



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 November 2017
EMA/787721/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): carvedilol

Procedure No.: PSUSA/00000575/201704



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
Cardiol 12,5 mg tabletti	not available	11868	ROCHE OY	FI
Cardiol 25 mg tabletti	not available	11017	ROCHE OY	FI
Cardiol® 12,5 mg tabletter	not available	11868	ROCHE OY	FI
Cardiol® 25 mg tabletter	not available	11017	ROCHE OY	FI
Carvedilol - 1 A Pharma 12,5 mg Tabletten	DE/H/1986/003	56447.02.00	1 A PHARMA GMBH	DE
Carvedilol - 1 A Pharma 50 mg Tabletten	DE/H/1986/005	56447.04.00	1 A PHARMA GMBH	DE
Carvedilol 12.5 mg Tablets	-	PL 40378/0138	TORRENT PHARMA LTD.	UK
Carvedilol 12.5mg Tablets	not available	PL 11311/0482	TILLOMED LABORATORIES LTD	UK
Carvedilol 25 mg Tablets	-	PL 40378/0139	TORRENT PHARMA LTD.	UK
Carvedilol 25mg Tablets	not available	PL 11311/0483	TILLOMED LABORATORIES LTD	UK
Carvedilol 3.125 mg film-coated tablets	PT/H/0588/001	MA807/05901	AUROBINDO PHARMA (MALTA) LIMITED	MT
Carvedilol 3.125 mg Tablets	-	PL 40378/0136	TORRENT PHARMA LTD.	UK
Carvedilol 3.125mg Tablets	not available	PL 11311/0480	TILLOMED LABORATORIES LTD	UK
Carvedilol 6.25 mg Tablets	-	PL 40378/0137	TORRENT PHARMA LTD.	UK
Carvedilol 6.25mg Tablets	not available	PL 11311/0481	TILLOMED LABORATORIES LTD	UK
Carvedilol Aurobindo 12,5 mg, filmomhulde tabletten	not available	RVG 107595	AUROBINDO PHARMA B.V.	NL
Carvedilol Aurobindo 3,125 mg comprimate filmate	PT/H/0588/001	4836/2012/02	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg comprimate filmate	PT/H/0588/001	4836/2012/03	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg comprimate filmate	PT/H/0588/001	4836/2012/04	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg comprimate filmate	PT/H/0588/001	4836/2012/05	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg comprimate filmate	PT/H/0588/001	4836/2012/06	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg comprimate filmate	PT/H/0588/001	4836/2012/07	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg comprimate filmate	PT/H/0588/001	4836/2012/08	AUROBINDO PHARMA (MALTA) LIMITED	RO

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Carvedilol Aurobindo 3,125 mg comprimate filmate	PT/H/0588/001	4836/2012/09	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg comprimate filmate	PT/H/0588/001	4836/2012/10	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg comprimate filmate	PT/H/0588/001	4836/2012/11	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg comprimate filmate	PT/H/0588/001	4836/2012/12	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg comprimate filmate	PT/H/0588/001	4836/2012/13	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg comprimate filmate	PT/H/0588/001	4836/2012/14	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg comprimate filmate	PT/H/0588/001	4836/2012/15	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg comprimate filmate	PT/H/0588/001	4836/2012/16	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg comprimate filmate	PT/H/0588/001	4836/2012/17	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg comprimate filmate	PT/H/0588/001	4836/2012/18	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg comprimate filmate	PT/H/0588/001	4836/2012/19	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg comprimate filmate	PT/H/0588/001	4836/2012/20	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg comprimate filmate	PT/H/0588/001	4836/2012/21	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg comprimate filmate	PT/H/0588/001	4836/2012/22	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg comprimate filmate	PT/H/0588/001	4836/2012/23	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg comprimate filmate	PT/H/0588/001	4836/2012/24	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg comprimate filmate	PT/H/0588/001	4836/2012/25	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg	PT/H/0588/001	4836/2012/26	AUROBINDO PHARMA (MALTA)	RO

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comprimato filmate			LIMITED	
Carvedilol Aurobindo 3,125 mg comprimato filmate	PT/H/0588/001	4836/2012/27	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg comprimato filmate	PT/H/0588/001	4836/2012/28	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg comprimato filmate	PT/H/0588/001	4836/2012/29	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg comprimato filmate	PT/H/0588/001	4836/2012/30	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg comprimato filmate	PT/H/0588/001	4836/2012/01	AUROBINDO PHARMA (MALTA) LIMITED	RO
Carvedilol Aurobindo 3,125 mg, filmomhulde tabletten	not available	RVG 107593	AUROBINDO PHARMA B.V.	NL
Carvedilol Hexal 12,5 mg Tabletten	DE/H/1985/003	56442.02.00	HEXAL AG	DE
Carvedilol HEXAL 3,125 mg tabletit	FI/H/0182/001	17068	HEXAL A/S	FI
Carvedilol Hexal 3,125 mg tablett	DE/H/1985/001	19094	HEXAL A/S	SE
Carvedilol HEXAL 50 mg tabletit	FI/H/0182/005	17072	HEXAL A/S	FI
Carvedilol Hexal 50 mg Tabletten	DE/H/1985/005	56442.04.00	HEXAL AG	DE
CARVEDILOL SANDOZ 3,125 MG TABLETTEN	DE/H/1985/001	RVG 28745	SANDOZ B.V.	NL
Carvedilol Sandoz 50 mg comprimés	DE/H/1985/005	0715/03/04/0006	HEXAL AG	LU
Carvedilol Sandoz 50 mg tabletten	DE/H/1985/005	BE484826	SANDOZ N.V.	BE
Carvedilol Sandoz 50 mg tabletten	DE/H/1985/005	BE251072	SANDOZ N.V.	BE
Carvedilol Sandoz 50 mg Tabletten	not available	70831.00.00	HEXAL AG	DE
CARVEDILOL SANDOZ 50 MG TABLETTEN	DE/H/1985/005	RVG 28749	SANDOZ B.V.	NL
Carvedilol Teva 12,5 mg, tabletten	not available	RVG 29079	TEVA NEDERLAND B.V.	NL
Carvedilol TEVA 25 mg comprime secable	not available	NL30497	TEVA SANTÉ	FR
Carvedilol Teva 25 mg, tabletten	not available	RVG 29080	TEVA NEDERLAND B.V.	NL
Carvedilol Teva 3,125 mg, tabletten	not available	RVG 29077	TEVA NEDERLAND B.V.	NL
Carvedilol Teva 6,25 mg, tabletten	not available	RVG 29078	TEVA NEDERLAND B.V.	NL
Carvipress 12,5 mg compresse	not available	027606060	VISUFARMA SPA	IT

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Carvipress 12,5 mg compresse	not available	027606072	VISUFARMA SPA	IT
Carvipress 25 mg compresse	not available	027606019	VISUFARMA SPA	IT
Carvipress 25 mg compresse	not available	027606084	VISUFARMA SPA	IT
Carvipress 3,125 mg compresse	not available	027606096	VISUFARMA SPA	IT
Carvipress 50 mg compresse	not available	027606021	VISUFARMA SPA	IT
Carvipress 6,25 mg compresse	not available	027606033	VISUFARMA SPA	IT
Carvipress 6,25 mg compresse	not available	027606045	VISUFARMA SPA	IT
Carvipress 6,25 mg compresse	not available	027606058	VISUFARMA SPA	IT
Coropres 25 mg comprimidos	not available	59.695	ROCHE FARMA, S.A.	ES
Coropres 6,25 mg comprimidos	not available	61.281	ROCHE FARMA, S.A.	ES
Dilatrend 12,5 mg - Tabletten	not available	1-21705	ROCHE AUSTRIA GMBH	AT
Dilatrend 12,5 mg compresse	not available	027604077	ROCHE S.P.A.	IT
Dilatrend 12,5 mg compresse	not available	027604065	ROCHE S.P.A.	IT
Dilatrend 12,5 mg comprimate	not available	7688/2015/01	ROCHE ROMANIA SRL	RO
Dilatrend 12,5 mg tablete	not available	UP/I-530-09/13-02/429	ROCHE D.O.O.	HR
Dilatrend 12,5 mg tablete	not available	5363-I-1818/09	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Dilatrend 12,5 mg tableta	not available	OGYI-T-4965/02	ROCHE (MAGYARORSZÁG) KFT	HU
Dilatrend 25 mg - Tabletten	not available	1-19553	ROCHE AUSTRIA GMBH	AT
Dilatrend 25 mg compresse	not available	027604014	ROCHE S.P.A.	IT
Dilatrend 25 mg compresse	not available	027604089	ROCHE S.P.A.	IT
Dilatrend 25 mg comprimate	not available	7689/2015/01	ROCHE ROMANIA SRL	RO
Dilatrend 25 mg tablete	not available	UP/I-530-09/13-02/430	ROCHE D.O.O.	HR
Dilatrend 25 mg tablete	not available	5363-I-1819/09	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Dilatrend 25 mg tabletes	not available	97-0394	ROCHE LATVIJA SIA	LV
Dilatrend 25 mg tablety	not available	77/0083/13-S	ROCHE SLOVENSKO S.R.O.	SK
DILATREND 25 tablety	not available	77/1015/92-S/C	ROCHE S. R. O.	CZ
Dilatrend 6,25 mg - Tabletten	not available	1-21706	ROCHE AUSTRIA GMBH	AT
Dilatrend 6,25 mg compresse	not available	027604038	ROCHE S.P.A.	IT
Dilatrend 6,25 mg compresse	not available	027604053	ROCHE S.P.A.	IT
Dilatrend 6,25 mg compresse	not available	027604040	ROCHE S.P.A.	IT
Dilatrend 6,25 mg comprimate	not available	7687/2015/01	ROCHE ROMANIA SRL	RO
Dilatrend 6,25 mg tablete	not available	UP/I-530-09/13-02/428	ROCHE D.O.O.	HR

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
Dilatrend 6,25 mg tablete	not available	5363-I-1817/09	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Dilatrend 6,25 mg tabletes	not available	97-0393	ROCHE LATVIJA SIA	LV
Dilatrend 6,25 mg tabletta	not available	OGYI-T-4965/03	ROCHE (MAGYARORSZÁG) KFT	HU
DILATREND 6,25 tablety	not available	77/1289/97-C	ROCHE S. R. O.	CZ
Dilatrend, 12,5 mg, tabletki	not available	R/7162	ROCHE POLSKA SP.O.O.	PL
Dilatrend, 25 mg, tabletki	not available	R/7176	ROCHE POLSKA SP.O.O.	PL
Dilatrend, 6,25 mg, tabletki	not available	R/7161	ROCHE POLSKA SP.O.O.	PL
Dilatrend® 12,5 mg, Tabletten	not available	36867.01.00	CHEPLAPHARM ARZNEIMITTEL GMBH	DE
Dilatrend® 12,5 mg, Tabletten	not available	36867.01.00	CHEPLAPHARM ARZNEIMITTEL GMBH	DE
Dilatrend® 12,5 mg/TAB, δισκία	not available	74113/10/02.08.2011	ROCHE (HELLAS) SA	GR
Dilatrend® 25 mg, Tabletten	not available	36867.02.00	CHEPLAPHARM ARZNEIMITTEL GMBH	DE
Dilatrend® 25 mg/TAB, δισκία	not available	74112/10/02.08.2011	ROCHE (HELLAS) SA	GR
Dilatrend® 6,25 mg, Tabletten	not available	36867.00.00	CHEPLAPHARM ARZNEIMITTEL GMBH	DE
Dilatrend® 6,25/TAB mg, δισκία	not available	74110/10/02.08.2011	ROCHE (HELLAS) SA	GR
Dilbloc 25 mg comprimidos	not available	4702080	ROCHE FARMACÉUTICA QUÍMICA, LDA.	PT
Dilbloc 25 mg Comprimidos	not available	4702189	ROCHE FARMACÉUTICA QUÍMICA, LDA.	PT
Dilbloc 25 mg Comprimidos	not available	4702288	ROCHE FARMACÉUTICA QUÍMICA, LDA.	PT
Dilbloc IC 6,25 mg comprimidos	not available	2532489	ROCHE FARMACÉUTICA QUÍMICA, LDA.	PT
Dilbloc IC 6,25 mg Comprimidos	not available	4701983	ROCHE FARMACÉUTICA QUÍMICA, LDA.	PT
Dimitone 25 mg comprimés	not available	BE150884	N.V. ROCHE S.A.	BE
Dimitone 25 mg comprimés	not available	2002106773	N.V. ROCHE S.A.	LU
Dimitone 25 mg tabletten	not available	BE150884	N.V. ROCHE S.A.	BE
Dimitone 25 mg Tabletten	not available	BE150884	N.V. ROCHE S.A.	BE
Dimitone 25 mg Tabletten	not available	2002106773	N.V. ROCHE S.A.	LU

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
Eucardic 12.5 mg Tablets	not available	PA 50/142/2	ROCHE PRODUCTS LTD	IE
Eucardic 25 mg Tablets	not available	PA 50/142/3	ROCHE PRODUCTS LTD	IE
Eucardic 3.125 mg Tablets	not available	PA 50/142/4	ROCHE PRODUCTS LTD	IE
Eucardic 6.25 mg Tablets	not available	PA 50/142/1	ROCHE PRODUCTS LTD	IE
Kredex 12,5 mg comprimés	not available	BE182987	N.V. ROCHE S.A.	BE
Kredex 12,5 mg comprimés	not available	2002106774	N.V. ROCHE S.A.	LU
Kredex 12,5 mg tabletten	not available	BE182987	N.V. ROCHE S.A.	BE
Kredex 12,5 mg Tabletten	not available	BE182987	N.V. ROCHE S.A.	BE
Kredex 12,5 mg Tabletten	not available	2002106774	N.V. ROCHE S.A.	LU
Kredex 12,5 mg tabletter	not available	11629	ROCHE AB	SE
KREDEX 12,5 mg, comprimé sécable	not available	3400934234514	ROCHE	FR
KREDEX 12,5 mg, comprimé sécable	not available	3400934234682	ROCHE	FR
KREDEX 12,5 mg, comprimé sécable	not available	3400934234743	ROCHE	FR
Kredex 25 mg comprimés	not available	BE150875	N.V. ROCHE S.A.	BE
Kredex 25 mg comprimés	not available	2002106775	N.V. ROCHE S.A.	LU
Kredex 25 mg tabletten	not available	BE150875	N.V. ROCHE S.A.	BE
Kredex 25 mg Tabletten	not available	BE150875	N.V. ROCHE S.A.	BE
Kredex 25 mg Tabletten	not available	2002106775	N.V. ROCHE S.A.	LU
Kredex 25 mg tabletter	not available	11630	ROCHE AB	SE
KREDEX 25 mg, comprimé sécable	not available	3400933424169	ROCHE	FR
KREDEX 25 mg, comprimé sécable	not available	3400934420238	ROCHE	FR
KREDEX 25 mg, comprimé sécable	not available	3400934263958	ROCHE	FR
KREDEX 25 mg, comprimé sécable	not available	3400934419928	ROCHE	FR
Kredex 6,25 mg comprimés	not available	BE182996	N.V. ROCHE S.A.	BE
Kredex 6,25 mg comprimés	not available	2002106776	N.V. ROCHE S.A.	LU
Kredex 6,25 mg tabletten	not available	BE182996	N.V. ROCHE S.A.	BE
Kredex 6,25 mg Tabletten	not available	BE182996	N.V. ROCHE S.A.	BE
Kredex 6,25 mg Tabletten	not available	2002106776	N.V. ROCHE S.A.	LU
KREDEX 6,25 mg, comprimé sécable	not available	3400934234392	ROCHE	FR
KREDEX 6,25 mg, comprimé	not available	3400934234453	ROCHE	FR

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sécable				
KREDEX 6,25 mg, comprimé sécable	not available	3400934233913	ROCHE	FR
KREDEX 6,25 mg, comprimé sécable	not available	3400934234163	ROCHE	FR
KREDEX 6,25 mg, comprimé sécable	not available	3400934234224	ROCHE	FR
KREDEX 6,25 mg, comprimé sécable	not available	3400934233852	ROCHE	FR
Дилатренд 12,5 mg таблетки	not available	II-3429	TCHAIKAPHARMA HIGH QUALITY MEDICINES, INC.	BG
Дилатренд 25 mg таблетки	not available	II-3431	TCHAIKAPHARMA HIGH QUALITY MEDICINES, INC.	BG
Дилатренд 6,25 mg таблетки	not available	II-3428	TCHAIKAPHARMA HIGH QUALITY MEDICINES, INC.	BG