

**Media Release****MEDICINES SAFETY COMMUNICATION****DISABLING AND POTENTIALLY PERMANENT SIDE EFFECTS ASSOCIATED WITH
THE USE OF QUINOLONE AND FLUOROQUINOLONE ANTIBIOTICS****To all Consumers and Healthcare Professionals****From: The Acting CEO of SAHPRA****Date: 30 November 2018**

The South African Health Products Regulatory Authority (SAHPRA) hereby informs the public of new safety information that became available on the oral, injectable and inhalation quinolone/fluoroquinolone antibiotics. New safety information indicates that some patients may experience adverse events that can impair their normal daily activities, taking a long time to go away (weeks to months) or that may not be fully reversible in a small percentage of patients even after the antibiotic has been stopped for up to 12 months or longer. Quinolone and fluoroquinolone antibiotics registered in South Africa are nalidixic acid, piperidic acid, ciprofloxacin, ofloxacin, moxifloxacin, gemifloxacin, norfloxacin, levofloxacin.

The majority of adverse events relate to muscles, ligaments, joints, and nervous system, including some psychiatric disorders, heart, blood vessel and blood sugar. Due to the new safety information, the use of these antibiotics has changed and patients are requested to consult with their general practitioners/specialists for more information and reassessment of their treatment with the implicated antibiotics. Patients are also urged to read the patient information leaflet that is contained in the package of these antibiotics or request their pharmacist for a copy of the patient information leaflet.

Patients are requested to report any adverse events to the National Adverse Drug Event Monitoring Centre at 021 447 1618 or the SAHPRA pharmacovigilance office at 012 395 9133 or using the adverse drug reaction reporting form, which can be accessed at https://www.sahpra.org.za/documents/86422f1b6.04_ARF1_v4.pdf and e-mail it to adr@health.gov.za

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