



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 January 2017
EMA/167321/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: moxifloxacin (systemic use)

Procedure no.: PSUSA/00009231/201605



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
Octegra 400 mg Επικαλυμμένο με λεπτό υμένιο δισκίο	DE/H/0156/001/DC	36031/19-5-2011	ELPEN PHARMACEUTICAL CO. INC.	GR
OCTEGRA 400 mg/250 ml διάλυμα για έγχυση.	DE/H/0156/002	36032/19-5-2011	ELPEN PHARMACEUTICAL CO. INC.	GR
Proflox 400 mg/250 ml solução para perfusão	DE/H/0156/002	5258033	CENTROFARMA LDA	PT
Proflox 400 mg comprimidos revestidos por película	DE/H/0156/001	3077484	CENTROFARMA LDA	PT
Proflox 400 mg comprimidos revestidos por película	DE/H/0156/001	3081585	CENTROFARMA LDA	PT
Proflox 400 mg comprimidos revestidos por película	DE/H/0156/001	3077583	CENTROFARMA LDA	PT
Octegra 400 mg/250 ml Infusionslösung	DE/H/0156/002	45264.00.01	BAYER PHARMA AG	DE
Octegra® 400 mg Filmtabletten	DE/H/0156/001	45264.00.00	BAYER PHARMA AG	DE
Octegra 400 mg compresse rivestite con film	DE/H/0156/001	034564017	BAYER PHARMA AG	IT
Octegra 400 mg compresse rivestite con film	DE/H/0156/001	034564031	BAYER PHARMA AG	IT
Octegra 400 mg compresse rivestite con film	DE/H/0156/001	034564029	BAYER PHARMA AG	IT
Octegra 400 mg compresse rivestite con film	DE/H/0156/001	034564169	BAYER PHARMA AG	IT
Octegra 400 mg compresse rivestite con film	DE/H/0156/001	034564056	BAYER PHARMA AG	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
Octegra 400 mg compresse rivestite con film	DE/H/0156/001	034564082	BAYER PHARMA AG	IT
Octegra 400 mg compresse rivestite con film	DE/H/0156/001	034564068	BAYER PHARMA AG	IT
Octegra 400 mg compresse rivestite con film	DE/H/0156/001	034564043	BAYER PHARMA AG	IT
Octegra 400 mg compresse rivestite con film	DE/H/0156/001	034564070	BAYER PHARMA AG	IT
Octegra 400 mg compresse rivestite con film	DE/H/0156/001	034564094	BAYER PHARMA AG	IT
Octegra 400 mg compresse rivestite con film	DE/H/0156/001	034564106	BAYER PHARMA AG	IT
Octegra 400 mg compresse rivestite con film	DE/H/0156/001	034564118	BAYER PHARMA AG	IT
Octegra 400 mg compresse rivestite con film	DE/H/0156/001	034564132	BAYER PHARMA AG	IT
Octegra 400 mg compresse rivestite con film	DE/H/0156/001	034564157	BAYER PHARMA AG	IT
Octegra 400 mg compresse rivestite con film	DE/H/0156/001	034564144	BAYER PHARMA AG	IT
Octegra 400 mg compresse rivestite con film	DE/H/0156/001	034564120	BAYER PHARMA AG	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
ACTIRA 400 mg compresse rivestite con film	DE/H/0158/001	034566012	BAYER SPA	IT
ACTIRA 400 mg compresse rivestite con film	DE/H/0158/001	034566125	BAYER SPA	IT
ACTIRA 400 mg compresse rivestite con film	DE/H/0158/001	034566048	BAYER SPA	IT
ACTIRA 400 mg compresse rivestite con film	DE/H/0158/001	034566137	BAYER SPA	IT
ACTIRA 400 mg compresse rivestite con film	DE/H/0158/001	034566051	BAYER SPA	IT
ACTIRA 400 mg compresse rivestite con film	DE/H/0158/001	034566152	BAYER SPA	IT
ACTIRA 400 mg compresse rivestite con film	DE/H/0158/001	034566075	BAYER SPA	IT
ACTIRA 400 mg compresse rivestite con film	DE/H/0158/001	034566101	BAYER SPA	IT
ACTIRA 400 mg compresse rivestite con film	DE/H/0158/001	034566087	BAYER SPA	IT
ACTIRA 400 mg compresse rivestite con film	DE/H/0158/001	034566099	BAYER SPA	IT
ACTIRA 400 mg compresse rivestite con film	DE/H/0158/001	034566063	BAYER 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
ACTIRA 400 mg compresse rivestite con film	DE/H/0158/001	034566113	BAYER SPA	IT
ACTIRA 400 mg compresse rivestite con film	DE/H/0158/001	034566149	BAYER SPA	IT
ACTIRA 400 mg compresse rivestite con film	DE/H/0158/001	034566164	BAYER SPA	IT
ACTIRA 400 mg compresse rivestite con film	DE/H/0158/001	034566024	BAYER SPA	IT
ACTIRA 400 mg compresse rivestite con film	DE/H/0158/001	034566036	BAYER SPA	IT
Actira 400 mg/250 ml solución para perfusión	DE/H/0158/002	71.508	BAYER HISPANIA SL	ES
Actira 400 mg/250 ml Infusionslösung	DE/H/0158/002	45372.00.01	BAYER PHARMA AG	DE
Moxifloxacin Bayfarma 400 mg comprimidos recubiertos con película	DE/H/0158/001	62.829	BAYER HISPANIA SL	ES
Actira® 400 mg Filmtabletten	DE/H/0158/001	45372.00.00	BAYER PHARMA AG	DE
Avalox 400 mg compresse rivestite con film	DE/H/0155/001	034436028	BAYER SPA	IT
Avalox 400 mg compresse rivestite con film	DE/H/0155/001	034436055	BAYER SPA	IT
Avalox 400 mg compresse rivestite con film	DE/H/0155/001	034436030	BAYER 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
Avalox 400 mg comprese rivestite con film	DE/H/0155/001	034436081	BAYER SPA	IT
Avelox 400 mg/250 ml oldatos infúzió	DE/H/0155/002	OGYI-T-7554/05	BAYER PHARMA AG	HU
Avelox 400 mg/250 ml oldatos infúzió	DE/H/0155/002	OGYI-T-7554/07	BAYER PHARMA AG	HU
Avelox 400 mg filmtabletta	DE/H/0155/001	OGYI-T-7554/02	BAYER PHARMA AG	HU
Avelox 400 mg filmtabletta	DE/H/0155/001	OGYI-T-7554/03	BAYER PHARMA AG	HU
Avalox 400 mg comprese rivestite con film	DE/H/0155/001	034436042	BAYER SPA	IT
Avalox 400 mg comprese rivestite con film	DE/H/0155/001	034436067	BAYER SPA	IT
Avalox 400 mg comprese rivestite con film	DE/H/0155/001	034436079	BAYER SPA	IT
Avelox 400 mg filmdragerade tabletter	DE/H/0155/001	14567	BAYER PHARMA AG	FI
Avelox 400 mg/250 ml infusionsvätska, lösning	DE/H/0155/002	17496	BAYER PHARMA AG	FI
Avelox 400 mg/250 ml solution for infusion	DE/H/0155/002	PA 1410/27/3	BAYER LTD	IE
Avelox 400 mg/250 ml Infusionslösung	DE/H/0155/002	BE241613	BAYER SA NV	BE
Avelox 400 mg/250 ml solution pour perfusion	DE/H/0155/002	BE241613	BAYER SA NV	BE
Avelox 400 mg/250 ml solution pour perfusion	DE/H/0155/002	BE241604	BAYER SA NV	BE
Avelox 400 mg/250 ml oplossing voor infusie	DE/H/0155/002	BE241604	BAYER SA NV	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
Avelox 400 mg/250 ml Infusionslösung	DE/H/0155/002	BE241604	BAYER SA NV	BE
Avelox 400 mg/250 ml Infusionslösung	DE/H/0155/002	0442/03/02/009	BAYER SA NV	LU
Avelox 400 mg comprimés pelliculés	DE/H/0155/001	BE223203	BAYER SA NV	BE
Avelox 400 mg Filmtabletten	DE/H/0155/001	BE223203	BAYER SA NV	BE
Avelox 400 mg Filmtabletten	DE/H/0155/001	0442/11071236	BAYER SA NV	LU
Avelox 400 mg / 250 ml διάλυμα για έγχυση	DE/H/0155/002	20658	BAYER HELLAS SA	CY
Avelox 400 mg/250 ml infuzní roztok	DE/H/0155/002	15/832/09-C	BAYER PHARMA AG	CZ
Avalox 400 mg/250 ml Infusionslösung	DE/H/0155/002	45263.00.01	BAYER VITAL GMBH	DE
Avelox 400 mg/250 ml Infusionslösung	DE/H/0155/002	1-24732	BAYER AUSTRIA GMBH	AT
Avelox 400 mg/250 ml infuusioneste, liuos	DE/H/0155/002	17496	BAYER PHARMA AG	FI
Avelox 400mg/250 ml infusionsvæske, opløsning	DE/H/0155/002	33994	BAYER PHARMA AG	DK
Avelox 400 mg/250 ml solution pour perfusion	DE/H/0155/002	0442/03/02/009	BAYER SA NV	LU
Avelox 400 mg/250 ml solution for infusion	DE/H/0155/002	PA 1410/27/2	BAYER LTD	IE
Avelox 400 mg / 250 ml διάλυμα για έγχυση	DE/H/0155/002	37726/24-5-2011	BAYER HELLAS SA	GR
Avelox, 400 mg/250 ml infusioonilahus	DE/H/0155/002	442404	BAYER PHARMA AG	EE
Avelox 400 mg/250 ml solution for infusion	DE/H/0155/002	PL 00010/0613	BAYER PLC	UK
Avelox 400 mg/250 ml infúzný roztok	DE/H/0155/002	42/0256/04-S	BAYER PHARMA AG	SK

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
Avelox 400 mg/250 ml infusionsvätska, lösning	DE/H/0155/002	18640	BAYER PHARMA AG	SE
Avelox 400 mg/250 ml raztopina za infundiranje	DE/H/0155/002	H/00/00242/003	BAYER D.O.O	SI
Avelox 400 mg/250 ml šķīdums infūzijām	DE/H/0155/002	04-0395	BAYER PHARMA AG	LV
Avelox, 400 mg/250 ml, roztwór do infuzji	DE/H/0155/002	16643	BAYER PHARMA AG	PL
Avelox 400 mg/250 ml oplossing voor infusie	DE/H/0155/002	RVG 28119	BAYER BV	NL
Avelox 400 mg/250 ml oplossing voor infusie	DE/H/0155/002	BE241613	BAYER SA NV	BE
IZILOX 400 mg/250 ml, solution pour perfusion	DE/H/0155/002	34009 576 926 0 5	BAYER HEALTHCARE	FR
IZILOX 400 mg/250 ml, solution pour perfusion	DE/H/0155/002	34009 576 927 7 3	BAYER HEALTHCARE	FR
IZILOX 400 mg/250 ml, solution pour perfusion	DE/H/0155/002	34009 576 928 3 4	BAYER HEALTHCARE	FR
IZILOX 400 mg/250 ml, solution pour perfusion	DE/H/0155/002	34009 576 930 8 4	BAYER HEALTHCARE	FR
Avelox 400 mg/250 ml infuzinis tirpalas	DE/H/0155/002	LT/1/04/0126/004	BAYER PHARMA AG	LT
Avelox 400 mg/250 ml infuzinis tirpalas	DE/H/0155/002	LT/1/04/0126/005	BAYER PHARMA AG	LT
Avelox 400 mg/250 ml infuzinis tirpalas	DE/H/0155/002	LT/1/04/0126/006	BAYER PHARMA AG	LT
Avelox 400 mg/250 ml infuzinis tirpalas	DE/H/0155/002	LT/1/04/0126/007	BAYER PHARMA AG	LT
Avelox 400 mg/250 ml oldatos infúzió	DE/H/0155/002	OGYI-T-7554/04	BAYER PHARMA AG	HU
Avelox 400 mg/250 ml oldatos infúzió	DE/H/0155/002	OGYI-T-7554/06	BAYER PHARMA AG	HU
Avelox 400 mg/250 ml solution for infusion	DE/H/0155/002	MA 513/02702	BAYER PLC	MT

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
Avelox 400 mg comprimidos revestidos por película	DE/H/0155/001	3079381	BAYHEALTH LDA.	PT
Avelox 400 mg comprimidos revestidos por película	DE/H/0155/001	3079688	BAYHEALTH LDA.	PT
Avelox 400 mg comprimidos revestidos por película	DE/H/0155/001	3079589	BAYHEALTH LDA.	PT
Avelox 400 mg comprimidos revestidos por película	DE/H/0155/001	3079886	BAYHEALTH LDA.	PT
Avelox 400 mg comprimidos revestidos por película	DE/H/0155/001	3079282	BAYHEALTH LDA.	PT
Avelox 400 mg comprimidos revestidos por película	DE/H/0155/001	3079480	BAYHEALTH LDA.	PT
Avelox 400 mg comprimidos revestidos por película	DE/H/0155/001	3079787	BAYHEALTH LDA.	PT
Avelox 400 mg filmomhulde tabletten	DE/H/0155/001	BE223203	BAYER SA NV	BE
Avelox 400 mg plêvele dengtos tabletês	DE/H/0155/001	LT/1/04/0126/001	BAYER PHARMA AG	LT
Avelox 400 mg plêvele dengtos tabletês	DE/H/0155/001	LT/1/04/0126/002	BAYER PHARMA AG	LT
Avelox 400 mg plêvele dengtos tabletês	DE/H/0155/001	LT/1/04/0126/011	BAYER PHARMA AG	LT
Avelox 400 mg plêvele dengtos tabletês	DE/H/0155/001	LT/1/04/0126/013	BAYER PHARMA AG	LT
Avelox 400 mg plêvele dengtos tabletês	DE/H/0155/001	LT/1/04/0126/008	BAYER PHARMA AG	LT
IZILOX 400 mg, comprimé pelliculé	DE/H/0155/001	563 532-9	BAYER HEALTHCARE	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
Avelox 400 mg plêvele dengtos tabletės	DE/H/0155/001	LT/1/04/0126/012	BAYER PHARMA AG	LT
IZILOX 400 mg, comprimé pelliculé	DE/H/0155/001	563 529-8	BAYER HEALTHCARE	FR
Avelox 400 mg plêvele dengtos tabletės	DE/H/0155/001	LT/1/04/0126/009	BAYER PHARMA AG	LT
Avelox 400 mg plêvele dengtos tabletės	DE/H/0155/001	LT/1/04/0126/010	BAYER PHARMA AG	LT
Avelox 400 mg plêvele dengtos tabletės	DE/H/0155/001	LT/1/04/0126/003	BAYER PHARMA AG	LT
IZILOX 400 mg, comprimé pelliculé	DE/H/0155/001	357 580-1	BAYER HEALTHCARE	FR
IZILOX 400 mg, comprimé pelliculé	DE/H/0155/001	357 579-3	BAYER HEALTHCARE	FR
IZILOX 400 mg, comprimé pelliculé	DE/H/0155/001	563 533-5	BAYER HEALTHCARE	FR
IZILOX 400 mg, comprimé pelliculé	DE/H/0155/001	563 530-6	BAYER HEALTHCARE	FR
IZILOX 400 mg, comprimé pelliculé	DE/H/0155/001	563 531-2	BAYER HEALTHCARE	FR
IZILOX 400 mg, comprimé pelliculé	DE/H/0155/001	357 577-0	BAYER HEALTHCARE	FR
IZILOX 400 mg, comprimé pelliculé	DE/H/0155/001	357 578-7	BAYER HEALTHCARE	FR
Avelox 400 mg δισκία επικαλυμμένα με λεπτό υμένιο	DE/H/0155/001	36038/24-5-2011	BAYER HELLAS SA	GR
Avelox 400 mg tabletti, kalvopäällysteinen	DE/H/0155/001	14567	BAYER PHARMA AG	FI
Avelox, filmoverttrukne tabletter	DE/H/0155/001	31011	BAYER PHARMA AG	DK
Avelox, 400 mg õhukese polümeerikattega tabletid	DE/H/0155/001	442304	BAYER PHARMA AG	EE

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
Avelox, 400 mg potahované tablety	DE/H/0155/001	15/017/01-C	BAYER PHARMA AG	CZ
Avelox 400 mg film-coated tablets	DE/H/0155/001	MA 513/02701	BAYER PLC	MT
Avelox 400 mg Filmtabletten	DE/H/0155/001	1-23494	BAYER AUSTRIA GMBH	AT
Avelox 400 mg δισκία επικαλυμμένα με λεπτό υμένιο	DE/H/0155/001	19636	BAYER HELLAS SA	CY
Avelox 400 mg apvalkotās tabletes	DE/H/0155/001	04-0394	BAYER PHARMA AG	LV
Avelox 400 mg filmomhulde tabletten	DE/H/0155/001	RVG 28118	BAYER BV	NL
Avalox® 400 mg Filmtabletten	DE/H/0155/001	45263.00.00	BAYER VITAL GMBH	DE
Avelox 400 mg filmtableta	DE/H/0155/001	OGYI-T-7554/01	BAYER PHARMA AG	HU
Avelox 400 mg film-coated tablets	DE/H/0155/001	PA1410/27/1	BAYER LTD	IE
Avelox 400 mg comprimés pelliculés	DE/H/0155/001	0442/11071236	BAYER SA NV	LU
Avelox, 400 mg, tabletki powlekane	DE/H/0155/001	11432	BAYER PHARMA AG	PL
Avelox 400 mg film-coated tablets	DE/H/0155/001	PL 00010/0291	BAYER PLC	UK
Avelox 400 mg filmdragerade tabletter	DE/H/0155/001	15694	BAYER PHARMA AG	SE
Avelox 400 400 mg filmom obalené tablety	DE/H/0155/001	42/0257/04-S	BAYER PHARMA AG	SK
Avelox 400 mg filmsko obložene tablete	DE/H/0155/001	H/00/00242/001	BAYER D.O.O	SI
Avelox 400 mg filmsko obložene tablete	DE/H/0155/001	H/00/00242/003	BAYER D.O.O	SI
Avelox 400 mg filmsko obložene tablete	DE/H/0155/001	H/00/00242/002	BAYER D.O.O	SI

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
Avelox 400 mg filmsko obložene tablete	DE/H/0155/001	H/00/00242/005	BAYER D.O.O	SI
Avelox 400 mg filmsko obložene tablete	DE/H/0155/001	H/00/00242/004	BAYER D.O.O	SI
Avelox 400 mg filmsko obložene tablete	DE/H/0155/001	H/00/00242/007	BAYER D.O.O	SI
Avelox 400 mg filmsko obložene tablete	DE/H/0155/001	H/00/00242/008	BAYER D.O.O	SI
Avelox 400 mg filmsko obložene tablete	DE/H/0155/001	H/00/00242/006	BAYER D.O.O	SI
Avalox 400 mg/250 ml soluzione per infusione	DE/H/0155/002	034436194	BAYER SPA	IT
Avalox 400 mg/250 ml soluzione per infusione	DE/H/0155/002	034436182	BAYER SPA	IT
Avalox 400 mg/250 ml soluzione per infusione	DE/H/0155/002	034436206	BAYER SPA	IT
Avalox 400 mg/250 ml soluzione per infusione	DE/H/0155/002	034436170	BAYER SPA	IT
Avalox 400 mg compresse rivestite con film	DE/H/0155/001	034436016	BAYER SPA	IT
Avelox 400 mg/250 ml solução para perfusão	DE/H/0155/002	5258025	BAYHEALTH LDA.	PT
Avelox 400 mg comprimidos revestidos por película	DE/H/0155/001	3079183	BAYHEALTH LDA.	PT
Avelox 400 mg, filmuhúðaðar töflur	not available	990307	BAYER PHARMA AG	IS
Avelox 400 mg/250 ml innrennslislyf, lausn	not available	IS/1/02/133/01	BAYER PHARMA AG	IS
Avelox 400 mg/250 ml otopina za infuziju	not available	HR-H-872942310-01	BAYER DOO	HR
Avelox 400 mg filmom obložene tablete	not available	HR-H-559424661-01	BAYER DOO	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
Avelox 400 mg filmom obložene tablete	not available	HR-H-559424661-02	BAYER DOO	HR
Авелокс 400 mg/250 ml инфузионен разтвор	not available	20030752	BAYER PHARMA AG	BG
Авелокс 400 mg филмирани таблетки	not available	20000430	BAYER PHARMA AG	BG
Avelox 400 mg/250 ml soluție perfuzabilă	not available	5326/2005/01-02-03-04	BAYER PHARMA AG	RO
Avelox 400 mg comprimate filmate	not available	5424/2005/01-16	BAYER PHARMA AG	RO