



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 December 2022
EMA/929400/2022
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: carvedilol

Procedure no.: PSUSA/00000575/202204



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
Carvedilol - 1 A Pharma 50 mg Tabletten	DE/H/1986/005	56447.04.00	1 A PHARMA GMBH	DE
Carvedilol - 1 A Pharma 12,5 mg Tabletten	DE/H/1986/003	56447.02.00	1 A PHARMA GMBH	DE
Carvedilol Teva 25 mg, tabletten	not available	RVG 29080	TEVA NEDERLAND B.V.	NL
Carvedilol Teva 6,25 mg, tabletten	not available	RVG 29078	TEVA NEDERLAND B.V.	NL
Dilatrend® 25 mg, Tabletten	not available	36867.02.00	CHEPLAPHARM ARZNEIMITTEL GMBH	DE
Dilatrend® 6,25 mg, Tabletten	not available	36867.00.00	CHEPLAPHARM ARZNEIMITTEL GMBH	DE
Dilatrend® 12,5 mg, Tabletten	not available	36867.01.00	CHEPLAPHARM ARZNEIMITTEL GMBH	DE
Dilatrend 12,5 mg - Tabletten	not available	1-21705	CHEPLAPHARM ARZNEIMITTEL GMBH	AT
Dilatrend 25 mg - Tabletten	not available	1-19553	CHEPLAPHARM ARZNEIMITTEL GMBH	AT

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 - Tabletten	not available	1-21706	CHEPLAPHARM ARZNEIMITTEL GMBH	AT
Carvipress 3,125 mg compresse	not available	027606096	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
Carvipress 12,5 mg compresse	not available	027606060	VISUFARMA SPA	IT
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

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
Carvipress 50 mg compresse	not available	027606021	VISUFARMA SPA	IT
Dilatrend® 25 mg, Tabletten	not available	36867.02.00	CHEPLAPHARM ARZNEIMITTEL GMBH	DE
Dilatrend® 6,25 mg, Tabletten	not available	36867.00.00	CHEPLAPHARM ARZNEIMITTEL GMBH	DE
Dilatrend® 12,5 mg, Tabletten	not available	36867.01.00	CHEPLAPHARM ARZNEIMITTEL GMBH	DE
Carvedilol Teva 3,125 mg, tabletten	not available	RVG 29077	TEVA NEDERLAND B.V.	NL
Carvedilol Aurobindo 3,125 mg, filmomhulde tabletten	not available	RVG 107593	AUROBINDO PHARMA B.V.	NL
Carvedilol Aurobindo 12,5 mg, filmomhulde tabletten	not available	RVG 107595	AUROBINDO PHARMA B.V.	NL
Dilatrend 12,5 mg tabletta	not available	OGYI-T-4965/02	CHEPLAPHARM ARZNEIMITTEL GMBH	HU
KREDEX 6,25 mg, comprimé sécable	not available	34009 342 341 6 3	CHEPLAPHARM ARZNEIMITTEL GMBH	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
KREDEX 6,25 mg, comprimé sécable	not available	34009 342 344 5 3	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
KREDEX 6,25 mg, comprimé sécable	not available	34009 342 343 9 2	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
KREDEX 6,25 mg, comprimé sécable	not available	34009 342 342 2 4	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
KREDEX 6,25 mg, comprimé sécable	not available	34009 342 339 1 3	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
KREDEX 6,25 mg, comprimé sécable	not available	34009 342 338 5 2	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
KREDEX 12,5 mg, comprimé sécable	not available	34009 342 345 1 4	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
KREDEX 12,5 mg, comprimé sécable	not available	34009 342 346 8 2	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
KREDEX 12,5 mg, comprimé sécable	not available	34009 342 347 4 3	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
KREDEX 25 mg, comprimé sécable	not available	34009 334 241 6 9	CHEPLAPHARM ARZNEIMITTEL GMBH	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
KREDEX 25 mg, comprimé sécable	not available	34009 344 202 3 8	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
KREDEX 25 mg, comprimé sécable	not available	34009 342 639 5 8	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
KREDEX 25 mg, comprimé sécable	not available	34009 344 199 2 8	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
Eucardic 6.25 mg Tablets	not available	PA2239/001/001	CHEPLAPHARM ARZNEIMITTEL GMBH	IE
Eucardic 12.5 mg Tablets	not available	PA2239/001/002	CHEPLAPHARM ARZNEIMITTEL GMBH	IE
Eucardic 25 mg Tablets	not available	PA2239/001/003	CHEPLAPHARM ARZNEIMITTEL GMBH	IE
Carvedilol 3.125mg Tablets	not available	PL 36687/0269	TORRENT PHARMA (UK) LTD.	XI
Carvedilol 6.25mg Tablets	not available	PL 36687/0270	TORRENT PHARMA (UK) LTD.	XI
Carvedilol 12.5 mg Tablets	not available	PL 36687/0271	TORRENT PHARMA (UK) LTD.	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
Carvedilol 25 mg Tablets	not available	PL 36687/0272	TORRENT PHARMA (UK) LTD.	XI
Carvedilol Teva 12,5 mg, tabletten	not available	RVG 29079	TEVA NEDERLAND B.V.	NL
DILATREND 6,25 tablety	not available	77/1289/97-C	CHEPLAPHARM ARZNEIMITTEL GMBH	CZ
DILATREND 25 tablety	not available	77/1015/92-S/C	CHEPLAPHARM ARZNEIMITTEL GMBH	CZ
Dilatrend 12,5 mg compresse	not available	027604065	CHEPLAPHARM ARZNEIMITTEL GMBH	IT
Dilatrend 12,5 mg compresse	not available	027604077	CHEPLAPHARM ARZNEIMITTEL GMBH	IT
Dilatrend 25 mg compresse	not available	027604089	CHEPLAPHARM ARZNEIMITTEL GMBH	IT
Dilatrend 25 mg compresse	not available	027604014	CHEPLAPHARM ARZNEIMITTEL GMBH	IT
Dilatrend 6,25 mg compresse	not available	027604053	CHEPLAPHARM ARZNEIMITTEL 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
Dilatrend 6,25 mg compresse	not available	027604040	CHEPLAPHARM ARZNEIMITTEL GMBH	IT
Dilatrend 6,25 mg compresse	not available	027604038	CHEPLAPHARM ARZNEIMITTEL GMBH	IT
Dilatrend® 12,5 mg/TAB, δισκία	not available	106831/17/06-06-2019	CHEPLAPHARM ARZNEIMITTEL GMBH	GR
Dilatrend® 25 mg/TAB, δισκία	not available	112948/17/06-06-2019	CHEPLAPHARM ARZNEIMITTEL GMBH	GR
Dilatrend® 6,25 mg/TAB, δισκία	not available	115696/17/06-06-2019	CHEPLAPHARM ARZNEIMITTEL GMBH	GR
Kredex 25 mg comprimés	not available	2002106775	CHEPLAPHARM ARZNEIMITTEL GMBH	LU
Kredex 25 mg Tabletten	not available	2002106775	CHEPLAPHARM ARZNEIMITTEL GMBH	LU
Kredex 6,25 mg comprimés	not available	2002106776	CHEPLAPHARM ARZNEIMITTEL GMBH	LU
Kredex 6,25 mg Tabletten	not available	2002106776	CHEPLAPHARM ARZNEIMITTEL GMBH	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
Dilbloc 25 mg Comprimidos	not available	4702080	CHEPLAPHARM ARZNEIMITTEL GMBH	PT
Dilbloc 25 mg Comprimidos	not available	4702288	CHEPLAPHARM ARZNEIMITTEL GMBH	PT
Dilbloc 25 mg Comprimidos	not available	4702189	CHEPLAPHARM ARZNEIMITTEL GMBH	PT
Dilbloc IC 6,25 mg Comprimidos	not available	4701983	CHEPLAPHARM ARZNEIMITTEL GMBH	PT
Dilbloc IC 6,25 mg Comprimidos	not available	2532489	CHEPLAPHARM ARZNEIMITTEL GMBH	PT
Eucardic 6.25 mg Tablets	not available	PA2239/001/001	CHEPLAPHARM ARZNEIMITTEL GMBH	IE
Eucardic 12.5 mg Tablets	not available	PA2239/001/002	CHEPLAPHARM ARZNEIMITTEL GMBH	IE
Eucardic 25 mg Tablets	not available	PA2239/001/003	CHEPLAPHARM ARZNEIMITTEL GMBH	IE
Дилатренд 6,25 mg таблетки	not available	II-3428	TCHAIKAPHARMA HIGH QUALITY MEDICINES, INC.	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
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
Carvedilol HEXAL 50 mg tabletit	FI/H/0182/005	17072	HEXAL A/S	FI
Carvedilol HEXAL 3,125 mg tabletit	FI/H/0182/001	17068	HEXAL A/S	FI
Dilatrend 6,25 mg tablete	not available	H/98/00474/001	CHEPLAPHARM ARZNEIMITTEL GMBH	SI
Dilatrend 25 mg tablete	not available	H/98/00474/003	CHEPLAPHARM ARZNEIMITTEL GMBH	SI
Dilatrend 12,5 mg tablete	not available	H/98/00474/002	CHEPLAPHARM ARZNEIMITTEL GMBH	SI
Coropres 25 mg comprimidos	not available	59.695	CHEPLAPHARM ARZNEIMITTEL GMBH	ES
Coropres 6,25 mg comprimidos	not available	61.281	CHEPLAPHARM ARZNEIMITTEL GMBH	ES

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
Carvedilol 3.125 mg film-coated tablets	MT/H/0452/001	MA807/05901	AUROBINDO PHARMA (MALTA) LIMITED	MT
Carvedilol Hexal 50 mg Tabletten	DE/H/1985/005	56442.04.00	HEXAL AG	DE
Carvedilol Hexal 12,5 mg Tabletten	DE/H/1985/003	56442.02.00	HEXAL AG	DE
Carvedilol Sandoz 50 mg, tabletten	DE/H/1985/005	RVG 28749	SANDOZ B.V.	NL
Carvedilol Sandoz 3,125 mg, tabletten	DE/H/1985/001	RVG 28745	SANDOZ B.V.	NL
Carvedilol Hexal 3,125 mg tabletter	DE/H/1985/001	19094	HEXAL A/S	SE
Kredex 25 mg comprimés	not available	BE150875	CHEPLAPHARM ARZNEIMITTEL GMBH	BE
Kredex 25 mg Tabletten	not available	BE150875	CHEPLAPHARM ARZNEIMITTEL GMBH	BE
Kredex 25 mg tabletten	not available	BE150875	CHEPLAPHARM ARZNEIMITTEL GMBH	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
Kredex 6,25 mg comprimés	not available	BE182996	CHEPLAPHARM ARZNEIMITTEL GMBH	BE
Kredex 6,25 mg tabletten	not available	BE182996	CHEPLAPHARM ARZNEIMITTEL GMBH	BE
Kredex 6,25 mg Tabletten	not available	BE182996	CHEPLAPHARM ARZNEIMITTEL GMBH	BE
Dilatrend, 6,25 mg, tabletki	not available	R/7161	CHEPLAPHARM ARZNEIMITTEL GMBH	PL
Dilatrend, 25 mg, tabletki	not available	R/7176	CHEPLAPHARM ARZNEIMITTEL GMBH	PL
Dilatrend, 12,5 mg, tabletki	not available	R/7162	CHEPLAPHARM ARZNEIMITTEL GMBH	PL
Dilatrend 12,5 mg - Tabletten	not available	1-21705	CHEPLAPHARM ARZNEIMITTEL GMBH	AT
Dilatrend 25 mg - Tabletten	not available	1-19553	CHEPLAPHARM ARZNEIMITTEL GMBH	AT
Dilatrend 6,25 mg - Tabletten	not available	1-21706	CHEPLAPHARM ARZNEIMITTEL GMBH	AT

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 25 mg tabletti	not available	11017	CHEPLAPHARM ARZNEIMITTEL GMBH	FI
Cardiol 25 mg tabletter	not available	11017	CHEPLAPHARM ARZNEIMITTEL GMBH	FI
Cardiol 12,5 mg tabletter	not available	11868	CHEPLAPHARM ARZNEIMITTEL GMBH	FI
Cardiol 12,5 mg tabletti	not available	11868	CHEPLAPHARM ARZNEIMITTEL GMBH	FI