
EMA to review persistence of side effects known to occur with quinolone and fluoroquinolone antibiotics

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Information on quinolone and fluoroquinolone antibiotics

- Quinolones and fluoroquinolones are a class of broad spectrum antibiotics that are active against so-called Gram-negative and Gram-positive bacteria.
- Quinolones and fluoroquinolones are widely prescribed in the EU and are important options for treating bacterial infections including serious and life-threatening infections.

In Malta four different fluoroquinolones antibiotics are authorised through national procedures. These are ciprofloxacin, levofloxacin, moxifloxacin and norfloxacin. For more details on fluoroquinolone containing products authorised in Malta refer to Annex 1 at the end of this document.

EMA's review to focus on long-lasting effects mainly affecting musculoskeletal and nervous systems

The European Medicines Agency (EMA) is reviewing systemic and inhaled quinolone and fluoroquinolone antibiotics to evaluate the persistence of serious side effects mainly affecting muscles, joints and the nervous system. These side effects are of particular importance when the medicines are used for less severe infections.

- The review concerns only inhaled medicines and medicines given systemically (by mouth or injection). Topical medicines, such as those applied directly to the skin, eyes or ears, are not included in this review.
- The review was initiated on 9 February 2017 at the request of German medicines authority (BfArM), under [Article 31 of Directive 2001/83/EC](#) and follows reports of long-lasting side effects in the German national safety database and the published literature.
- There has been no previous EU-wide review specifically focusing on the persistence of the side effects, but the side effects themselves are known and are covered in the EU prescribing information for these medicines.

The EMA's Pharmacovigilance Risk Assessment Committee (PRAC) will now evaluate all available data and determine whether there is a need to introduce new measures to minimise these risks or modify how the medicines are used. The PRAC recommendations will then be sent to the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion. The final stage of the review procedure is the adoption by the European Commission of a legally binding decision applicable in all EU Member States.

In Malta

Information for healthcare professionals and patients

- Until the final decision is published healthcare professionals using these medicines should continue to follow the official prescribing information.
- Healthcare professionals are encouraged to refer to the product information when prescribing fluoroquinolone antibiotics. Such information can be accessed from the Medicines Authority's website by searching for the product in the [online database](#).
- Patients who have any questions about their treatment should speak to their doctor.

For more information on this issue please refer to the European Medicines Agency's [press release](#)

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on quinolone and fluoroquinolone antibiotics. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form (available from: <http://www.medicinesauthority.gov.mt/adrportal>) and sent by mail to Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or email to postlicensing.medicinesauthority@gov.mt or to the marketing authorisation holder or their local representatives.

Post-Licensing Directorate Medicines Authority

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Annex 1: Table of fluoroquinolone antibiotic containing medicinal products authorised in Malta

Active Ingredients	Medicine Name	Pharmaceutical Forms	Classification	Authorisation Number	Authorization Holder
Ciprofloxacin 100 milligram(s)	Ciprofloxacin Ibigen 100mg/50ml solution for infusion	Solution for infusion	POM	MA965/00201	Ibigen S.r.L
Ciprofloxacin 2 milligram(s)/millilitre	Ciproxin solution for infusion 100mg/50ml	Solution for infusion	POM	MA513/00701	Bayer PLC
Ciprofloxacin 2 milligram(s)/millilitre	Topistin	Solution for infusion	POM	AA228/01102	Elpen Pharmaceutical Co. Inc.
Ciprofloxacin 2 milligram(s)/millilitre	Topistin	Solution for infusion	POM	AA228/01101	Elpen Pharmaceutical Co. Inc.
Ciprofloxacin 2 milligram(s)/millilitre	Revionorm	Solution for infusion	POM	AA1025/01001	Norma Hellas S.A.
Ciprofloxacin 2 milligram(s)/millilitre	Ciprofloxacin 2mg/ml solution for infusion	Solution for infusion	POM	AA292/00501	Villerton Invest S.A.
Ciprofloxacin 2 milligram(s)/millilitre	Ciprofloxacin solution for infusion 2mg/ml	Solution for infusion	POM	AA565/06003	Central Procurement & Supplies Unit
Ciprofloxacin 2 milligram(s)/millilitre	Nafloxin injectable solution for infusion 200mg/100ml	Solution for infusion	POM	AA1001/00801	COOPER S.A. Pharmaceuticals
Ciprofloxacin 2 milligram(s)/millilitre	Nafloxin solution for infusion 200mg/100ml	Solution for infusion	POM	AA729/15301	Cherubino Limited
Ciprofloxacin 2 milligram(s)/millilitre	Ciprofloxacin solution for infusion 2mg/ml	Solution for infusion	POM	AA1124/00101	Noridem Enterprises Ltd
Ciprofloxacin 2 milligram(s)/millilitre	Ciprofloaxcin solution for infusion 2mg/ml	Solution for infusion	POM	AA729/07902	Cherubino Limited
Ciprofloxacin 200 milligram(s)	Aristin-c	Solution for infusion	POM	MA240/00103	Anfarm Hellas S.A.
Ciprofloxacin 200 milligram(s)	Ciproxin solution for infusion 200mg/100ml	Solution for infusion	POM	MA513/00705	Bayer PLC
Ciprofloxacin 200 milligram(s)	Ciprofloxacin Ibigen 200mg/100ml solution for infusion	Solution for infusion	POM	MA965/00202	Ibigen S.r.L
Ciprofloxacin 250 milligram(s)	Medociprin	Film-coated tablet	POM	MA032/01802	Medochemie Limited

Ciprofloxacin 250 milligram(s)	Ciproxin 250mg film-coated tablets	Tablet	POM	MA513/00703	Bayer PLC
Ciprofloxacin 250 milligram(s)	Zindolin 250 tablets	Film-coated tablet	POM	MA084/02601	Remedica Limited
Ciprofloxacin 250 milligram(s)	Viprolox 250	Film-coated tablet	POM	MA115/00501	Delorbis Pharmaceuticals Limited
Ciprofloxacin 250 milligram(s)	Sepcen film-coated tablets 250mg	Film-coated tablet	POM	MA120/00202	Especialidades Farmaceuticas Centrum SA
Ciprofloxacin 250 milligram(s)	Siprox	Film-coated tablet	POM	MA155/01902	Actavis h.f.
Ciprofloxacin 250 milligram(s)	Aristin-c	Film-coated tablet	POM	MA240/00101	Anfarm Hellas S.A.
Ciprofloxacin 250 milligram(s)	Ciproxin tablets 250mg	Tablet	POM	PI908/02902A	NeoFarma Pharmaceuticals Limited
Ciprofloxacin 250 milligram(s)	Ciprofloxacin 250mg film-coated tablets	Film-coated tablet	POM	AA054/04901	Accord Healthcare Limited
Ciprofloxacin 250 milligram(s)	Ciprinol 250mg film-coated tablets	Film-coated tablet	POM	AA604/01101	KRKA DD Novo Mesto
Ciprofloxacin 250 milligram(s)	Ciprolen tablet, film coated 250mg	Film-coated tablet	POM	AA984/00301	S.C. AC Helcor Pharma S.R.L.
Ciprofloxacin 250 milligram(s)	Ciproxin tablets 250mg	Tablet	POM	PI555/04301A	Ecosse Limited
Ciprofloxacin 250 milligram(s)	Ciprofloxacin 250mg film-coated tablets	Film-coated tablet	POM	AA565/06002	Central Procurement & Supplies Unit
Ciprofloxacin 250 milligram(s)	Ciprofloxacin tablet, film coated 250mg	Film-coated tablet	POM	AA565/06004	Central Procurement & Supplies Unit
Ciprofloxacin 250 milligram(s)/5 millilitre	Ciproxin granules and solvent for oral suspension 250mg/5ml	Granules for oral suspension	POM	AA565/09901	Central Procurement & Supplies Unit
Ciprofloxacin 400 milligram(s)	Ciprofloxacin Ibigen 400mg/200ml solution for infusion	Solution for infusion	POM	MA965/00203	Ibigen S.r.L
Ciprofloxacin 500 milligram(s)	Medociprin	Film-coated tablet	POM	MA032/01801	Medochemie Limited
Ciprofloxacin 500 milligram(s)	Ciproxin 500mg film-coated tablets	Tablet	POM	MA513/00704	Bayer PLC
Ciprofloxacin 500 milligram(s)	Viprolox 500	Film-coated tablet	POM	MA115/00502	Delorbis Pharmaceuticals Limited

Ciprofloxacin 500 milligram(s)	Sepcen film-coated tablets 500mg	Film-coated tablet	POM	MA120/00201	Especialidades Farmaceuticas Centrum SA
Ciprofloxacin 500 milligram(s)	Siprox	Film-coated tablet	POM	MA155/01901	Actavis h.f.
Ciprofloxacin 500 milligram(s)	Aristin-c	Film-coated tablet	POM	MA240/00102	Anfarm Hellas S.A.
Ciprofloxacin 500 milligram(s)	Ciproxin 500mg film-coated tablets	Film-coated tablet	POM	PI908/02901A	NeoFarma Pharmaceuticals Limited
Ciprofloxacin 500 milligram(s)	Ciproxin film-coated tablets 500mg	Film-coated tablet	POM	PI555/04302A	Ecosse Limited
Ciprofloxacin 500 milligram(s)	Ciprinol 500mg film-coated tablets	Film-coated tablet	POM	AA604/01102	KRKA DD Novo Mesto
Ciprofloxacin 500 milligram(s)	Ciprolen tablet, film coated 500mg	Film-coated tablet	POM	AA984/00302	S.C. AC Helcor Pharma S.R.L.
Ciprofloxacin 500 milligram(s)	Ciproxin tablet, film coated 500mg	Film-coated tablet	POM	PI521/07701A	Medicem Limited
Ciprofloxacin hydrochloride 250 milligram(s)	Cifox tablet, film coated 250mg	Film-coated tablet	POM	AA1122/00201	Rowex Ltd
Ciprofloxacin hydrochloride 250 milligram(s)	Profloxin tablet, film coated 250mg	Film-coated tablet	POM	AA1045/03301	Clonmel Healthcare Limited
Ciprofloxacin hydrochloride 500 milligram(s)	Cifox tablet, film coated 500mg	Film-coated tablet	POM	AA1122/00202	Rowex Ltd
Ciprofloxacin hydrochloride 500 milligram(s)	Profloxin tablet, film coated 500mg	Film-coated tablet	POM	AA1045/03302	Clonmel Healthcare Limited
Ciprofloxacin hydrochloride 750 milligram(s)	Cifox tablet, film coated 750mg	Film-coated tablet	POM	AA1122/00203	Rowex Ltd
Ciprofloxacin lactate 2 milligram(s)/millilitre	Ciprofloxacin 2mg/ml, solution for infusion	Solution for infusion	POM	AA244/20902	P & D Pharmaceuticals Limited
Ciprofloxacin lactate 2 milligram(s)/millilitre	Ciprofloxacin 2mg/ml solution for infusion	Solution for infusion	POM	AA1107/00201	Claris Lifesciences UK Limited
Levofloxacin 250 milligram(s)	Levoxa 250mg film-coated tablets	Film-coated tablet	POM	MA628/00501	Actavis Group PTC ehf
Levofloxacin 250 milligram(s)	Levofloxacin 250mg film-coated tablets	Film-coated tablet	POM	AA054/07301	Accord Healthcare Limited
Levofloxacin 250 milligram(s)	Levofloxacin Beximco coated tablets 250mg	Film-coated tablet	POM	MA1034/00201	Beximco Pharma UK Ltd

Levofloxacin 5 milligram(s)	Levofloxacin solution for infusion 5mg/ml	Solution for infusion	POM	AA244/40501	P & D Pharmaceuticals Limited
Levofloxacin 5 milligram(s)	Levofloxacin solution for infusion 5mg/ml	Solution for infusion	POM	PI244/40502A	P & D Pharmaceuticals Limited
Levofloxacin 5 milligram(s)/millilitre	Levofloxacin mylan solution for infusion 500mg/100ml	Solution for infusion	POM	MA767/00202	Mylan S.A.S.
Levofloxacin 5 milligram(s)/millilitre	Levofloxacin 5mg/ml solution for infusion	Solution for infusion	POM	MA134/00901	Fresenius Kabi Limited
Levofloxacin 5 milligram(s)/millilitre	Levofloxacin solution for infusion 5mg/ml	Solution for infusion	POM	MA628/04501	Actavis Group PTC ehf
Levofloxacin 5 milligram(s)/millilitre	Levofloxacin mylan solution for infusion 250mg/50ml	Solution for infusion	POM	MA767/00201	Mylan S.A.S.
Levofloxacin 5 milligram(s)/millilitre	Levofloxacin ibigen 5mg/ml solution for infusion	Solution for infusion	POM	MA965/00101	Ibigen S.r.L
Levofloxacin 5 milligram(s)/millilitre	Levofloxacin solution for infusion 5mg per ml	Solution for infusion	POM	AA188/01801	DEMO S.A. Pharmaceutical Industry
Levofloxacin 5 milligram(s)/millilitre	Evoxil solution for infusion 5mg/ml	Solution for infusion	POM	AA672/00802	Beacon Pharmaceuticals Limited
Levofloxacin 500 milligram(s)	Tavanic 500mg film-coated tablet	Film-coated tablet	POM	MA082/03502	Sanofi Malta Limited
Levofloxacin 500 milligram(s)	Levoxa 500mg film-coated tablets	Film-coated tablet	POM	MA628/00502	Actavis Group PTC ehf
Levofloxacin 500 milligram(s)	Levofloxacin 500mg film-coated tablets	Film-coated tablet	POM	AA054/07302	Accord Healthcare Limited
Levofloxacin 500 milligram(s)	Evoxil 500mg film coated tablet	Film-coated tablet	POM	AA672/00801	Beacon Pharmaceuticals Limited
Levofloxacin 500 milligram(s)	Tavanic 500mg film-coated tablet	Film-coated tablet	POM	PI515/04701A	AlphaFarma Limited
Levofloxacin 500 milligram(s)	Amesol 500mg film-coated tablets	Film-coated tablet	POM	AA032/09101	Medochemie Limited
Levofloxacin 500 milligram(s)	Trissil 500mg film-coated tablets	Film-coated tablet	POM	AA037/00801	PIAM Farmaceutici S.p.A.
Levofloxacin 500 milligram(s)	Tavanic coated tablets 500mg	Film-coated tablet	POM	PI908/07801A	NeoFarma Pharmaceuticals Limited

Levofloxacin 500 milligram(s)	Floxaval 500mg film-coated tablets	Film-coated tablet	POM	AA115/02101	Delorbis Pharmaceuticals Limited
Levofloxacin 500 milligram(s)	Levofloxacin Beximco coated tablets 500mg	Film-coated tablet	POM	MA1034/00202	Beximco Pharma UK Ltd
Levofloxacin 500/100 milligram(s)/millilitre	Levofloxacin/cooper 500mg/100ml solution for i.v. Infusion	Solution for infusion	POM	AA1001/00901	COOPER S.A. Pharmaceuticals
Moxifloxacin 400 milligram(s)	Avelox 400mg film-coated tablets	Film-coated tablet	POM	MA513/02701	Bayer PLC
Moxifloxacin 400 milligram(s)	Avelox 400mg/250ml solution for infusion	Solution for infusion	POM	MA513/02702	Bayer PLC
Norfloxacin 400 milligram(s)	Fluseminal	Film-coated tablet	POM	MA240/00401	Anfarm Hellas S.A.
Norfloxacin 400 milligram(s)	Norflosal	Film-coated tablet	POM	AA982/00701	TAD Pharma GmbH
Norfloxacin 400 milligram(s)	Uroflox, 400mg, film-coated tablets	Film-coated tablet	POM	AA004/00201	Bial - Portela & C S.A.
Norfloxacin 400 milligram(s)	Trizolin 400 tablets	Film-coated tablet	POM	AA084/09801	Remedica Limited

Feedback Form

The Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this form (address side up), stapling the ends and then posting (no stamp required).

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