



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

25 January 2024  
EMA/15401/2024  
Human Medicines Division

## List of nationally authorised medicinal products

Active substance(s): moxifloxacin (systemic use)

Procedure No. PSUSA/00009231/202305



<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Avelox 400 mg/250 ml solution for infusion	DE/H/0155/002	PL 00010/0613	BAYER PLC	XI
Avelox 400 mg film-coated tablets	DE/H/0155/001	PL 00010/0291	BAYER PLC	XI
Avelox 400 mg comprimate filmate	DE/H/0155/001	14285/2022/01-25	BAYER AG	RO
Avelox 400 mg/250 ml soluție perfuzabilă	DE/H/0155/002	14286/2022-01-02-03-04	BAYER AG	RO
Avalox 400 mg compresse rivestite con film	DE/H/0155/001	034436220	BAYER SPA	IT
Avalox 400 mg compresse rivestite con film	DE/H/0155/001	034436218	BAYER SPA	IT
Avalox 400 mg compresse rivestite con film	DE/H/0155/001	034436244	BAYER SPA	IT
Avalox 400 mg compresse rivestite con film	DE/H/0155/001	034436257	BAYER SPA	IT
Avalox 400 mg compresse rivestite con film	DE/H/0155/001	034436269	BAYER SPA	IT
Avalox 400 mg compresse rivestite con film	DE/H/0155/001	034436232	BAYER SPA	IT
Avalox 400 mg compresse rivestite con film	DE/H/0155/001	034436271	BAYER SPA	IT
Avalox 400 mg compresse rivestite con film	DE/H/0155/001	034436283	BAYER SPA	IT
Avalox 400 mg compresse rivestite con film	DE/H/0155/001	034436028	BAYER SPA	IT

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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
Avalox 400 mg compresse 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 AG	HU
Avelox 400 mg/250 ml oldatos infúzió	DE/H/0155/002	OGYI-T-7554/07	BAYER AG	HU
Avelox 400 mg filmdragerade tabletter	DE/H/0155/001	OGYI-T-7554/02	BAYER AG	HU
Avelox 400 mg filmdragerade tabletter	DE/H/0155/001	OGYI-T-7554/03	BAYER AG	HU
Avalox 400 mg compresse rivestite con film	DE/H/0155/001	034436042	BAYER SPA	IT
Avalox 400 mg compresse rivestite con film	DE/H/0155/001	034436067	BAYER SPA	IT
Avalox 400 mg compresse rivestite con film	DE/H/0155/001	034436079	BAYER SPA	IT
Avelox® 400 mg filmdragerade tabletter	DE/H/0155/001	14567	BAYER AG	FI
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
Avelox 400 mg/250 ml Infusionslösung	DE/H/0155/002	BE241604	BAYER SA NV	BE

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Avelox 400 mg comprimés pelliculés	DE/H/0155/001	BE533502	BAYER SA NV	BE
Avelox 400 mg Filmtabletten	DE/H/0155/001	BE533502	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 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 διάλυμα για έγχυση	DE/H/0155/002	37726/24-05-2011	BAYER HELLAS SA	GR
Avelox, 400 mg/250 ml infusioonilahus	DE/H/0155/002	442404	BAYER AG	EE
Avelox 400 mg/250 ml infúzny roztok	DE/H/0155/002	42/0256/04-S	BAYER AG	SK
Avelox 400 mg/250 ml šķīdums infūzijām	DE/H/0155/002	04-0395	BAYER AG	LV
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 AG	LT
Avelox 400 mg/250 ml infuzinis tirpalas	DE/H/0155/002	LT/1/04/0126/005	BAYER AG	LT
Avelox 400 mg/250 ml infuzinis tirpalas	DE/H/0155/002	LT/1/04/0126/006	BAYER AG	LT

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Avelox 400 mg/250 ml infuzinis tirpalas	DE/H/0155/002	LT/1/04/0126/007	BAYER AG	LT
Avelox 400 mg/250 ml oldatos infúzió	DE/H/0155/002	OGYI-T-7554/04	BAYER AG	HU
Avelox 400 mg/250 ml oldatos infúzió	DE/H/0155/002	OGYI-T-7554/06	BAYER AG	HU
Avelox 400 mg comprimidos revestidos por película	DE/H/0155/001	3079381	BAYER PORTUGAL LDA	PT
Avelox 400 mg comprimidos revestidos por película	DE/H/0155/001	3079688	BAYER PORTUGAL LDA	PT
Avelox 400 mg comprimidos revestidos por película	DE/H/0155/001	3079589	BAYER PORTUGAL LDA	PT
Avelox 400 mg comprimidos revestidos por película	DE/H/0155/001	3079886	BAYER PORTUGAL LDA	PT
Avelox 400 mg comprimidos revestidos por película	DE/H/0155/001	3079282	BAYER PORTUGAL LDA	PT
Avelox 400 mg comprimidos revestidos por película	DE/H/0155/001	3079480	BAYER PORTUGAL LDA	PT
Avelox 400 mg comprimidos revestidos por película	DE/H/0155/001	3079787	BAYER PORTUGAL LDA	PT
Avelox 400 mg filmomhulde tabletten	DE/H/0155/001	BE533502	BAYER SA NV	BE
Avelox 400 mg plévele dengtos tabletés	DE/H/0155/001	LT/1/04/0126/001	BAYER AG	LT
Avelox 400 mg plévele dengtos tabletés	DE/H/0155/001	LT/1/04/0126/002	BAYER AG	LT
Avelox 400 mg plévele dengtos tabletés	DE/H/0155/001	LT/1/04/0126/011	BAYER AG	LT
Avelox 400 mg plévele dengtos tabletés	DE/H/0155/001	LT/1/04/0126/013	BAYER AG	LT
Avelox 400 mg plévele	DE/H/0155/001	LT/1/04/0126/008	BAYER AG	LT

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dengtos tabletės				
IZILOX 400 mg, comprimé pelliculé	DE MRP MAA FOR MOXIFLOXACIN - 05	34009 563 532 9 3	BAYER HEALTHCARE	FR
Avelox 400 mg plėvele dengtos tabletės	DE/H/0155/001	LT/1/04/0126/012	BAYER AG	LT
IZILOX 400 mg, comprimé pelliculé	DE/H/0155/001	34009 563 529 8 2	BAYER HEALTHCARE	FR
Avelox 400 mg plėvele dengtos tabletės	DE/H/0155/001	LT/1/04/0126/009	BAYER AG	LT
Avelox 400 mg plėvele dengtos tabletės	DE/H/0155/001	LT/1/04/0126/010	BAYER AG	LT
Avelox 400 mg plėvele dengtos tabletės	DE/H/0155/001	LT/1/04/0126/003	BAYER AG	LT
IZILOX 400 mg, comprimé pelliculé	DE MRP MAA FOR MOXIFLOXACIN - 05	34009 357 580 1 9	BAYER HEALTHCARE	FR
IZILOX 400 mg, comprimé pelliculé	DE MRP MAA FOR MOXIFLOXACIN - 05	34009 357 579 3 7	BAYER HEALTHCARE	FR
IZILOX 400 mg, comprimé pelliculé	DE/H/0155/001	34009 563 533 5 4	BAYER HEALTHCARE	FR
IZILOX 400 mg, comprimé pelliculé	DE MRP MAA FOR MOXIFLOXACIN - 05	34009 563 530 6 4	BAYER HEALTHCARE	FR
IZILOX 400 mg, comprimé pelliculé	DE MRP MAA FOR MOXIFLOXACIN - 05	34009 563 531 2 5	BAYER HEALTHCARE	FR
IZILOX 400 mg, comprimé pelliculé	DE/H/0155/001	34009 357 577 0 8	BAYER HEALTHCARE	FR
IZILOX 400 mg, comprimé pelliculé	DE MRP MAA FOR MOXIFLOXACIN - 05	34009 357 578 7 6	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 AG	FI
Avelox, filmovertrukne tabletter	DE/H/0155/001	31011	BAYER AB	DK
Avelox, 400 mg õhukese polümeerikattega tabletid	DE/H/0155/001	442304	BAYER AG	EE
Avelox 400 mg	DE/H/0155/001	15/017/01-C	BAYER AG	CZ

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potahované tablety				
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 AG	LV
Avalox® 400 mg Filmtabletten	DE/H/0155/001	45263.00.00	BAYER VITAL GMBH	DE
Avelox 400 mg filmtabletta	DE/H/0155/001	OGYI-T-7554/01	BAYER AG	HU
Avelox 400 mg comprimés pelliculés	DE/H/0155/001	0442/11071236	BAYER SA NV	LU
Avelox 400 mg filmdragerade tabletter	DE/H/0155/001	15694	BAYER AB	SE
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 comprimidos revestidos por película	DE/H/0155/001	3079183	BAYER PORTUGAL LDA	PT
Avelox 400 mg/250 ml solution pour perfusion	DE/H/0155/002	2011071235	BAYER SA NV	LU
Avelox 400 mg/250 ml Infusionslösung	DE/H/0155/002	2011071235	BAYER SA NV	LU
Actira 400 mg/250 ml solución para perfusión	DE/H/0155/002	83.222	BAYER HISPANIA SL	ES
Avelox 400 mg filmomhulde tabletten	DE/H/0155/001	BE533511	BAYER SA NV	BE

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Avelox 400 mg Filmtabletten	DE/H/0155/001	BE533511	BAYER SA NV	BE
Avelox 400 mg comprimés pelliculés	DE/H/0155/001	BE533511	BAYER SA NV	BE
Avelox 400 mg comprimés pelliculés	DE/H/0155/001	BE223203	BAYER SA NV	BE
Avelox 400 mg filmomhulde tabletten	DE/H/0155/001	BE223203	BAYER SA NV	BE
Avelox 400 mg Filmtabletten	DE/H/0155/001	BE223203	BAYER SA NV	BE
IZILOX 400 mg, comprimé pelliculé	DE/H/0155/001	34009 301 590 9 5	BAYER HEALTHCARE	FR
IZILOX 400 mg, comprimé pelliculé	DE/H/0155/001	34009 301 591 1 8	BAYER HEALTHCARE	FR
IZILOX 400 mg, comprimé pelliculé	DE/H/0155/001	34009 301 591 0 1	BAYER HEALTHCARE	FR
IZILOX 400 mg, comprimé pelliculé	DE/H/0155/001	34009 550 590 9 7	BAYER HEALTHCARE	FR
IZILOX 400 mg, comprimé pelliculé	DE/H/0155/001	34009 550 591 0 3	BAYER HEALTHCARE	FR
IZILOX 400 mg, comprimé pelliculé	DE/H/0155/001	34009 550 591 2 7	BAYER HEALTHCARE	FR
IZILOX 400 mg, comprimé pelliculé	DE/H/0155/001	34009 550 590 8 0	BAYER HEALTHCARE	FR
IZILOX 400 mg, comprimé pelliculé	DE/H/0155/001	34009 550 590 7 3	BAYER HEALTHCARE	FR
АВЕЛОКС 400 мг филмирани таблетки	DE/H/0155/001	20000430	BAYER AG	BG
Avelox 400 mg/250 ml solution for infusion	DE/H/0155/002	MA639/01602	BAYER LTD	MT