



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 September 2019
EMA/474202/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: bisoprolol / hydrochlorothiazide

Procedure no.: PSUSA/00000420/201811

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An agency of the European Union



Product full name	MRP/DCP or CP Authorisation number	National Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
WYTENS 2,5 mg/6,25 mg, comprimé pelliculé	not available	345 738-4	MEDA PHARMA SAS	FR
WYTENS 2,5 mg/6,25 mg, comprimé pelliculé	not available	357 010-0	MEDA PHARMA SAS	FR
WYTENS 2,5 mg/6,25 mg, comprimé pelliculé	not available	345 740-9	MEDA PHARMA SAS	FR
WYTENS 2,5 mg/6,25 mg, comprimé pelliculé	not available	345 739-0	MEDA PHARMA SAS	FR
WYTENS 2,5 mg/6,25 mg, comprimé pelliculé	not available	357 011-7	MEDA PHARMA SAS	FR
WYTENS 2,5 mg/6,25 mg, comprimé pelliculé	not available	388 721-6	MEDA PHARMA SAS	FR
WYTENS 2,5 mg/6,25 mg, comprimé pelliculé	not available	388 723-9	MEDA PHARMA SAS	FR
WYTENS 2,5 mg/6,25 mg, comprimé pelliculé	not available	388 719-1	MEDA PHARMA SAS	FR
WYTENS 2,5 mg/6,25 mg, comprimé pelliculé	not available	388 722-2	MEDA PHARMA SAS	FR
WYTENS 2,5 mg/6,25 mg, comprimé pelliculé	not available	388 724-5	MEDA PHARMA SAS	FR
WYTENS 5 mg/6,25 mg, comprimé pelliculé	not available	345 743-8	MEDA PHARMA SAS	FR
WYTENS 5 mg/6,25 mg, comprimé pelliculé	not available	357 012-3	MEDA PHARMA SAS	FR
WYTENS 5 mg/6,25 mg, comprimé pelliculé	not available	345 744-4	MEDA PHARMA SAS	FR

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WYTENS 5 mg/6,25 mg, comprimé pelliculé	not available	345 745-0	MEDA PHARMA SAS	FR
WYTENS 5 mg/6,25 mg, comprimé pelliculé	not available	388 725.1	MEDA PHARMA SAS	FR
WYTENS 5 mg/6,25 mg, comprimé pelliculé	not available	357 014-6	MEDA PHARMA SAS	FR
WYTENS 5 mg/6,25 mg, comprimé pelliculé	not available	388 728.0	MEDA PHARMA SAS	FR
WYTENS 5 mg/6,25 mg, comprimé pelliculé	not available	388 729.7	MEDA PHARMA SAS	FR
WYTENS 5 mg/6,25 mg, comprimé pelliculé	not available	388 726.8	MEDA PHARMA SAS	FR
WYTENS 10 mg/6,25 mg, comprimé pelliculé	not available	345 749 6	MEDA PHARMA SAS	FR
WYTENS 10 mg/6,25 mg, comprimé pelliculé	not available	357 015 2	MEDA PHARMA SAS	FR
WYTENS 10 mg/6,25 mg, comprimé pelliculé	not available	345 750 4	MEDA PHARMA SAS	FR
WYTENS 10 mg/6,25 mg, comprimé pelliculé	not available	345 751 0	MEDA PHARMA SAS	FR
WYTENS 10 mg/6,25 mg, comprimé pelliculé	not available	388 734.0	MEDA PHARMA SAS	FR
WYTENS 10 mg/6,25 mg, comprimé pelliculé	not available	357 016 9	MEDA PHARMA SAS	FR
WYTENS 10 mg/6,25 mg, comprimé pelliculé	not available	388 732.8	MEDA PHARMA SAS	FR

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WYTENS 10 mg/6,25 mg, comprimé pelliculé	not available	388 730.5	MEDA PHARMA SAS	FR
WYTENS 10 mg/6,25 mg, comprimé pelliculé	not available	388 733.4	MEDA PHARMA SAS	FR
WYTENS 10 mg/6,25 mg, comprimé pelliculé	not available	388 731.1	MEDA PHARMA SAS	FR
Emcoretic Mitis 5 mg / 12,5 mg Filmtabletten	not available	BE162802	MERCK N.V./S.A.	BE
Emcoretic 10 mg / 25 mg Filmtabletten	not available	BE162793	MERCK N.V./S.A.	BE
Emcoretic Mitis 5 mg / 12,5 mg comprimés pelliculés	not available	BE162802	MERCK N.V./S.A.	BE
Emcoretic 10 mg / 25 mg comprimés pelliculés	not available	BE162793	MERCK N.V./S.A.	BE
Emcoretic 10 mg / 25 mg filmomhulde tabletten	not available	BE162793	MERCK N.V./S.A.	BE
Emcoretic Mitis 5 mg / 12,5 mg filmomhulde tabletten	not available	BE162802	MERCK N.V./S.A.	BE
Lodoz 2,5 mg / 6,25 mg filmom obložene tablete	not available	HR-H-721781521	MERCK D.O.O	HR
Lodoz 5 mg / 6,25 mg filmom obložene tablete	not available	HR-H-374007129	MERCK D.O.O	HR
Lodoz 10 mg / 6,25 mg filmom obložene tablete	not available	HR-H-693599830	MERCK D.O.O	HR
Bisoprolol-HCT Sandoz 10 mg/25 mg - Filmtabletten	DE/H/0653/002	1-29141	SANDOZ GMBH	AT

Product full name	MRP/DCP or CP Authorisation number	National Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
BIBLOC H 5 mg/12.5 mg film-coated tablets	DE/H/0653/001	20100329	SANDOZ PHARMACEUTICALS D.D.	BG
MAXSOTEN 10mg/25mg, Filmtabletten	not available	BE 165855	MYLAN EPD BVBA/SPRL	BE
MAXSOTEN 10mg/25mg comprimés pelliculés	not available	BE 165855	MYLAN EPD BVBA/SPRL	BE
MAXSOTEN 10mg/25mg filmomhulde tabletten	not available	BE 165855	MYLAN EPD BVBA/SPRL	BE
Bisoprolol-HCT Arcana 5 mg/12,5 mg Filmtabletten	not available	1-23188	ARCANA ARZNEIMITTEL GMBH	AT
Лодоз 10 mg/6,25 mg, филмирани таблетки	not available	20050130	MERCK KGAA	BG
Лодоз 2,5 mg/6,25 mg, филмирани таблетки	not available	20050141	MERCK KGAA	BG
Лодоз 5 mg/6,25 mg, филмирани таблетки	not available	20050142	MERCK KGAA	BG
Concor plus 5 mg/12,5 mg - Filmtabletten	not available	1-20079	MERCK GESELLSCHAFT MBH	AT
Bisoprolol-ratiopharm® comp. 10 mg/25 mg Filmtabletten	not available	33198.01.00	RATIOPHARM GMBH	DE
Bisoprolol-ratiopharm® comp. 5 mg/12,5 mg Filmtabletten	not available	33198.00.00	RATIOPHARM GMBH	DE
Lodoz 2,5 mg/6,25 mg comprimés pelliculés	not available	BE365793	MERCK N.V./S.A.	BE
Lodoz 5 mg/6,25 mg comprimés pelliculés	not available	BE365802	MERCK N.V./S.A.	BE

Product full name	MRP/DCP or CP Authorisation number	National Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Lodoz 2,5 mg/6,25 mg Bisoprololfumarat / Hydrochlorothiazid Filmtabletten	not available	BE365793	MERCK N.V./S.A.	BE
Lodoz 5 mg/6,25 mg Bisoprololfumarat / Hydrochlorothiazid Filmtabletten	not available	BE365802	MERCK N.V./S.A.	BE
Lodoz 2,5 mg/6,25 mg filmomhulde tabletten	not available	BE365793	MERCK N.V./S.A.	BE
Lodoz 5 mg/6,25 mg filmomhulde tabletten	not available	BE365802	MERCK N.V./S.A.	BE
LODOZ 10 mg/6,25 mg comprimate filmate	not available	9843/2017/01	MERCK KGAA	RO
LODOZ 10 mg/6,25 mg comprimate filmate	not available	9843/2017/02	MERCK KGAA	RO
LODOZ 2,5 mg/6,25 mg comprimate filmate	not available	9841/2017/01	MERCK KGAA	RO
LODOZ 2,5 mg/6,25 mg comprimate filmate	not available	9841/2017/02	MERCK KGAA	RO
LODOZ 5 mg/6,25 mg comprimate filmate	not available	9842/2017/01	MERCK KGAA	RO
LODOZ 5 mg/6,25 mg comprimate filmate	not available	9842/2017/02	MERCK KGAA	RO
LODOZ 5 mg/6,25 mg comprimate filmate	not available	9842/2017/03	MERCK KGAA	RO
LODOZ 10 mg/6,25 mg comprimate filmate	not available	9842/2017/03	MERCK KGAA	RO

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LODOZ 10 mg/6,25 mg comprimé filmaté	not available	9843/2017/03	MERCK KGAA	RO
LODOZ 2,5 mg/6,25 mg comprimé filmaté	not available	9841/2017/03	MERCK KGAA	RO
Concor 10 Plus 10 mg + 25 mg comprimidos revestidos	not available	3643483	MERCK, S.A.	PT
Concor 10 Plus 10 mg + 25 mg comprimidos revestidos	not available	2200087	MERCK, S.A.	PT
Concor 10 Plus 10 mg + 25 mg comprimidos revestidos	not available	4624284	MERCK, S.A.	PT
Concor 10 Plus 10 mg + 25 mg comprimidos revestidos	not available	4624185	MERCK, S.A.	PT
LODOZ 10 mg/6,25 mg, comprimé pelliculé	FR/H/0196/003	386 973-8	MERCK SANTÉ S.A.S.	FR
LODOZ 10 mg/6,25 mg, comprimé pelliculé	FR/H/0196/003	386 974-4	MERCK SANTÉ S.A.S.	FR
Lodoz 5 mg /6,25 mg, compresse rivestite con film	FR/H/0196/002	035583069	MERCK SERONO S.P.A.	IT
Lodoz 2,5 mg /6,25 mg, compresse rivestite con film	FR/H/0196/001	035583160	MERCK SERONO S.P.A.	IT
Lodoz 2,5 mg /6,25 mg, compresse rivestite con film	FR/H/0196/001	035583020	MERCK SERONO S.P.A.	IT
Lodoz 2,5 mg /6,25 mg, compresse rivestite con film	FR/H/0196/001	035583172	MERCK SERONO S.P.A.	IT
Lodoz 2,5 mg /6,25 mg, compresse rivestite con film	FR/H/0196/001	035583032	MERCK SERONO S.P.A.	IT

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Lodoz 2,5 mg /6,25 mg, compresse rivestite con film	FR/H/0196/001	035583184	MERCK SERONO S.P.A.	IT
Lodoz 2,5 mg /6,25 mg, compresse rivestite con film	FR/H/0196/001	035583044	MERCK SERONO S.P.A.	IT
Lodoz 2,5 mg /6,25 mg, compresse rivestite con film	FR/H/0196/001	035583196	MERCK SERONO S.P.A.	IT
Lodoz 2,5 mg /6,25 mg, compresse rivestite con film	FR/H/0196/001	035583057	MERCK SERONO S.P.A.	IT
Lodoz 2,5 mg /6,25 mg, compresse rivestite con film	FR/H/0196/001	035583208	MERCK SERONO S.P.A.	IT
Lodoz 5 mg /6,25 mg, compresse rivestite con film	FR/H/0196/002	035583210	MERCK SERONO S.P.A.	IT
Lodoz 5 mg /6,25 mg, compresse rivestite con film	FR/H/0196/002	035583071	MERCK SERONO S.P.A.	IT
Lodoz 5 mg /6,25 mg, compresse rivestite con film	FR/H/0196/002	035583083	MERCK SERONO S.P.A.	IT
Lodoz 5 mg /6,25 mg, compresse rivestite con film	FR/H/0196/002	035583234	MERCK SERONO S.P.A.	IT
Lodoz 5 mg /6,25 mg, compresse rivestite con film	FR/H/0196/002	035583095	MERCK SERONO S.P.A.	IT
Lodoz 5 mg /6,25 mg, compresse rivestite con film	FR/H/0196/002	035583246	MERCK SERONO S.P.A.	IT
Lodoz 5 mg /6,25 mg, compresse rivestite con film	FR/H/0196/002	035583107	MERCK SERONO S.P.A.	IT
Lodoz 5 mg /6,25 mg, compresse rivestite con film	FR/H/0196/002	035583259	MERCK SERONO S.P.A.	IT

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Lodoz 10 mg /6,25 mg, compresse rivestite con film	FR/H/0196/003	035583119	MERCK SERONO S.P.A.	IT
Lodoz 10 mg /6,25 mg, compresse rivestite con film	FR/H/0196/003	035583261	MERCK SERONO S.P.A.	IT
Lodoz 10 mg /6,25 mg, compresse rivestite con film	FR/H/0196/003	035583121	MERCK SERONO S.P.A.	IT
Lodoz 10 mg /6,25 mg, compresse rivestite con film	FR/H/0196/003	035583273	MERCK SERONO S.P.A.	IT
Lodoz 10 mg /6,25 mg, compresse rivestite con film	FR/H/0196/003	035583133	MERCK SERONO S.P.A.	IT
Lodoz 10 mg /6,25 mg, compresse rivestite con film	FR/H/0196/003	035583285	MERCK SERONO S.P.A.	IT
Lodoz 10 mg /6,25 mg, compresse rivestite con film	FR/H/0196/003	035583145	MERCK SERONO S.P.A.	IT
Lodoz 10 mg /6,25 mg, compresse rivestite con film	FR/H/0196/003	035583297	MERCK SERONO S.P.A.	IT
Lodoz 10 mg /6,25 mg, compresse rivestite con film	FR/H/0196/003	035583309	MERCK SERONO S.P.A.	IT
LODOZ 10 mg/6,25 mg, comprimé pelliculé	FR/H/0196/003	34009 386 977 3 5	MERCK SANTÉ S.A.S.	FR
LODOZ 10 mg/6,25 mg, comprimé pelliculé	FR/H/0196/003	34009 386 975 0 6	MERCK SANTÉ S.A.S.	FR
LODOZ 10 mg/6,25 mg, comprimé pelliculé	FR/H/0196/003	34009 386 976 7 4	MERCK SANTÉ S.A.S.	FR
LODOZ 2,5 mg/6,25 mg, comprimé pelliculé	FR/H/0196/001	34009 386 967 8 3	MERCK SANTÉ S.A.S.	FR

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LODOZ 2,5 mg/6,25 mg, comprimé pelliculé	FR/H/0196/001	34009 386 963 2 5	MERCK SANTÉ S.A.S.	FR
LODOZ 2,5 mg/6,25 mg, comprimé pelliculé	FR/H/0196/001	34009 386 964 9 3	MERCK SANTÉ S.A.S.	FR
LODOZ 2,5 mg/6,25 mg, comprimé pelliculé	FR/H/0196/001	34009 386 965 5 4	MERCK SANTÉ S.A.S.	FR
LODOZ 2,5 mg/6,25 mg, comprimé pelliculé	FR/H/0196/001	34009 386 966 1 5	MERCK SANTÉ S.A.S.	FR
LODOZ 5 mg/6,25 mg, comprimé pelliculé	FR/H/0196/002	34009 386 972 1 6	MERCK SANTÉ S.A.S.	FR
LODOZ 5 mg/6,25 mg, comprimé pelliculé	FR/H/0196/002	34009 386 968 4 4	MERCK SANTÉ S.A.S.	FR
LODOZ 5 mg/6,25 mg, comprimé pelliculé	FR/H/0196/002	34009 386 969 0 5	MERCK SANTÉ S.A.S.	FR
LODOZ 5 mg/6,25 mg, comprimé pelliculé	FR/H/0196/002	34009 386 970 9 4	MERCK SANTÉ S.A.S.	FR
LODOZ 5 mg/6,25 mg, comprimé pelliculé	FR/H/0196/002	34009 386 971 5 5	MERCK SANTÉ S.A.S.	FR
Lodoz 2,5 mg/6,25 mg tabletter, filmdrasjerte	FR/H/0196/001	01-7698	MERCK KGAA	NO
Lodoz 5 mg/6,25 mg tabletter, filmdrasjerte	FR/H/0196/002	01-7699	MERCK KGAA	NO
LODOZ 10 mg/6,25 mg, comprimé pelliculé	FR/H/0196/003	34009 345 905 8 0	MERCK SANTÉ S.A.S.	FR
LODOZ 10 mg/6,25 mg, comprimé pelliculé	FR/H/0196/003	34009 356 758 1 1	MERCK SANTÉ S.A.S.	FR

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LODOZ 10 mg/6,25 mg, comprimé pelliculé	FR/H/0196/003	34009 345 906 4 1	MERCK SANTÉ S.A.S.	FR
LODOZ 10 mg/6,25 mg, comprimé pelliculé	FR/H/0196/003	34009 345 907 0 2	MERCK SANTÉ S.A.S.	FR
LODOZ 10 mg/6,25 mg, comprimé pelliculé	FR/H/0196/003	34009 356 759 8 9	MERCK SANTÉ S.A.S.	FR
LODOZ 2,5 mg/6,25 mg, comprimé pelliculé	FR/H/0196/001	34009 345 896 9 0	MERCK SANTÉ S.A.S.	FR
LODOZ 2,5 mg/6,25 mg, comprimé pelliculé	FR/H/0196/001	34009 356 754 6 0	MERCK SANTÉ S.A.S.	FR
LODOZ 2,5 mg/6,25 mg, comprimé pelliculé	FR/H/0196/001	34009 356 755 2 1	MERCK SANTÉ S.A.S.	FR
LODOZ 2,5 mg/6,25 mg, comprimé pelliculé	FR/H/0196/001	34009 345 895 2 2	MERCK SANTÉ S.A.S.	FR
LODOZ 2,5 mg/6,25 mg, comprimé pelliculé	FR/H/0196/001	34009 345 897 5 1	MERCK SANTÉ S.A.S.	FR
LODOZ 5 mg/6,25 mg, comprimé pelliculé	FR/H/0196/002	34009 356 756 9 9	MERCK SANTÉ S.A.S.	FR
LODOZ 5 mg/6,25 mg, comprimé pelliculé	FR/H/0196/002	34009 345 901 2 2	MERCK SANTÉ S.A.S.	FR
LODOZ 5 mg/6,25 mg, comprimé pelliculé	FR/H/0196/002	34009 345 902 9 0	MERCK SANTÉ S.A.S.	FR
LODOZ 5 mg/6,25 mg, comprimé pelliculé	FR/H/0196/002	34009 345 900 6 1	MERCK SANTÉ S.A.S.	FR
LODOZ 5 mg/6,25 mg, comprimé pelliculé	FR/H/0196/002	34009 356 757 5 0	MERCK SANTÉ S.A.S.	FR

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Lodoz 10 mg /6,25 mg, compresse rivestite con film	FR/H/0196/003	035583158	MERCK SERONO S.P.A.	IT
Lodoz 2,5 mg /6,25 mg, compresse rivestite con film	FR/H/0196/001	035583018	MERCK SERONO S.P.A.	IT
Lodoz 5 mg /6,25 mg, compresse rivestite con film	FR/H/0196/002	035583222	MERCK SERONO S.P.A.	IT
Lodoz 10/6,25 filmom obalené tablety	not available	58/0292/03-S	MERCK SPOL.S.R.O.	SK
Lodoz 2,5/6,25 filmom obalené tablety	not available	58/0290/03-S	MERCK SPOL.S.R.O.	SK
Lodoz 5/6,25 filmom obalené tablety	not available	58/0291/03-S	MERCK SPOL.S.R.O.	SK
Concor Plus 5 mg/12,5 mg filmtabletta	not available	OGYI-T-6547/02	MERCK KFT.	HU
Concor Plus 5 mg/12,5 mg filmtabletta	not available	OGYI-T-6547/01	MERCK KFT.	HU
Concor Plus 5 mg/12,5 mg filmtabletta	not available	OGYI-T-6547/03	MERCK KFT.	HU
Emcoretic 10 mg/25 mg comprimidos recubiertos con película	not available	60.243	MERCK, S.L.	ES
Lodoz 10 mg/6,25 mg apvalkotās tabletes	not available	03-0490	MERCK KGAA	LV
Lodoz 2,5 mg/6,25 mg apvalkotās tabletes	not available	03-0488	MERCK KGAA	LV
Lodoz 5 mg/6,25 mg apvalkotās tabletes	not available	03-0489	MERCK KGAA	LV
Concor® 10 plus; Filmtabletten	not available	194985	MERCK SERONO GMBH	LU

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Concor® 10 plus; Filmdabletten	not available	194968	MERCK SERONO GMBH	LU
Concor® 5 plus; Filmdabletten	not available	194954	MERCK SERONO GMBH	LU
Concor® 5 plus; Filmdabletten	not available	194937	MERCK SERONO GMBH	LU
Concor® 10 plus; Filmdabletten	not available	29007.01.00	MERCK SERONO GMBH	DE
Concor® 5 plus; Filmdabletten	not available	29007.00.00	MERCK SERONO GMBH	DE
Emconcor comp 10 mg/25 mg tableti, kalvopäällysteinen	not available	12099	MERCK KGAA	FI
Emconcor comp 5 mg/12,5 mg tableti, kalvopäällysteinen	not available	12098	MERCK KGAA	FI
LODOZ 10 mg/6,25 mg potahované tablety	not available	58/359/03-C	MERCK SPOL.S.R.O.	CZ
LODOZ 2,5 mg/6,25 mg potahované tablety	not available	58/357/03-C	MERCK SPOL.S.R.O.	CZ
LODOZ 5 mg/6,25 mg potahované tablety	not available	58/358/03-C	MERCK SPOL.S.R.O.	CZ
Lodoz 10 mg/6,25 mg filmsko obložene tablete	not available	H/04/00936/003	MERCK D.O.O.	SI
Lodoz 2,5 mg/6,25 mg filmsko obložene tablete	not available	H/04/00936/001	MERCK D.O.O.	SI
Lodoz 5 mg/6,25 mg filmsko obložene tablete	not available	H/04/00936/002	MERCK D.O.O.	SI
Bisoprolol dura plus 5 mg/12,5 mg Filmdabletten	not available	59799.00.00	MYLAN DURA GMBH	DE
Bisoprolol dura plus 10 mg/25 mg Filmdabletten	not available	59799.01.00	MYLAN DURA GMBH	DE