06 July 2022
EMA/319330/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): alfuzosin

Procedure No. PSUSA/00000084/202211

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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
Xatral SR 5 mg Filmtabletten	AT/H/1071/001	1-21754	SANOFI-AVENTIS GMBH OSTERREICH	AT
Xatral SR 5 mg Filmtabletten	AT/H/1071/001	1-21754	SANOFI-AVENTIS GMBH OSTERREICH	AT
Xatral SR 5 mg Filmtabletten	AT/H/1071/001	1-21754	SANOFI-AVENTIS GMBH OSTERREICH	AT
Xatral SR 5 mg Filmtabletten	AT/H/1071/001	1-21754	SANOFI-AVENTIS GMBH OSTERREICH	AT
Xatral Retard 5 mg comprimés à libération prolongée	not available	BE173171	SANOFI BELGIUM	BE
Xatral Retard 5 mg comprimés à libération prolongée	not available	BE173171	SANOFI BELGIUM	BE
Xatral Retard 5 mg Retardtabletten	not available	BE173171	SANOFI BELGIUM	BE
Xatral Retard 5 mg Retardtabletten	not available	BE173171	SANOFI BELGIUM	BE
Xatral Retard 5 mg tabletten met verlengde afgifte	not available	BE173171	SANOFI BELGIUM	BE
Xatral Retard 5 mg tabletten met verlengde afgifte	not available	BE173171	SANOFI BELGIUM	BE
Xatral Uno 10 mg comprimés à libération prolongée	not available	BE220805	SANOFI BELGIUM	BE
Xatral Uno 10 mg comprimés à libération prolongée	not available	BE 220805	SANOFI BELGIUM	BE
Xatral Uno 10 mg Retardtabletten	not available	BE220805	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
Xatral Uno 10 mg Retardtabletten	not available	BE 220805	SANOFI BELGIUM	BE
Xatral Uno 10 mg tabletten met verlengde afgifte.	not available	BE220805	SANOFI BELGIUM	BE
Xatral Uno 10 mg tabletten met verlengde afgifte.	not available	BE220805	SANOFI BELGIUM	BE
XATRAL 5 mg δισκία επικαλυμμένα με υμένιο βραδείας αποδέσμευσης	not available	17139	SANOFI-AVENTIS GROUPE	CY
XATRAL 5 mg δισκία επικαλυμμένα με υμένιο βραδείας αποδέσμευσης	not available	17139	SANOFI-AVENTIS GROUPE	CY
XATRAL OD 10 mg δισκία παρατεταμένης αποδέσμευσης	not available	19244	SANOFI-AVENTIS GROUPE	CY
Alfuzosin Winthrop 2,5 mg Filmtabletten	not available	32177.00.00	WINTHROP ARZNEIMITTEL GMBH	DE
Alfuzosin Winthrop 5 mg Retardtabletten	not available	34637.00.00	WINTHROP ARZNEIMITTEL GMBH	DE
Alfuzosin Winthrop uno 10 mg Retardtabletten	DE/H/2130/001	52204.00.00	WINTHROP ARZNEIMITTEL GMBH	DE
Alfuzosin Zentiva 10 mg Retardtabletten	DE/H/2131/001	52203.00.00	ZENTIVA PHARMA GMBH	DE
UroXatral 10 mg Retardtabletten	DE/H/2129/001	52202.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
UroXatral 10 mg Retardtabletten	DE/H/2129/001	52202.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
UroXatral® 10 mg Retardtabletten	DE/H/2129/001	52202.00.00	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
UroXatral® 10 mg Retardtabletten	DE/H/2129/001	52202.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
UroXatral® 10 mg Retardtabletten	DE/H/2129/001	52202.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
XATRAL SR, 10 mg toimeainet prolongeeritult vabastavad tabletid	not available	345201	SANOFI-AVENTIS GROUPE	EE
Benestan 2,5 mg comprimidos recubiertos con película	not available	60031	SANOFI-AVENTIS, S.A.	ES
Benestan Retard 5 mg comprimidos de liberación prolongada	not available	60767	SANOFI-AVENTIS, S.A.	ES
Unibenestan 10 mg comprimidos de liberación prolongada	not available	63605	SANOFI-AVENTIS, S.A.	ES
XATRAL® CR 10 mg depottablett	not available	13973	SANOFI OY	FI
XATRAL® CR 10 mg depottablett	not available	13973	SANOFI OY	FI
XATRAL® CR 10 mg depottablett	not available	13973	SANOFI OY	FI
XATRAL® CR 10 mg depottabletti	not available	13973	SANOFI OY	FI
XATRAL® CR 10 mg depottabletti	not available	13973	SANOFI OY	FI
XATRAL® CR 10 mg depottabletti	not available	13973	SANOFI OY	FI
ALFUZOSINE ZENTIVA LP 10 mg, comprimé à libération prolongée	not available	34009 372 306 4 3	ZENTIVA 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
ALFUZOSINE ZENTIVA LP 10 mg, comprimé à libération prolongée	not available	34009 561 629 5 6	ZENTIVA FRANCE	FR
ALFUZOSINE ZENTIVA LP 10 mg, comprimé à libération prolongée	not available	34009 561 628 9 5	ZENTIVA FRANCE	FR
ALFUZOSINE ZENTIVA LP 10 mg, comprimé à libération prolongée	not available	34009 351 109 5 4	ZENTIVA FRANCE	FR
ALFUZOSINE ZENTIVA LP 10 mg, comprimé à libération prolongée	not available	34009 351 110 3 6	ZENTIVA FRANCE	FR
XATRAL 2,5 mg, comprimé pelliculé	not available	34009 330 160-1 2	SANOFI-AVENTIS FRANCE	FR
XATRAL 2,5 mg, comprimé pelliculé	not available	34009 556 232-3 6	SANOFI-AVENTIS FRANCE	FR
XATRAL 2,5 mg, comprimé pelliculé	not available	34009 330 161-8 0	SANOFI-AVENTIS FRANCE	FR
XATRAL 2,5 mg, comprimé pelliculé	not available	34009 330 162-4 1	SANOFI-AVENTIS FRANCE	FR
XATRAL LP 10 MG, COMPRIME A LIBERATION PROLONGEE	not available	34009 351 104 3 5	SANOFI-AVENTIS FRANCE	FR
XATRAL LP 10 MG, COMPRIME A LIBERATION PROLONGEE	not available	34009 561 624 3 7	SANOFI-AVENTIS FRANCE	FR
XATRAL LP 10 MG, COMPRIME A LIBERATION PROLONGEE	not available	34009 561 623 7 6	SANOFI-AVENTIS FRANCE	FR
XATRAL LP 10 MG, COMPRIME A LIBERATION PROLONGEE	not available	34009 387 233 8 0	SANOFI-AVENTIS FRANCE	FR
XATRAL LP 10 MG, COMPRIME A LIBERATION PROLONGEE	not available	34009 351 106 6 4	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
XATRAL 5 mg δισκία επικαλυμμένα με υμένιο βραδείας αποδέσμευσης	not available	41973/10/31-05-2011	SANOFI-AVENTIS AEBE	GR
XATRAL 5 mg δισκία επικαλυμμένα με υμένιο βραδείας αποδέσμευσης	not available	41973/10/31-05-2011	SANOFI-AVENTIS AEBE	GR
XATRAL 5 mg δισκία επικαλυμμένα με υμένιο βραδείας αποδέσμευσης	not available	41973/10/31-05-2011	SANOFI-AVENTIS AEBE	GR
XATRAL 5 mg δισκία επικαλυμμένα με υμένιο βραδείας αποδέσμευσης	not available	41973/10/31-05-2011	SANOFI-AVENTIS AEBE	GR
XATRAL 5 mg δισκία επικαλυμμένα με υμένιο βραδείας αποδέσμευσης	not available	41973/10/31-05-2011	SANOFI-AVENTIS AEBE	GR
XATRAL OD 10 mg δισκία παρατεταμένης αποδέσμευσης	not available	41975/10/31-05-2011	SANOFI-AVENTIS MONOPROSOPI A.E.B.E	GR
XATRAL OD 10 mg δισκία παρατεταμένης αποδέσμευσης	not available	41975/10/31-05-2011	SANOFI-AVENTIS AEBE	GR
XATRAL OD 10 mg δισκία παρατεταμένης αποδέσμευσης	not available	41975/10/31-05-2011	SANOFI-AVENTIS MONOPROSOPI A.E.B.E	GR
XATRAL OD 10 mg δισκία παρατεταμένης αποδέσμευσης	not available	41975/10/31-05-2011	SANOFI-AVENTIS MONOPROSOPI A.E.B.E	GR
XATRAL OD 10 mg δισκία παρατεταμένης αποδέσμευσης	not available	41975/10/31-05-2011	SANOFI-AVENTIS MONOPROSOPI A.E.B.E	GR
XATRAL OD 10 mg δισκία παρατεταμένης αποδέσμευσης	not available	41975/10/31-05-2011	SANOFI-AVENTIS MONOPROSOPI A.E.B.E	GR
XATRAL OD 10 mg δισκία παρατεταμένης αποδέσμευσης	not available	41975/10/31-05-2011	SANOFI-AVENTIS MONOPROSOPI A.E.B.E	GR
Alfetim SR 5 mg retard filmtabletta	not available	OGYI-T-8022/02	SANOFI-AVENTIS ZRT	HU

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Alfetim SR 5 mg retard filmtabletta	not available	OGYI-T-8022/03	SANOFI-AVENTIS ZRT	HU
Alfetim UNO 10 mg retard tabletta	not available	OGYI-T-8022/01	SANOFI-AVENTIS ZRT	HU
XATRAL® 10MG PROLONGED RELEASE TABLETS	not available	PA 540/162/3	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	IE
XATRAL® 10MG PROLONGED RELEASE TABLETS	not available	PA 540/162/3	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	IE
XATRAL® 10MG PROLONGED RELEASE TABLETS	not available	PA 540/162/3	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	IE
ALFUZOSINA ZENTIVA 10 mg compresse a rilascio prolungato	not available	027878040	ZENTIVA ITALIA S.R.L.	IT
ALFUZOSINA ZENTIVA 10 mg compresse a rilascio prolungato	not available	027878038	ZENTIVA ITALIA S.R.L.	IT
ALFUZOSINA ZENTIVA 2,5 mg compresse rivestite	not available	027878014	ZENTIVA ITALIA S.R.L.	IT
ALFUZOSINA ZENTIVA 5 mg compresse rivestite a rilascio prolungato	not available	027878026	ZENTIVA ITALIA S.R.L.	IT
MITTOVAL 10 mg compresse a rilascio prolungato	not available	026670048	SANOFI S.R.L.	IT
MITTOVAL 10 mg compresse a rilascio prolungato	not available	026670051	SANOFI S.R.L.	IT
MITTOVAL 2,5 mg compresse rivestite	not available	026670024	SANOFI S.R.L.	IT
XATRAL 10 mg compresse a rilascio prolungato	not available	027314057	SANOFI S.R.L.	IT
XATRAL 10 mg compresse a rilascio prolungato	not available	027314044	SANOFI S.R.L.	IT

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XATRAL 2,5 mg compresse rivestite	not available	027314018	SANOFI S.R.L.	IT
Xatral SR 10 mg pailginto atpalaidavimo tabletės	not available	LT/1/95/1636/004	SANOFI-AVENTIS GROUPE	LT
Xatral Retard 5 mg comprimés à libération prolongée	not available	0225398	SANOFI BELGIUM	LU
XATRAL UNO 10 MG COMPRIMES A LIBERATION PROLONGEE	not available	0304961	SANOFI BELGIUM	LU
XATRAL SR 10 mg ilgstošās darbības tabletes	not available	99-0702	SANOFI-AVENTIS GROUPE	LV
XATRAL SR 10 mg ilgstošās darbības tabletes	not available	99-0702	SANOFI-AVENTIS GROUPE	LV
XATRAL XL 10 mg, prolonged-release tablet	not available	MA1359/03501	SANOFI S.R.L.	MT
DALFAZ SR 5, 5 mg, tabletki powlekane o przedłużonym uwalnianiu	not available	8127	SANOFI-AVENTIS FRANCE	PL
DALFAZ SR 5, 5 mg, tabletki powlekane o przedłużonym uwalnianiu	not available	8127	SANOFI-AVENTIS FRANCE	PL
DALFAZ SR 5, 5 mg, tabletki powlekane o przedłużonym uwalnianiu	not available	8127	SANOFI-AVENTIS FRANCE	PL
DALFAZ UNO, 10 mg, tabletki o przedłużonym uwalnianiu	not available	8378	SANOFI-AVENTIS FRANCE	PL
DALFAZ UNO, 10 mg, tabletki o przedłużonym uwalnianiu	not available	8378	SANOFI-AVENTIS FRANCE	PL
Alfuzosina Zentiva, 10 mg, comprimidos de libertação modificada	not available	3080785	ZENTIVA PORTUGAL, LDA	PT

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Alfuzosina Zentiva, 10 mg, comprimidos de libertação modificada	not available	3080686	ZENTIVA PORTUGAL, LDA	PT
Benestan OD 10 mg comprimidos de libertação modificada	not available	3080983	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
XATRAL SR 10 MG	not available	11628/2019/02	SANOFI ROMANIA SRL	RO
XATRAL SR 10 MG	not available	11628/2019/01	SANOFI ROMANIA SRL	RO
XATRAL OD 10 MG DEPOTTABLETT	SE/H/0112/003	15468	SANOFI AB	SE
XATRAL OD 10 MG DEPOTTABLETT	SE/H/0112/003	15468	SANOFI AB	SE
XATRAL OD 10 MG DEPOTTABLETT	SE/H/0112/003	15468	SANOFI AB	SE
Alfuzosin Hydrochloride 2.5mg Tablets	not available	PL 17780/0220	ZENTIVA PHARMA UK LIMITED	XI
Besavar XL 10mg Tablets	not available	PL 17780/0221	ZENTIVA PHARMA UK LIMITED	XI
Xatral XL 10 mg prolonged release tablets	not available	PL 04425/0657	AVENTIS PHARMA LTD	XI
Xatral XL 10 mg prolonged release tablets	not available	PL 04425/0657	AVENTIS PHARMA LTD	XI
Xatral XL 10 mg prolonged release tablets	not available	PL 04425/0657	AVENTIS PHARMA LTD	XI
Xatral XL 10 mg prolonged release tablets	not available	PL 04425/0657	AVENTIS PHARMA LTD	XI

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Xatral XL 10 mg prolonged release tablets	not available	PL 04425/0657	AVENTIS PHARMA LTD	XI