
PRAC recommends restriction use of quinolones and fluoroquinolones

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Information on quinolones and fluoroquinolones

- Fluoroquinolones and quinolones are a class of broad-spectrum antibiotics that are active against bacteria of both Gram-negative and Gram-positive classes.
- The review covered the following medicines: ciprofloxacin, flumequine, levofloxacin, lomefloxacin, moxifloxacin, norfloxacin, ofloxacin, pefloxacin, prulifloxacin and rufloxacin (fluoroquinolone antibiotics); cinoxacin, nalidixic acid, piperimidic acid (quinolone antibiotics).
- The review concerned only medicines given systemically (by mouth or injection) and inhaled medicines.

In Malta four different fluoroquinolone 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 I](#) at the end of this document.

Information from the EMA about long-lasting side effects of quinolones and fluoroquinolones

In February 2017, the Pharmacovigilance Risk Assessment Committee (PRAC) started a review on fluoroquinolone and quinolone antibiotics (used by mouth, injection or inhalation) under Article 31 of Directive 2001/83/EC. The review was carried out due to the disabling and potentially long-lasting side effects reported with these medicines.

PRAC's recommendation is to remove some medicines from the market, including all those that contain a quinolone antibiotic because they are authorised only for infections that should no longer be treated with this class of antibiotics.

For the fluoroquinolones which are staying on the market, PRAC recommends:

- To not use fluoroquinolones:
 - To treat infections that might get better without treatment or are not severe (such as throat infections);
 - For preventing traveller's diarrhoea or recurring lower urinary tract infections (urine infections that do not extend beyond the bladder);
 - To treat patients who have previously had serious side effects with a fluoroquinolone or quinolone antibiotic;
 - To treat mild or moderately severe infections unless other antibacterial medicines commonly recommended for these infections cannot be used.
- Fluoroquinolones should be used with caution especially for the elderly, patients with kidney problems, patients who have had an organ transplantation or those who are being treated with a systemic corticosteroid. These patients are at higher risk of tendon injury caused by fluoroquinolone and quinolone antibiotics.

The PRAC recommendations will now be sent to EMA's Committee for Medicinal Products for Human Use (CHMP), which will adopt the Agency's final opinion.

In Malta

For Healthcare Professionals

- Patients should be advised to stop treatment with a fluoroquinolone antibiotic at the first sign of a side effect involving muscles, tendons or bones (such as inflamed or torn tendon, muscle pain or weakness, and joint pain or swelling) or the nervous system (such as feeling pins and needles, tiredness, depression, confusion, suicidal thoughts, sleep disorders, vision and hearing problems, and altered taste and smell).

Prescribing information of individual fluoroquinolone antibiotics will be updated to reflect the restricted use.

For more information, please see the European Medicines Agency's [Quinolone- and fluoroquinolone-containing medicinal products referral](#)

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on Fluoroquinolone and quinolone 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	Status
Ciprofloxacin 250 milligram(s)	Medociprin	Film-coated tablet	POM	MA032/01801	Medochemie Limited	Authorised
Ciprofloxacin 250 milligram(s)	Medociprin	Film-coated tablet	POM	MA032/01802	Medochemie Limited	Authorised
Ciprofloxacin 500 milligram(s)	Ciproxin 250mg Film-coated Tablets	Tablet	POM	MA513/00703	Bayer PLC	Authorised
Ciprofloxacin 250 milligram(s)	Ciproxin 500mg Film-coated Tablets	Tablet	POM	MA513/00704	Bayer PLC	Authorised
Ciprofloxacin Hydrochloride 250 milligram(s)	Zindolin 250 Tablets	Film-coated tablet	POM	MA084/02601	Remedica Limited	Authorised
Ciprofloxacin 500 milligram(s)	Viprolox 250mg Film coated tablets	Film-coated tablet	POM	MA115/00501	Delorbis Pharmaceuticals Limited	Authorised
Ciprofloxacin 500 milligram(s)	Viprolox 500mg Film-coated tablets	Film-coated tablet	POM	MA115/00502	Delorbis Pharmaceuticals Limited	Authorised
Ciprofloxacin 250 milligram(s)	Sepcen Film-coated Tablets 500mg	Film-coated tablet	POM	MA120/00201	Especialidades Farmaceuticas Centrium SA	Authorised
Ciprofloxacin 500 milligram(s)	Sepcen Film-coated Tablets 250mg	Film-coated tablet	POM	MA120/00202	Especialidades Farmaceuticas Centrium SA	Authorised
Ciprofloxacin 250 milligram(s)	Siprox 500mg film coated tablets	Film-coated tablet	POM	MA628/17902	Actavis Group PTC ehf	Authorised
Ciprofloxacin 250 milligram(s)	Siprox 250mg film coated tablets	Film-coated tablet	POM	MA628/17901	Actavis Group PTC ehf	Authorised
Ciprofloxacin 200 milligram(s)	Aristin-C	Film-coated tablet	POM	MA240/00101	Anfarm Hellas S.A.	Authorised
Ciprofloxacin 2 milligram(s)/millilitre	Aristin-C	Film-coated tablet	POM	MA240/00102	Anfarm Hellas S.A.	Authorised
Ciprofloxacin 200 milligram(s)	Aristin-C	Solution for infusion	POM	MA240/00103	Anfarm Hellas S.A.	Authorised
Ciprofloxacin 400 milligram(s)	Ciproxin Solution for Infusion 100mg/50ml	Solution for infusion	POM	MA513/00701	Bayer PLC	Authorised
Ciprofloxacin 500 milligram(s)	Ciproxin Solution for Infusion 200mg/100ml	Solution for infusion	POM	MA513/00705	Bayer PLC	Authorised
Ciprofloxacin 250 milligram(s)	Ciprofloxacin Ibigen 100mg/50ml solution for infusion	Solution for infusion	POM	MA965/00201	Ibigen S.r.L	Authorised
Ciprofloxacin 2 milligram(s)/millilitre	Ciprofloxacin Ibigen 200mg/100ml solution for infusion	Solution for infusion	POM	MA965/00202	Ibigen S.r.L	Authorised
Ciprofloxacin 2 milligram(s)/millilitre	Ciprofloxacin Ibigen 400mg/200ml solution for infusion	Solution for infusion	POM	MA965/00203	Ibigen S.r.L	Authorised
Ciprofloxacin 500 milligram(s)	Ciproxin 500mg Film-Coated Tablets	Film-coated tablet	POM	PI908/02901A	NeoFarma Pharmaceuticals Limited	Authorised

Active ingredients	Medicine Name	Pharmaceutical Forms	Classification	Authorisation Number	Authorization Holder	Status
Ciprofloxacin 250 milligram(s)	Ciproxin Film-coated Tablets 500mg	Film-coated tablet	POM	PI555/04302A	Ecosse Limited	Authorised
Ciprofloxacin 500 milligram(s)	Ciproxin Tablets 250mg	Film-coated tablet	POM	PI908/02902A	NeoFarma Pharmaceuticals Limited	Authorised
Ciprofloxacin Lactate 2 milligram(s)/millilitre	Ciprofloxacin 250mg Film-Coated Tablets	Film-coated tablet	POM	AA054/04901	Accord Healthcare Limited	Authorised
Ciprofloxacin 250 milligram(s)	Revionorm Solution for Infusion 200mg/100ml	Solution for infusion	POM	AA1025/01001	Norma Hellas S.A.	Authorised
Ciprofloxacin 2 milligram(s)/millilitre	Ciprofloxacin 2mg/ml solution for infusion	Solution for infusion	POM	AA292/00501	Villerton Invest S.A.	Authorised
Ciprofloxacin Lactate 2 milligram(s)/millilitre	Ciprinol 250mg film-coated Tablets	Film-coated tablet	POM	AA604/01101	KRKA DD Novo Mesto	Authorised
Ciprofloxacin 2 milligram(s)/millilitre	Ciprinol 500mg film-coated Tablets	Film-coated tablet	POM	AA604/01102	KRKA DD Novo Mesto	Authorised
Ciprofloxacin Hydrochloride 250 milligram(s)	Ciprolen Tablet, film coated 250mg	Film-coated tablet	POM	AA984/00301	S.C. AC Helcor Pharma S.R.L.	Authorised
Ciprofloxacin Hydrochloride 500 milligram(s)	Ciprolen Tablet, film coated 500mg	Film-coated tablet	POM	AA984/00302	S.C. AC Helcor Pharma S.R.L.	Authorised
Ciprofloxacin hydrochloride 750 milligram(s)	Ciproxin Tablets 250mg	Tablet	POM	PI555/04301A	Ecosse Limited	Authorised
Ciprofloxacin 2 milligram(s)/millilitre	Ciprofloxacin 2mg/ml, Solution for Infusion	Solution for infusion	POM	AA244/20902	P & D Pharmaceuticals Limited	Authorised
Ciprofloxacin Hydrochloride 250 milligram(s)	Ciprofloxacin Solution for Infusion 2mg/ml	Solution for infusion	POM	AA565/06003	Central Procurement & Supplies Unit	Authorised
Ciprofloxacin Hydrochloride 500 milligram(s)	Ciprofloxacin 250mg Film-coated Tablets	Film-coated tablet	POM	AA565/06002	Central Procurement & Supplies Unit	Authorised
Ciprofloxacin 500 milligram(s)	Nafloxin Injectable Solution for Infusion 200mg/100ml	Solution for infusion	POM	AA1001/00801	COOPER S.A. Pharmaceuticals	Authorised
Ciprofloxacin 250 milligram(s)	Ciproxin Granules and Solvent for Oral Suspension 250mg/5ml	Granules for oral suspension	POM	AA565/09901	Central Procurement & Supplies Unit	Authorised
Ciprofloxacin 2 milligram(s)/millilitre	Ciprofloxacin 2mg/ml Solution for Infusion	Solution for infusion	POM	AA1107/00201	Claris Lifesciences UK Limited	Authorised
Ciprofloxacin 2 milligram(s)/millilitre	Nafloxin Solution for Infusion 200mg/100ml	Solution for infusion	POM	AA729/15301	Cherubino Limited	Authorised
Norfloxacin 400 milligram(s)	Cifox Tablet, film coated 250mg	Film-coated tablet	POM	AA1122/00201	Rowex Ltd	Authorised
Norfloxacin 400 milligram(s)	Cifox Tablet, film coated 500mg	Film-coated tablet	POM	AA1122/00202	Rowex Ltd	Authorised
Norfloxacin 400 milligram(s)	Cifox Tablet, film coated 750mg	Film-coated tablet	POM	AA1122/00203	Rowex Ltd	Authorised
Norfloxacin 400 milligram(s)	Ciprofloxacin Solution for Infusion 2mg/ml	Solution for infusion	POM	AA1124/00101	Noridem Enterprises Ltd	Authorised

Active ingredients	Medicine Name	Pharmaceutical Forms	Classification	Authorisation Number	Authorization Holder	Status
Levofloxacin 5 milligram(s)/millilitre	Profloxin Tablet, film coated 250mg	Film-coated tablet	POM	AA1045/03301	Clonmel Healthcare Limited	Authorised
Levofloxacin 500 milligram(s)	Profloxin Tablet, film coated 500mg	Film-coated tablet	POM	AA1045/03302	Clonmel Healthcare Limited	Authorised
Levofloxacin 5 milligram(s)/millilitre	Ciproxin Tablet, film coated 500mg	Film-coated tablet	POM	PI521/07701A	Medicem Limited	Authorised
Levofloxacin 250 milligram(s)	Ciprofloxacin Tablet, film coated 250mg	Film-coated tablet	POM	AA565/06004	Central Procurement & Supplies Unit	Authorised
Levofloxacin 500 milligram(s)	Ciprofloxacin Solution for Infusion 2mg/ml	Solution for infusion	POM	AA729/07902	Cherubino Limited	Authorised
Levofloxacin 5 milligram(s)/millilitre	Ciprofloxacin Kabi 200mg/100ml solution for infusion	Solution for infusion	POM	AA1123/00601	Fresenius Kabi Italia S.r.l	Authorised
Levofloxacin 5 milligram(s)/millilitre	Fluseminal	Film-coated tablet	POM	MA240/00401	Anfarm Hellas S.A.	Authorised
Levofloxacin 5 milligram(s)/millilitre	Norflosal	Film-coated tablet	POM	AA982/00701	TAD Pharma GmbH	Authorised
Levofloxacin 500 milligram(s)	UROFLOX, 400mg, film-coated Tablets	Film-coated tablet	POM	AA004/00201	Bial - Portela & C S.A.	Authorised
Levofloxacin 500 milligram(s)	Trizolin 400 Tablet, film coated 400mg	Film-coated tablet	POM	AA084/09801	Remedica Limited	Authorised
Levofloxacin 500 milligram(s)	Levofloxacin Mylan Solution for Infusion 500mg/100ml	Solution for infusion	POM	MA767/00202	Mylan S.A.S.	Authorised
Levofloxacin 500 milligram(s)	Tavanic 500mg film-coated tablet	Film-coated tablet	POM	MA082/03502	Sanofi Malta Limited	Authorised
Levofloxacin 500/100 milligram(s)/millilitre	Levofloxacin 5mg/ml solution for infusion	Solution for infusion	POM	MA134/00901	Fresenius Kabi Limited	Authorised
Levofloxacin 250 milligram(s)	Levoxa 250mg film-coated Tablets	Film-coated tablet	POM	MA628/00501	Actavis Group PTC ehf	Authorised
Levofloxacin 500 milligram(s)	Levoxa 500mg film-coated Tablets	Film-coated tablet	POM	MA628/00502	Actavis Group PTC ehf	Authorised
Levofloxacin 5 milligram(s)	Levofloxacin Solution for Infusion 5mg/ml (50ml vial)	Solution for infusion	POM	MA628/04501	Actavis Group PTC ehf	Authorised
Levofloxacin 5 milligram(s)	Levofloxacin Mylan Solution for Infusion 250mg/50ml	Solution for infusion	POM	MA767/00201	Mylan S.A.S.	Authorised
Levofloxacin 5 milligram(s)/millilitre	Levofloxacin Ibigen 5mg/ml solution for infusion	Solution for infusion	POM	MA965/00101	Ibigen S.r.L	Authorised
Levofloxacin 500 milligram(s)	Levofloxacin 250mg Film-coated Tablets	Film-coated tablet	POM	AA054/07301	Accord Healthcare Limited	Authorised

Active ingredients	Medicine Name	Pharmaceutical Forms	Classification	Authorisation Number	Authorization Holder	Status
Levofloxacin 500 milligram(s)	Levofloxacin 500mg Film-coated Tablets	Film-coated tablet	POM	AA054/07302	Accord Healthcare Limited	Authorised
Moxifloxacin 400 milligram(s)	AMESOL 500mg Film-Coated Tablets	Film-coated tablet	POM	AA032/09101	Medochemie Limited	Authorised
Moxifloxacin 400 milligram(s)	Levofloxacin Solution for Infusion 5mg per ml	Solution for infusion	POM	AA188/01801	DEMO S.A. Pharmaceutical Industry	Authorised
Levofloxacin 500 milligram(s)	Tavanic Coated Tablets 500mg	Film-coated tablet	POM	PI908/07801A	NeoFarma Pharmaceuticals Limited	Authorised
Levofloxacin 500 milligram(s)	Floxaval 500mg Film-coated tablets	Film-coated tablet	POM	AA115/02101	Delorbis Pharmaceuticals Limited	Authorised
Levofloxacin 500mg/100 milligram(s)/millilitre	Levofloxacin/cooper 500mg/100ml solution for I.V. infusion	Solution for infusion	POM	AA1001/00901	COOPER S.A. Pharmaceuticals	Authorised
Levofloxacin 250 milligram(s)	Levofloxacin Beximco Coated Tablets 250mg	Film-coated tablet	POM	MA1034/00201	Beximco Pharma UK Ltd	Authorised
Levofloxacin 500 milligram(s)	Levofloxacin Beximco Coated Tablets 500mg	Film-coated tablet	POM	MA1034/00202	Beximco Pharma UK Ltd	Authorised
Levofloxacin 500mg/100 milligram(s)/millilitre	Levofloxacin Solution for Infusion 5mg/ml	Solution for infusion	POM	AA244/40501	P & D Pharmaceuticals Limited	Authorised
Levofloxacin 500mg/100 milligram(s)/millilitre	Levofloxacin Solution for Infusion 5mg/ml	Solution for infusion	POM	PI244/40502A	P & D Pharmaceuticals Limited	Authorised
Levofloxacin 500mg/100 milligram(s)/millilitre	Levofloxacin Solution for Infusion 5mg/ml (100ml vial)	Solution for infusion	POM	MA628/04502	Actavis Group PTC ehf	Authorised
Levofloxacin 500 milligram(s)	Levofloxacin 500mg Film-coated Tablets	Film-coated tablet	POM	AA565/24101	Central Procurement & Supplies Unit	Authorised
Levofloxacin 500 milligram(s)	TRISSIL 500mg film-coated tablets	Film-coated tablet	POM	AA037/00802	PIAM Farmaceutici S.p.A.	Authorised
Levofloxacin 500 milligram(s)	Levofloxacin Tablet, film coated 500mg	Film-coated tablet	POM	AA565/24102	Central Procurement & Supplies Unit	Authorised
Moxifloxacin 400 milligram(s)	Avelox 400mg film-coated Tablets	Film-coated tablet	POM	MA513/02701	Bayer PLC	Authorised
Moxifloxacin 400 mg/250 milligram(s)/millilitre	Avelox 400mg/250ml solution for infusion	Solution for infusion	POM	MA513/02702	Bayer PLC	Authorised

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

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