150 MG/3 ML OTOPIKA ZA INJEKCIJU ILI INFUZIJU	not available	UP/I-530-09/12-02/357	SANOFI-AVENTIS CROATIA D.O.O.	HR
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
CORDARONE X 200MG TABLETS	not available	PA 540/142/2	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	IE
CORDARONE X INTRAVENOUS 150MG/3ML 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

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CORDARONE X 200MG TABLETS	not available	PA 540/142/2	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	not available	853696(IS)	SANOFI-AVENTIS NORGE AS	IS
CORDARONE	not available	853697	SANOFI-AVENTIS NORGE AS	IS
CORDARONE	not available	853696	SANOFI-AVENTIS NORGE AS	IS
CORDARONE	not available	890017	SANOFI-AVENTIS NORGE AS	IS
CORDARONE	not available	025035039	SANOFI SPA	IT
CORDARONE	not available	025035027	SANOFI SPA	IT
CORDARONE	not available	025035015	SANOFI SPA	IT
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
CORDARONE 50 MG/ML CONCENTRATE FOR SOLUTION FOR INJECTION/ INFUSION	not available	LT/1/96/1502/002	UAB SANOFI-AVENTIS LIETUVA	LT
CORDARONE 200 mg tabletės	not available	LT/1/96/1502/001	UAB SANOFI-AVENTIS LIETUVA	LT
CORDARONE 200 MG TABLETS	not available	97-0599	SANOFI-AVENTIS LATVIA SIA	LV
CORDARONE 50 MG/ML CONCENTRATE FOR SOLUTION FOR INJECTION/ INFUSION	not available	96-0386	SANOFI-AVENTIS LATVIA SIA	LV
CORDARONE 200 MG	not available	MA082/04702	SANOFI MALTA LTD	MT
CORDARONE 150 MG/3 ML, SOLUTION INJECTABLE IV EN AMPOULES	not available	MA082/04701	SANOFI MALTA LTD	MT

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CORDARONE	not available	RVG 10937	SANOFI-AVENTIS NETHERLANDS B.V.	NL
CORDARONE	not available	RVG 10937	SANOFI-AVENTIS NETHERLANDS B.V.	NL
CORDARONE	not available	7617	SANOFI-AVENTIS NORGE AS	NO
CORDARONE	not available	7416	SANOFI-AVENTIS NORGE AS	NO
CORDARONE	not available	7415	SANOFI-AVENTIS NORGE AS	NO
CORDARONE	not available	7415	SANOFI-AVENTIS NORGE AS	NO
CORDARONE	not available	R/1637	SANOFI-AVENTIS FRANCE	PL
CORDARONE	not available	R/1636	SANOFI-AVENTIS FRANCE	PL
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	not available	5713/2005/02	SANOFI ROMANIA SRL	RO
CORDARONE 200 MG	not available	5713/2005/01	SANOFI ROMANIA SRL	RO
CORDARONE	not available	10572	SANOFI AB	SE
CORDARONE	not available	11032	SANOFI AB	SE
CORDARONE	not available	10656	SANOFI AB	SE
CORDARONE	not available	10572	SANOFI AB	SE
CORDARONE 150 MG/3 ML	not available	13/0134/82-C/S	SANOFI-AVENTIS SLOVAKIA SRO	SK
CORDARONE 200 MG	not available	13/135/82-C/S	SANOFI-AVENTIS SLOVAKIA SRO	SK
Amiodarone 200 mg Tablets	not available	PL 44041/0001	NOUMED LIFE SCIENCES	UK
Amiodarone 100 mg Tablets	not available	PL 21880/0095	MEDREICH PLC	UK
Amiodarone 200 mg Tablets	not available	PL 21880/0096	MEDREICH PLC	UK

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CORDARONE X 200	not available	PL 17780/0587	WINTHROP PHARMACEUTICALS UK LTD	UK
CORDARONE X INTRAVENOUS	not available	PL 04425/0643	AVENTIS PHARMA LTD	UK
CORDARONE X INTRAVENOUS	not available	PL 04425/0643	AVENTIS PHARMA LTD	UK
CORDARONE X 200	not available	PL 17780/0587	WINTHROP PHARMACEUTICALS UK LTD	UK
CORDARONE X 100	not available	PL 17780/0586	WINTHROP PHARMACEUTICALS UK LTD	UK
CORDARONE X 100	not available	PL 17780/0586	WINTHROP PHARMACEUTICALS UK LTD	UK