

## Quinolones (the -floxacin): the risks

**Systemic fluoroquinolones must only be prescribed when other antibiotics commonly recommended for that infection are inappropriate (MHRA drug safety update 2024).**

*This article was updated in January 2024.*

There have been longstanding concerns about the safety of fluoroquinolones, and advice from both the European Medicines Agency and the MHRA to restrict prescribing has been in place since 2018 (EMA Pharmacovigilance Risk Assessment Committee 2018, MHRA 2018).

In January 2024, the MHRA updated its guidance to introduce further limitations on the prescribing of fluoroquinolones (MHRA 2024).

### The antibiotics involved

In the UK, five fluoroquinolones are available:

- Ciprofloxacin.
- Levofloxacin.
- Moxifloxacin.
- Norfloxacin.
- Ofloxacin.

### The warning

Systemic (taken by mouth, inhalation or injection) fluoroquinolones can cause long-lasting, potentially irreversible or disabling side-effects which can affect multiple body systems and senses.

Systemic fluoroquinolones must only be used when:

- There is resistance to other first-line antibiotics recommended for the infection.
- Other first-line antibiotics are contraindicated in an individual patient.
- Other first-line antibiotics have caused side-effects in the patient that require treatment to be stopped.
- Treatment with other first-line antibiotics has failed.

This advice is in addition to previous MHRA recommendations that fluoroquinolones should not be prescribed for non-severe or self-limiting infections, or for non-bacterial conditions (MHRA 2018). Fluoroquinolones should not be used to prevent traveller's diarrhoea, treat recurrent lower urinary tract infections, or treat people who have had previous serious side-effects from quinolones (EMA 2018).

Use particular caution in those with higher risk of tendon injury (MHRA 2023):

- In older people.
- In renal impairment.
- After organ transplant.
- If on systemic corticosteroids.

### The risks and what to look out for

	Symptoms/risk groups	Action (and reference)
<b>Musculoskeletal system</b>	This includes: <ul style="list-style-type: none"> <li>• Inflamed/torn tendons.</li> <li>• Muscle pain/weakness.</li> <li>• Joint pain/joint swelling.</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Stop treatment at the first sign of any side-effects.</b></li> </ul> (EMA October 2018)
<b>Neurological symptoms</b>	This includes: <ul style="list-style-type: none"> <li>• Pins and needles.</li> <li>• Tiredness/sleep disorders.</li> <li>• Depression/suicidal thoughts.</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Stop treatment at the first sign of any side-effects.</b></li> </ul> (EMA October 2018)

	<ul style="list-style-type: none"> <li>• Confusion.</li> <li>• Vision/hearing problems.</li> <li>• Altered taste/smell.</li> </ul>	
<b>Aortic aneurysm and dissection</b>	<p>Those who may be at particular risk (and, remember, these risks are greater in the elderly in whom special care should be taken):</p> <ul style="list-style-type: none"> <li>• Known aortic aneurysm/previous dissection.</li> <li>• Family history of aneurysms.</li> <li>• Conditions that increase the risk of aneurysm/dissection: <ul style="list-style-type: none"> <li>◦ Hypertension.</li> <li>◦ Known atherosclerosis.</li> <li>◦ Marfan’s syndrome.</li> <li>◦ Ehlers-Danlos syndrome.</li> <li>◦ Giant cell arteritis.</li> <li>◦ Takayasu arteritis.</li> <li>◦ Behcet’s disease.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• <b>Before use, make a careful risk–benefit assessment.</b></li> <li>• <b>Warn patients, especially older patients, about this rare risk and the importance of seeking immediate medical help in the event of sudden-onset severe abdominal chest, back or abdominal pain.</b></li> </ul> <p>(MHRA Nov 2018)</p>
<b>Seizures</b>	<ul style="list-style-type: none"> <li>• Fluoroquinolones increase the risk of seizures in those with AND without a history of seizures.</li> <li>• Taking NSAIDs at the time may increase this risk.</li> </ul>	<ul style="list-style-type: none"> <li>• No advice is given on what to do with this information! (BNF – accessed February 2024)</li> </ul>
<b>Mental health</b>	<ul style="list-style-type: none"> <li>• Fluoroquinolones can cause psychiatric side-effects or worsen existing psychiatric symptoms, including depression and psychosis; this can happen as early as following the first dose, and last a considerable time after treatment is completed.</li> <li>• In rare cases, side-effects can lead to thoughts or attempts of suicide, and have been associated with the completed suicide of a patient without a history of psychiatric disorders (MHRA 2023).</li> </ul>	<ul style="list-style-type: none"> <li>• Check for history of mental health disorders before prescribing fluoroquinolones.</li> <li>• Warn patients to be alert to changes in mood or behaviour, including thoughts of self-harm, even some time after treatment is complete, and to report these if they occur.</li> <li>• Treatment should be stopped at the first sign of side-effects (MHRA 2023).</li> </ul>

*And don't forget to report any of the symptoms on a Yellow Card!*




### **How great is the risk?**

For aortic aneurysm/dissection, the EMA suggests that the increased risk is small:

- 82 extra cases/million patients treated in the first 60 days after treatment (when compared with amoxicillin use).
- That is a small number but is against a background rate of about 30–300 cases/million people/year in the general population.

### **When does the risk occur?**

- Tendon rupture has been reported within 48 hours of treatment, and the risk of rupture remains high for months after quinolone treatment.
- Aneurysm/dissections have been noted to be a risk for at least 60 days after treatment.

	<p><b>Quinolones: the risks</b></p> <ul style="list-style-type: none"> <li>• <b>Systemic fluoroquinolones must only be prescribed when other antibiotics commonly recommended for that infection are inappropriate (MHRA drug safety update 2024).</b></li> <li>• Fluoroquinolones increase the risk of: <ul style="list-style-type: none"> <li>◦ Musculoskeletal damage, especially tendon rupture.</li> <li>◦ Neurological symptoms.</li> <li>◦ Aortic aneurysm and dissection.</li> <li>◦ Seizures.</li> <li>◦ Mental health disorders, including psychosis and suicide.</li> </ul> </li> <li>• In the event of these adverse events, the drug should be stopped immediately. Remember to report this on a Yellow Card.</li> <li>• They should NOT be used to prevent travellers' diarrhoea or treat recurrent UTIs.</li> </ul>
	<p>Audit your prescribing to see:</p> <ul style="list-style-type: none"> <li>• Do you have anyone on long-term treatment with these drugs?</li> <li>• Anyone with these drugs on repeat?</li> <li>• How often do you prescribe these drugs, and are the indications in line with the guidance? If not, look up what would be the alternative you could use in these situations.</li> </ul>
	

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