

# Possible New Levaquin Side Effect: Pseudotumor Cerebri Syndrome (PTCS)

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A new study suggests that oral fluoroquinolones, including [Levaquin](#), may be associated with yet another debilitating side effect: pseudotumor cerebri syndrome or PTCS.

PTCS (also known as idiopathic intracranial hypertension (IIH) or benign intracranial hypertension (BIH)) is a neurological condition marked by increased pressure around the brain in the absence of a tumor or other diseases. People who suffer from PTCS may experience a stroke-like headache, nausea, and vomiting, as well as pulsatile tinnitus (sensation of rhythmic sounds in the ears), double vision and other visual symptoms. If untreated, PTCS may cause the optic nerve to swell, which can progress to vision loss.

## Fluoroquinolone Antibiotics and PTCS

According to researchers from the British Columbia Children's Hospital, Vancouver, Canada, case reports published in the past have tied PTCS to Levaquin and Cipro. However, there have never been any large epidemiologic studies conducted to quantify this risk..

For their study, published online last month in the journal [Neurology](#), the research team searched the LifeLink Database for cases with an ICD-9-CM code for BIH, as well as an MRI or CT scan and a lumbar puncture within 10 to 30 days of the code. They also identified 10 controls for each case. Current fluoroquinolone users were identified as those who had received an oral fluoroquinolone prescription within 15 to 30 days of their BIH diagnosis.

“From a cohort of 6,110,723 people, there were 339 cases of PTCS and 3,390 corresponding controls. In the primary analysis, the adjusted RR for current users of fluoroquinolones for both the 15-day and 30-day definitions were 5.67 (95% confidence interval [CI] 2.72–11.83) and 4.15 (95% CI 2.29–7.50), respectively,” the study authors wrote. “The risk with tetracycline antibiotics was also increased, with RRs for 15 and 30 days of current use of 2.68 (0.89–8.11) and 3.64 (1.67–7.91), respectively.”

The findings suggested that current use of oral fluoroquinolones is associated with an increased risk of PTCS. Though rare, the study authors advised that patients using these antibiotics seek medical attention if they experience symptoms of raised intracranial pressure including headaches, tinnitus, and double vision

## Fluoroquinolone Side Effects

Fluoroquinolone like Levaquin, Cipro and Avelox make up about 15% of the 260 million oral antibiotics prescribed in the U.S. each year. This study is not the first time these drugs have been linked to potentially serious side effects.

In August 2013, the U.S. Food & Drug Administration (FDA) ordered the manufacturers of oral and injectable fluoroquinolones to modify label information regarding their potential association with a serious and often permanent form of nerve damage called peripheral neuropathy. While mention of the condition had been added to fluoroquinolone labels in 2004, the agency determined that the prescribing information did not reflect the possible rapid onset of the condition, or the potential for permanent nerve damage.

Since then, hundreds of people have [filed peripheral neuropathy lawsuits against the makers of Avelox, Cipro and Levaquin](#). Most of these cases are now undergoing pretrial proceedings in the U.S. District Court, District of Minnesota.

In 2008, fluoroquinolone labels were updated with a black box warning regarding a risk of tendon injuries, including rupture of the Achilles tendon.

In May 2016, the FDA modified the black box warning to state that fluoroquinolone antibiotics should not be used to treat sinusitis, bronchitis and uncomplicated UTIs when other options are available, as their risks generally outweigh their benefits. The warning followed an agency review that suggested fluoroquinolones could cause multiple and permanent side effects involving the tendons, muscles, joints, nerves and central nervous system.