



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 July 2018
EMA/537159/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: alfuzosin

Procedure No.: PSUSA/00000084/201711



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 2,5 mg, filmomhulde tabletten	not available	RVG 13689	SANOFI-AVENTIS NETHERLANDS B.V.	NL
XATRAL 5 mg δισκία επικαλυμμένα με υμένιο βραδείας αποδέσμευσης	not available	41973/10/31-05-2011	SANOFI-AVENTIS AEBE	GR
XATRAL SR 10 MG	not available	7893/2006/02	SANOFI ROMANIA SRL	RO
UroXatral® 2,5 mg Filmtabletten Alfuzosinhydrochlorid	not available	18111.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
UroXatral® 2,5 mg Filmtabletten Alfuzosinhydrochlorid	not available	18111.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
UroXatral® 2,5 mg Filmtabletten Alfuzosinhydrochlorid	not available	18111.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
UroXatral® 2,5 mg Filmtabletten Alfuzosinhydrochlorid	not available	18111.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
XATRAL 10 MG	not available	027314057	SANOFI SPA	IT
XATRAL	not available	027314018	SANOFI SPA	IT
MITTOVAL	not available	026670048	SANOFI SPA	IT
MITTOVAL	not available	026670024	SANOFI SPA	IT
XATRAL 10 MG	not available	027314044	SANOFI SPA	IT
MITTOVAL	not available	026670051	SANOFI SPA	IT
XATRAL SR 10 MG PROLONGED-RELEASE TABLETS	not available	99-0702	SANOFI-AVENTIS LATVIA SIA	LV
XATRAL SR 10 MG PROLONGED-RELEASE TABLETS	not available	99-0702	SANOFI-AVENTIS LATVIA SIA	LV
XATRAL SR 5 MG SUSTAINED RELEASE TABLETS	not available	MA082/05001	SANOFI MALTA LTD	MT
XATRAL XL 10 MG PROLONGED RELEASE TABLETS	not available	MA082/05002	SANOFI MALTA LTD	MT
Xatral SR 10 mg pailginto atpalaidavimo tabletes	not available	LT/1/95/1636/004	UAB SANOFI-AVENTIS LIETUVA	LT

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
ALFUZOSINA ZENTIVA, 10 MG, COMPRIMIDOS DE LIBERTAÇÃO MODIFICADA	not available	3080686	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
ALFUZOSINA ZENTIVA, 10 MG, COMPRIMIDOS DE LIBERTAÇÃO MODIFICADA	not available	3080785	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Benestan OD 10 mg comprimidos de libertação modificada	not available	3080983	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Benestan 2,5 mg comprimidos revestidos	not available	2135697	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Benestan OD 10 mg comprimidos de libertação modificada	not available	3080884	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Benestan 2,5 mg comprimidos revestidos	not available	2135796	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
XATRAL XR 10 MG, TABLETTEN MET VERLENGDE AFGIFTE	not available	RVG 23923	SANOFI-AVENTIS NETHERLANDS B.V.	NL
Xatral 2,5 mg, filmomhulde tabletten	not available	RVG 13689	SANOFI-AVENTIS NETHERLANDS B.V.	NL
XATRAL XR 10 MG, TABLETTEN MET VERLENGDE AFGIFTE	not available	RVG 23923	SANOFI-AVENTIS NETHERLANDS B.V.	NL
Xatral 2,5 mg, filmomhulde tabletten	not available	RVG 13689	SANOFI-AVENTIS NETHERLANDS B.V.	NL
XATRAL XR 10 MG, TABLETTEN MET VERLENGDE AFGIFTE	not available	RVG 23923	SANOFI-AVENTIS NETHERLANDS B.V.	NL
Xatral 2,5 mg, filmomhulde tabletten	not available	RVG 13689	SANOFI-AVENTIS NETHERLANDS B.V.	NL
XATRAL 2,5 MG, COMPRIME PELLICULE	not available	330 160-1	SANOFI-AVENTIS FRANCE	FR
ALFUZOSINE ZENTIVA LP 10 MG,	not available	561 629-5	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
COMPRIME A LIBERATION PROLONGEE				
ALFUZOSINE ZENTIVA LP 10 MG, COMPRIME A LIBERATION PROLONGEE	not available	351 110-3	SANOFI-AVENTIS FRANCE	FR
XATRAL LP 10 MG, COMPRIME A LIBERATION PROLONGEE	not available	351 104-3	SANOFI-AVENTIS FRANCE	FR
ALFUZOSINE ZENTIVA LP 10 MG, COMPRIME A LIBERATION PROLONGEE	not available	351 109-5	SANOFI-AVENTIS FRANCE	FR
XATRAL 2,5 MG, COMPRIME PELLICULE	not available	556 232-3	SANOFI-AVENTIS FRANCE	FR
ALFUZOSINE ZENTIVA LP 10 MG, COMPRIME A LIBERATION PROLONGEE	not available	372 306-4	SANOFI-AVENTIS FRANCE	FR
XATRAL LP 10 MG, COMPRIME A LIBERATION PROLONGEE	not available	561 624-3	SANOFI-AVENTIS FRANCE	FR
ALFUZOSINE ZENTIVA LP 10 MG, COMPRIME A LIBERATION PROLONGEE	not available	561 628-9	SANOFI-AVENTIS FRANCE	FR
XATRAL 2,5 MG, COMPRIME PELLICULE	not available	330 161-8	SANOFI-AVENTIS FRANCE	FR
XATRAL LP 10 MG, COMPRIME A LIBERATION PROLONGEE	not available	561 623-7	SANOFI-AVENTIS FRANCE	FR
XATRAL LP 10 MG, COMPRIME A LIBERATION PROLONGEE	not available	387 233-8	SANOFI-AVENTIS FRANCE	FR
XATRAL 2,5 MG, COMPRIME PELLICULE	not available	330 162-4	SANOFI-AVENTIS FRANCE	FR
XATRAL LP 10 MG, COMPRIME A LIBERATION PROLONGEE	not available	351 106-6	SANOFI-AVENTIS FRANCE	FR
XATRAL SR, 10 mg toimeainet prolongeeritult vabastavad tabletid	not available	345201	SANOFI-AVENTIS ESTONIA OÜ	EE
ALFUZOSIN WINTHROP 5 MG RETARDTABLETTEN	not available	34637.00.00	WINTHROP ARZNEIMITTEL GMBH	DE
ALFUZOSIN WINTHROP 2.5 MG FILMTABLETTEN	not available	32177.00.00	WINTHROP ARZNEIMITTEL 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
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 5 MG RETARDTABLETTEN	not available	34637.00.00	WINTHROP ARZNEIMITTEL GMBH	DE
ALFUZOSIN WINTHROP 2.5 MG FILMTABLETTEN	not available	32177.00.00	WINTHROP ARZNEIMITTEL GMBH	DE
ALFUZOSIN WINTHROP 2.5 MG FILMTABLETTEN	not available	32177.00.00	WINTHROP ARZNEIMITTEL GMBH	DE
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
Xatral LP 5 mg comprimate cu eliberare prelungită	not available	1026/2008/01	SANOFI ROMANIA SRL	RO
XATRAL SR 10 MG	not available	7893/2006/01	SANOFI ROMANIA SRL	RO
Xatral LP 5 mg comprimate cu eliberare prelungită	not available	1026/2008/02	SANOFI ROMANIA SRL	RO
BENESTAN RETARD 5 MG COMPRIMIDOS DE LIBERACION PROLONGADA	not available	60767	SANOFI-AVENTIS, S.A.	ES
UNIBENESTAN 10 MG COMPRIMIDOS DE LIBERACION PROLONGADA	not available	63605	SANOFI-AVENTIS, S.A.	ES
BENESTAN 2.5 MG COMPRIMIDOS RECUBIERTOS CON PELICULA	not available	60031	SANOFI-AVENTIS, S.A.	ES
BESAVAR XL	not available	PL 17780/0221	WINTHROP PHARMACEUTICALS UK LTD	UK

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
BESAVAR XL	not available	PL 17780/0221	WINTHROP PHARMACEUTICALS UK LTD	UK
ALFUZOSIN HYDROCHLORIDE 2.5MG TABLETS	not available	PL 17780/0220	WINTHROP PHARMACEUTICALS UK LTD	UK
BESAVAR XL	not available	PL 17780/0221	WINTHROP PHARMACEUTICALS UK LTD	UK
BESAVAR XL	not available	PL 17780/0221	WINTHROP PHARMACEUTICALS UK LTD	UK
BESAVAR XL	not available	PL 17780/0221	WINTHROP PHARMACEUTICALS UK LTD	UK
ALFUZOSIN HYDROCHLORIDE 2.5MG TABLETS	not available	PL 17780/0220	WINTHROP PHARMACEUTICALS UK LTD	UK
ALFUZOSIN HYDROCHLORIDE 2.5MG TABLETS	not available	PL 17780/0220	WINTHROP PHARMACEUTICALS UK LTD	UK
Xatral XL 10 mg prolonged release tablets	not available	PL 04425/0657	AVENTIS PHARMA LTD	UK
Xatral XL 10 mg prolonged release tablets	not available	PL 04425/0657	AVENTIS PHARMA LTD	UK
Xatral XL 10 mg prolonged release tablets	not available	PL 04425/0657	AVENTIS PHARMA LTD	UK
Xatral 2.5 mg film coated tablet	not available	PL 04425/0655	AVENTIS PHARMA LTD	UK
Xatral XL 10 mg prolonged release tablets	not available	PL 04425/0657	AVENTIS PHARMA LTD	UK
Xatral XL 10 mg prolonged release tablets	not available	PL 04425/0657	AVENTIS PHARMA LTD	UK
Xatral Retard 5mg comprimés à libération	not available	BE173171	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
prolongée				
XATRAL UNO 10 mg tabletten met verlengde afgifte	not available	BE220805	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 Retard 5mg comprimés à libération prolongée	not available	BE173171	SANOFI BELGIUM	BE
Xatral Retard 5 mg tabletten met verlengde afgifte	not available	BE173171	SANOFI BELGIUM	BE
XATRAL XL 10 MG	not available	019244	SANOFI-AVENTIS CYPRUS LTD	CY
XATRAL CR 10 MG DEPOTTABLETTI	not available	13973	SANOFI OY	FI
Xatral, filmoevertrukne tabletter	not available	13404	SANOFI-AVENTIS DENMARK A/S	DK
XATRAL CR 10 MG DEPOTTABLETTI	not available	13973	SANOFI OY	FI
XATRAL CR 10 MG DEPOTTABLETTI	not available	13973	SANOFI OY	FI
Xatral, filmoevertrukne tabletter	not available	13404	SANOFI-AVENTIS DENMARK A/S	DK
XATRAL 5 mg επικαλυμμένα με λεπτό υμένιο δισκία βραδείας αποδέσμευσης	not available	17139	SANOFI-AVENTIS CYPRUS LTD	CY
Alfetim SR 5 mg retard filmtabletta	not available	OGYI-T-8022/02	SANOFI-AVENTIS ZRT	HU
XATRAL 5 mg δισκία επικαλυμμένα με υμένιο βραδείας αποδέσμευσης	not available	41973/10/31-05-2011	SANOFI-AVENTIS AEBE	GR
XATRAL 5-SR	not available	77/0275/96-S	SANOFI-AVENTIS SLOVAKIA SRO	SK
XATRAL 2,5 mg επικαλυμμένα με λεπτό	not available	41971/10/31-05-2011	SANOFI-AVENTIS AEBE	GR

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
υμένιο δισκία				
DALFAZ SR 5, 5 mg, tabletki powlekane o przedluzonym uwalnianiu	not available	8127	SANOFI-AVENTIS FRANCE	PL
DALFAZ, 2,5 mg, tabletki powlekane	not available	R/6812	SANOFI-AVENTIS FRANCE	PL
Alfetim UNO 10 mg retard tablettá	not available	OGYI-T-8022/01	SANOFI-AVENTIS ZRT	HU
ΧΑΤΡΑΛ 5 mg δισκία επικαλυμμένα με υμένιο βραδείας αποδέσμευσης	not available	41973/10/31-05-2011	SANOFI-AVENTIS AEBE	GR
DALFAZ SR 5, 5 mg, tabletki powlekane o przedluzonym uwalnianiu	not available	8127	SANOFI-AVENTIS FRANCE	PL
DALFAZ UNO, 10 mg, tabletki o przedluzonym uwalnianiu	not available	8378	SANOFI-AVENTIS FRANCE	PL
DALFAZ SR 5, 5 mg, tabletki powlekane o przedluzonym uwalnianiu	not available	8127	SANOFI-AVENTIS FRANCE	PL
ΧΑΤΡΑΛ 5 mg δισκία επικαλυμμένα με υμένιο βραδείας αποδέσμευσης	not available	41973/10/31-05-2011	SANOFI-AVENTIS AEBE	GR
Alfetim SR 5 mg retard filmtablettá	not available	OGYI-T-8022/03	SANOFI-AVENTIS ZRT	HU
ΧΑΤΡΑΛ 5 mg δισκία επικαλυμμένα με υμένιο βραδείας αποδέσμευσης	not available	41973/10/31-05-2011	SANOFI-AVENTIS AEBE	GR
DALFAZ UNO, 10 mg, tabletki o przedluzonym uwalnianiu	not available	8378	SANOFI-AVENTIS FRANCE	PL
ΧΑΤΡΑΛ OD 10 mg δισκία παρατεταμένης αποδέσμευσης	not available	41975/10/31-05-2011	SANOFI-AVENTIS AEBE	GR
ΧΑΤΡΑΛ 2,5 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	41971/10/31-05-2011	SANOFI-AVENTIS AEBE	GR
ΧΑΤΡΑΛ 2,5 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	41971/10/31-05-2011	SANOFI-AVENTIS AEBE	GR
ΧΑΤΡΑΛ OD 10 mg δισκία παρατεταμένης αποδέσμευσης	not available	41975/10/31-05-2011	SANOFI-AVENTIS AEBE	GR

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XATRAL 5-SR	not available	77/0275/96-S	SANOFI-AVENTIS SLOVAKIA SRO	SK
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 AEBE	GR
XATRAL 2.5MG FILM COATED TABLETS	not available	PA 540/162/1	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
XATRAL 2.5MG FILM COATED TABLETS	not available	PA 540/162/1	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	IE
XATRAL 2.5MG FILM COATED TABLETS	not available	PA 540/162/1	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 Retard 5 mg comprimés à libération prolongée	not available	583/98/12/4785	SANOFI BELGIUM	LU
ALFUZOSINA ZENTIVA	not available	027878026	ZENTIVA ITALIA SRL	IT
ALFUZOSINA ZENTIVA	not available	027878040	ZENTIVA ITALIA SRL	IT
ALFUZOSINA ZENTIVA	not available	027878014	ZENTIVA ITALIA SRL	IT
ALFUZOSINA ZENTIVA	not available	027878038	ZENTIVA ITALIA SRL	IT
Benestan AP 5 mg comprimidos de libertação prolongada	not available	2382695	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Benestan AP 5 mg comprimidos de libertação prolongada	not available	2382794	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT

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
ALFUZOSINA ZENTIVA 2,5 MG COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	not available	60033	ZENTIVA, K.S.	ES
ALFUZOSINA ZENTIVA 10 MG COMPRIMIDOS DE LIBERACION PROLONGADA EFG	not available	63604	ZENTIVA, K.S.	ES
ALFUZOSINA ZENTIVA 5 MG COMPRIMIDOS DE LIBERACION PROLONGADA EFG	not available	62832	ZENTIVA, K.S.	ES
ALFUZOSINA ZENTIVA 2,5 MG COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	not available	60033	ZENTIVA, K.S.	ES
Xatral Uno 10 mg comprimés à libération prolongée	not available	0005/03/03/7178	SANOFI BELGIUM	LU
XATRAL LP 5 mg, comprimé pelliculé à libération prolongée	not available	336 615-0	SANOFI-AVENTIS FRANCE	FR
XATRAL LP 5 mg, comprimé pelliculé à libération prolongée	not available	558 144-4	SANOFI-AVENTIS FRANCE	FR
XATRAL LP 5 mg, comprimé pelliculé à libération prolongée	not available	336 619-6	SANOFI-AVENTIS FRANCE	FR
XATRAL LP 5 mg, comprimé pelliculé à libération prolongée	not available	336 617-3	SANOFI-AVENTIS FRANCE	FR
XATRAL LP 5 mg, comprimé pelliculé à libération prolongée	not available	336 616-7	SANOFI-AVENTIS FRANCE	FR
Xatral 2,5 mg, filmomhulde tabletten	not available	RVG 13689	SANOFI-AVENTIS NETHERLANDS B.V.	NL
XATRAL 5 mg δισκία επικαλυμμένα με υμένιο βραδείας αποδέσμευσης	not available	41973/10/31-05-2011	SANOFI-AVENTIS AEBE	GR

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 10 MG	not available	7893/2006/02	SANOFI ROMANIA SRL	RO
UroXatral® 2,5 mg Filmtabletten Alfuzosinhydrochlorid	not available	18111.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
UroXatral® 2,5 mg Filmtabletten Alfuzosinhydrochlorid	not available	18111.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
UroXatral® 2,5 mg Filmtabletten Alfuzosinhydrochlorid	not available	18111.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
UroXatral® 2,5 mg Filmtabletten Alfuzosinhydrochlorid	not available	18111.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
XATRAL 10 MG	not available	027314057	SANOFI SPA	IT
XATRAL	not available	027314018	SANOFI SPA	IT
MITTOVAL	not available	026670048	SANOFI SPA	IT
MITTOVAL	not available	026670024	SANOFI SPA	IT
XATRAL 10 MG	not available	027314044	SANOFI SPA	IT
MITTOVAL	not available	026670051	SANOFI SPA	IT
XATRAL SR 10 MG PROLONGED-RELEASE TABLETS	not available	99-0702	SANOFI-AVENTIS LATVIA SIA	LV
XATRAL SR 10 MG PROLONGED-RELEASE TABLETS	not available	99-0702	SANOFI-AVENTIS LATVIA SIA	LV
XATRAL SR 5 MG SUSTAINED RELEASE TABLETS	not available	MA082/05001	SANOFI MALTA LTD	MT
XATRAL XL 10 MG PROLONGED RELEASE TABLETS	not available	MA082/05002	SANOFI MALTA LTD	MT
Xatral SR 10 mg pailginto atpalaidavimo tabletes	not available	LT/1/95/1636/004	UAB SANOFI-AVENTIS LIETUVA	LT
ALFUZOSINA ZENTIVA, 10 MG, COMPRIMIDOS DE LIBERTAÇÃO MODIFICADA	not available	3080686	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT

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
ALFUZOSINA ZENTIVA, 10 MG, COMPRIMIDOS DE LIBERTAÇÃO MODIFICADA	not available	3080785	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Benestan OD 10 mg comprimidos de libertação modificada	not available	3080983	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Benestan 2,5 mg comprimidos revestidos	not available	2135697	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Benestan OD 10 mg comprimidos de libertação modificada	not available	3080884	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Benestan 2,5 mg comprimidos revestidos	not available	2135796	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
XATRAL XR 10 MG, TABLETTEN MET VERLENGDE AFGIFTE	not available	RVG 23923	SANOFI-AVENTIS NETHERLANDS B.V.	NL
Xatral 2,5 mg, filmomhulde tabletten	not available	RVG 13689	SANOFI-AVENTIS NETHERLANDS B.V.	NL
XATRAL XR 10 MG, TABLETTEN MET VERLENGDE AFGIFTE	not available	RVG 23923	SANOFI-AVENTIS NETHERLANDS B.V.	NL
Xatral 2,5 mg, filmomhulde tabletten	not available	RVG 13689	SANOFI-AVENTIS NETHERLANDS B.V.	NL
XATRAL XR 10 MG, TABLETTEN MET VERLENGDE AFGIFTE	not available	RVG 23923	SANOFI-AVENTIS NETHERLANDS B.V.	NL
Xatral 2,5 mg, filmomhulde tabletten	not available	RVG 13689	SANOFI-AVENTIS NETHERLANDS B.V.	NL
XATRAL 2,5 MG, COMPRIME PELLICULE	not available	330 160-1	SANOFI-AVENTIS FRANCE	FR
ALFUZOSINE ZENTIVA LP 10 MG, COMPRIME A LIBERATION PROLONGEE	not available	561 629-5	SANOFI-AVENTIS FRANCE	FR
ALFUZOSINE ZENTIVA LP 10 MG, COMPRIME A LIBERATION PROLONGEE	not available	351 110-3	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 LP 10 MG, COMPRIME A LIBERATION PROLONGEE	not available	351 104-3	SANOFI-AVENTIS FRANCE	FR
ALFUZOSINE ZENTIVA LP 10 MG, COMPRIME A LIBERATION PROLONGEE	not available	351 109-5	SANOFI-AVENTIS FRANCE	FR
XATRAL 2,5 MG, COMPRIME PELLICULE	not available	556 232-3	SANOFI-AVENTIS FRANCE	FR
ALFUZOSINE ZENTIVA LP 10 MG, COMPRIME A LIBERATION PROLONGEE	not available	372 306-4	SANOFI-AVENTIS FRANCE	FR
XATRAL LP 10 MG, COMPRIME A LIBERATION PROLONGEE	not available	561 624-3	SANOFI-AVENTIS FRANCE	FR
ALFUZOSINE ZENTIVA LP 10 MG, COMPRIME A LIBERATION PROLONGEE	not available	561 628-9	SANOFI-AVENTIS FRANCE	FR
XATRAL 2,5 MG, COMPRIME PELLICULE	not available	330 161-8	SANOFI-AVENTIS FRANCE	FR
XATRAL LP 10 MG, COMPRIME A LIBERATION PROLONGEE	not available	561 623-7	SANOFI-AVENTIS FRANCE	FR
XATRAL LP 10 MG, COMPRIME A LIBERATION PROLONGEE	not available	387 233-8	SANOFI-AVENTIS FRANCE	FR
XATRAL 2,5 MG, COMPRIME PELLICULE	not available	330 162-4	SANOFI-AVENTIS FRANCE	FR
XATRAL LP 10 MG, COMPRIME A LIBERATION PROLONGEE	not available	351 106-6	SANOFI-AVENTIS FRANCE	FR
XATRAL SR, 10 mg toimeainet prolongeeritult vabastavad tabletid	not available	345201	SANOFI-AVENTIS ESTONIA OÜ	EE
ALFUZOSIN WINTHROP 5 MG RETARDTABLETTEN	not available	34637.00.00	WINTHROP ARZNEIMITTEL GMBH	DE
ALFUZOSIN WINTHROP 2.5 MG FILMTABLETTEN	not available	32177.00.00	WINTHROP ARZNEIMITTEL GMBH	DE
ALFUZOSIN WINTHROP 2.5 MG FILMTABLETTEN	not available	32177.00.00	WINTHROP ARZNEIMITTEL GMBH	DE
ALFUZOSIN WINTHROP 5 MG	not available	34637.00.00	WINTHROP ARZNEIMITTEL	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
RETARDTABLETTEN			GMBH	
ALFUZOSIN WINTHROP 5 MG RETARDTABLETTEN	not available	34637.00.00	WINTHROP ARZNEIMITTEL GMBH	DE
ALFUZOSIN WINTHROP 2.5 MG FILMTABLETTEN	not available	32177.00.00	WINTHROP ARZNEIMITTEL GMBH	DE
ALFUZOSIN WINTHROP 2.5 MG FILMTABLETTEN	not available	32177.00.00	WINTHROP ARZNEIMITTEL GMBH	DE
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
Xatral LP 5 mg comprimate cu eliberare prelungită	not available	1026/2008/01	SANOFI ROMANIA SRL	RO
XATRAL SR 10 MG	not available	7893/2006/01	SANOFI ROMANIA SRL	RO
Xatral LP 5 mg comprimate cu eliberare prelungită	not available	1026/2008/02	SANOFI ROMANIA SRL	RO
BENESTAN RETARD 5 MG COMPRIMIDOS DE LIBERACION PROLONGADA	not available	60767	SANOFI-AVENTIS, S.A.	ES
UNIBENESTAN 10 MG COMPRIMIDOS DE LIBERACION PROLONGADA	not available	63605	SANOFI-AVENTIS, S.A.	ES
BENESTAN 2.5 MG COMPRIMIDOS RECUBIERTOS CON PELICULA	not available	60031	SANOFI-AVENTIS, S.A.	ES
BESAVAR XL	not available	PL 17780/0221	WINTHROP PHARMACEUTICALS UK LTD	UK
BESAVAR XL	not available	PL 17780/0221	WINTHROP PHARMACEUTICALS UK LTD	UK

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
ALFUZOSIN HYDROCHLORIDE 2.5MG TABLETS	not available	PL 17780/0220	WINTHROP PHARMACEUTICALS UK LTD	UK
BESAVAR XL	not available	PL 17780/0221	WINTHROP PHARMACEUTICALS UK LTD	UK
BESAVAR XL	not available	PL 17780/0221	WINTHROP PHARMACEUTICALS UK LTD	UK
BESAVAR XL	not available	PL 17780/0221	WINTHROP PHARMACEUTICALS UK LTD	UK
ALFUZOSIN HYDROCHLORIDE 2.5MG TABLETS	not available	PL 17780/0220	WINTHROP PHARMACEUTICALS UK LTD	UK
ALFUZOSIN HYDROCHLORIDE 2.5MG TABLETS	not available	PL 17780/0220	WINTHROP PHARMACEUTICALS UK LTD	UK
Xatral XL 10 mg prolonged release tablets	not available	PL 04425/0657	AVENTIS PHARMA LTD	UK
Xatral XL 10 mg prolonged release tablets	not available	PL 04425/0657	AVENTIS PHARMA LTD	UK
Xatral XL 10 mg prolonged release tablets	not available	PL 04425/0657	AVENTIS PHARMA LTD	UK
Xatral 2.5 mg film coated tablet	not available	PL 04425/0655	AVENTIS PHARMA LTD	UK
Xatral XL 10 mg prolonged release tablets	not available	PL 04425/0657	AVENTIS PHARMA LTD	UK
Xatral XL 10 mg prolonged release tablets	not available	PL 04425/0657	AVENTIS PHARMA LTD	UK
Xatral Retard 5mg comprimés à libération prolongée	not available	BE173171	SANOFI BELGIUM	BE
XATRAL UNO 10 mg tabletten met verlengde afgifte	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 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 Retard 5mg comprimés à libération prolongée	not available	BE173171	SANOFI BELGIUM	BE
Xatral Retard 5 mg tabletten met verlengde afgifte	not available	BE173171	SANOFI BELGIUM	BE
XATRAL XL 10 MG	not available	019244	SANOFI-AVENTIS CYPRUS LTD	CY
XATRAL CR 10 MG DEPOTTABLETTI	not available	13973	SANOFI OY	FI
Xatral, filmoverttrukne tabletter	not available	13404	SANOFI-AVENTIS DENMARK A/S	DK
XATRAL CR 10 MG DEPOTTABLETTI	not available	13973	SANOFI OY	FI
XATRAL CR 10 MG DEPOTTABLETTI	not available	13973	SANOFI OY	FI
Xatral, filmoverttrukne tabletter	not available	13404	SANOFI-AVENTIS DENMARK A/S	DK
XATRAL 5 mg επικαλυμμένα με λεπτό υμένιο δισκία βραδείας αποδέσμευσης	not available	17139	SANOFI-AVENTIS CYPRUS LTD	CY
Alfetim SR 5 mg retard filmtabletta	not available	OGYI-T-8022/02	SANOFI-AVENTIS ZRT	HU
XATRAL 5 mg δισκία επικαλυμμένα με υμένιο βραδείας αποδέσμευσης	not available	41973/10/31-05-2011	SANOFI-AVENTIS AEBE	GR
XATRAL 5-SR	not available	77/0275/96-S	SANOFI-AVENTIS SLOVAKIA SRO	SK
XATRAL 2,5 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	197380105	SANOFI-AVENTIS AEBE	GR
XATRAL 2,5 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	41971/10/31-05-2011	SANOFI-AVENTIS AEBE	GR

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
DALFAZ SR 5, 5 mg, tabletki powlekane o przedluzonym uwalnianiu	not available	8127	SANOFI-AVENTIS FRANCE	PL
DALFAZ, 2,5 mg, tabletki powlekane	not available	R/6812	SANOFI-AVENTIS FRANCE	PL
Alfetim UNO 10 mg retard tableta	not available	OGYI-T-8022/01	SANOFI-AVENTIS ZRT	HU
XATRAL 5 mg δισκία επικαλυμμένα με υμένιο βραδείας αποδέσμευσης	not available	41973/10/31-05-2011	SANOFI-AVENTIS AEBE	GR
DALFAZ SR 5, 5 mg, tabletki powlekane o przedluzonym uwalnianiu	not available	8127	SANOFI-AVENTIS FRANCE	PL
XATRAL 2,5 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	197380104	SANOFI-AVENTIS AEBE	GR
DALFAZ UNO, 10 mg, tabletki o przedluzonym uwalnianiu	not available	8378	SANOFI-AVENTIS FRANCE	PL
DALFAZ SR 5, 5 mg, tabletki powlekane o przedluzonym uwalnianiu	not available	8127	SANOFI-AVENTIS FRANCE	PL
XATRAL 5 mg δισκία επικαλυμμένα με υμένιο βραδείας αποδέσμευσης	not available	41973/10/31-05-2011	SANOFI-AVENTIS AEBE	GR
Alfetim SR 5 mg retard filmtableta	not available	OGYI-T-8022/03	SANOFI-AVENTIS ZRT	HU
XATRAL 5 mg δισκία επικαλυμμένα με υμένιο βραδείας αποδέσμευσης	not available	41973/10/31-05-2011	SANOFI-AVENTIS AEBE	GR
DALFAZ UNO, 10 mg, tabletki o przedluzonym uwalnianiu	not available	8378	SANOFI-AVENTIS FRANCE	PL
XATRAL OD 10 mg δισκία παρατεταμένης αποδέσμευσης	not available	41975/10/31-05-2011	SANOFI-AVENTIS AEBE	GR
XATRAL 2,5 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	41971/10/31-05-2011	SANOFI-AVENTIS AEBE	GR
XATRAL 2,5 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	41971/10/31-05-2011	SANOFI-AVENTIS AEBE	GR
XATRAL OD 10 mg δισκία παρατεταμένης	not available	41975/10/31-05-2011	SANOFI-AVENTIS AEBE	GR

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
αποδέσμευσης				
XATRAL 5-SR	not available	77/0275/96-S	SANOFI-AVENTIS SLOVAKIA SRO	SK
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 AEBE	GR
XATRAL 2.5MG FILM COATED TABLETS	not available	PA 540/162/1	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
XATRAL 2.5MG FILM COATED TABLETS	not available	PA 540/162/1	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	IE
XATRAL 2.5MG FILM COATED TABLETS	not available	PA 540/162/1	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 Retard 5 mg comprimés à libération prolongée	not available	583/98/12/4785	SANOFI BELGIUM	LU
URION 2,5 mg, comprimé pelliculé	not available	3400933312466	ZAMBON FRANCE S.A.	FR
URION 2,5 mg, comprimé pelliculé	not available	3400933312527	ZAMBON FRANCE S.A.	FR
URION 2,5 mg, comprimé pelliculé	not available	3400933312695	ZAMBON FRANCE S.A.	FR
URION 2,5 mg, comprimé pelliculé	not available	340093331856	ZAMBON FRANCE S.A.	FR
Xatral SR 5 mg Filmtabletten	SE/H/0112/002	1-21754	SANOFI-AVENTIS GMBH OSTERREICH	AT
Xatral OD 10 mg depottablett	SE/H/0112/003	15468	SANOFI AB	SE

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	SE/H/0112/002	1-21754	SANOFI-AVENTIS GMBH OSTERREICH	AT
Xatral SR 5 mg Filmtabletten	SE/H/0112/002	1-21754	SANOFI-AVENTIS GMBH OSTERREICH	AT
ALFUZOSINA ZENTIVA	not available	027878026	ZENTIVA ITALIA SRL	IT
ALFUZOSINA ZENTIVA	not available	027878040	ZENTIVA ITALIA SRL	IT
ALFUZOSINA ZENTIVA	not available	027878014	ZENTIVA ITALIA SRL	IT
ALFUZOSINA ZENTIVA	not available	027878038	ZENTIVA ITALIA SRL	IT
Benestan AP 5 mg comprimidos de liberação prolongada	not available	2382695	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Benestan AP 5 mg comprimidos de liberação prolongada	not available	2382794	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
ALFUZOSINA ZENTIVA 2,5 MG COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	not available	60033	ZENTIVA, K.S.	ES
ALFUZOSINA ZENTIVA 10 MG COMPRIMIDOS DE LIBERACION PROLONGADA EFG	not available	63604	ZENTIVA, K.S.	ES
ALFUZOSINA ZENTIVA 5 MG COMPRIMIDOS DE LIBERACION PROLONGADA EFG	not available	62832	ZENTIVA, K.S.	ES
ALFUZOSINA ZENTIVA 2,5 MG COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	not available	60033	ZENTIVA, K.S.	ES
Xatral Uno 10 mg comprimés à libération prolongée	not available	0005/03/03/7178	SANOFI BELGIUM	LU
XATRAL LP 5 mg, comprimé pelliculé à libération prolongée	not available	336 615-0	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 LP 5 mg, comprimé pelliculé à libération prolongée	not available	558 144-4	SANOFI-AVENTIS FRANCE	FR
XATRAL LP 5 mg, comprimé pelliculé à libération prolongée	not available	336 619-6	SANOFI-AVENTIS FRANCE	FR
XATRAL LP 5 mg, comprimé pelliculé à libération prolongée	not available	336 617-3	SANOFI-AVENTIS FRANCE	FR
XATRAL LP 5 mg, comprimé pelliculé à libération prolongée	not available	336 616-7	SANOFI-AVENTIS FRANCE	FR
Xatral SR 5 mg Filmdoublets	SE/H/0112/002	1-21754	SANOFI-AVENTIS GMBH OSTERREICH	AT
Xatral uno 10 mg Retardtablets	SE/H/0112/003	1-24019	SANOFI-AVENTIS GMBH OSTERREICH	AT
Xatral uno 10 mg Retardtablets	SE/H/0112/003	1-24019	SANOFI-AVENTIS GMBH OSTERREICH	AT
Xatral OD 10 mg depottablett	SE/H/0112/003	15468	SANOFI AB	SE
Xatral SR 5 mg Filmdoublets	SE/H/0112/002	1-21754	SANOFI-AVENTIS GMBH OSTERREICH	AT
Xatral uno 10 mg Retardtablets	SE/H/0112/003	1-24019	SANOFI-AVENTIS GMBH OSTERREICH	AT
Xatral OD 10 mg depottablett	SE/H/0112/003	15468	SANOFI AB	SE
Xatral SR 5 mg Filmdoublets	SE/H/0112/002	1-21754	SANOFI-AVENTIS GMBH OSTERREICH	AT
Xatral SR 5 mg Filmdoublets	SE/H/0112/002	1-21754	SANOFI-AVENTIS GMBH OSTERREICH	AT
Xatral OD 10 mg depottablett	SE/H/0112/003	15468	SANOFI AB	SE
Xatral 5 mg depottabletter	SE/H/0112/002	12494	SANOFI AB	SE
Xatral 2,5 mg filmdragerade tabletter	SE/H/0112/001	12493	SANOFI AB	SE
Xatral 5 mg depottabletter	SE/H/0112/002	12494	SANOFI AB	SE

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 depottabletter	SE/H/0112/002	12494	SANOFI AB	SE
Xatral 5 mg depottabletter	SE/H/0112/002	12494	SANOFI AB	SE
Alfuzosinehydrochloride retard Teva 10 mg, tabletten met verlengde afgifte	not available	RVG 102424	TEVA NEDERLAND B.V.	NL
Xatral SR 5 mg Filmtabletten	SE/H/0112/002	1-21754	SANOFI-AVENTIS GMBH OSTERREICH	AT
Xatral uno 10 mg Retardtabletten	SE/H/0112/003	1-24019	SANOFI-AVENTIS GMBH OSTERREICH	AT
Xatral uno 10 mg Retardtabletten	SE/H/0112/003	1-24019	SANOFI-AVENTIS GMBH OSTERREICH	AT
Xatral OD 10 mg depottablett	SE/H/0112/003	15468	SANOFI AB	SE
Xatral SR 5 mg Filmtabletten	SE/H/0112/002	1-21754	SANOFI-AVENTIS GMBH OSTERREICH	AT
Xatral uno 10 mg Retardtabletten	SE/H/0112/003	1-24019	SANOFI-AVENTIS GMBH OSTERREICH	AT
Xatral OD 10 mg depottablett	SE/H/0112/003	15468	SANOFI AB	SE
Xatral SR 5 mg Filmtabletten	SE/H/0112/002	1-21754	SANOFI-AVENTIS GMBH OSTERREICH	AT
Xatral SR 5 mg Filmtabletten	SE/H/0112/002	1-21754	SANOFI-AVENTIS GMBH OSTERREICH	AT
Xatral OD 10 mg depottablett	SE/H/0112/003	15468	SANOFI AB	SE
Xatral 5 mg depottabletter	SE/H/0112/002	12494	SANOFI AB	SE
Xatral 2,5 mg filmdragerade tabletter	SE/H/0112/001	12493	SANOFI AB	SE
Xatral 5 mg depottabletter	SE/H/0112/002	12494	SANOFI AB	SE
Xatral 5 mg depottabletter	SE/H/0112/002	12494	SANOFI AB	SE
Xatral 5 mg depottabletter	SE/H/0112/002	12494	SANOFI AB	SE