

Please see below a statement you can use in your reporting (attributable to Janssen Pharmaceuticals, not an individual).

At Janssen, our first priority is the well-being of the people who use our medicines. We work closely with the FDA to ensure appropriate safety information is included in the labels of our medicines.

LEVAQUIN® (levofloxacin) has been used for more than 20 years to treat bacterial infections, including those that may be serious or life-threatening. LEVAQUIN® is part of the important fluoroquinolone class of anti-infective prescription medications, and its safety profile remains well-known and established.

For your background: The safety profile of LEVAQUIN is well-known and disclosed within the label for the medicine: <http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/LEVAQUIN-pi.pdf> [[janssenlabels.com](http://www.janssenlabels.com)].

Additionally, we decided to discontinue LEVAQUIN® in 2017 due to the wide availability of alternative treatment options, and our focus on developing innovative medicines designed to address unmet medical patient needs.

As a result of our voluntary discontinuation of this product, our New Drug Applications for LEVAQUIN® (IV and oral solution) were officially withdrawn by US FDA in June 2017. The voluntary withdrawal was formally announced in the US Federal Register. Subsequently, we discontinued the manufacturing of LEVAQUIN® tablets in the United States in December 2017. However, unexpired LEVAQUIN® tablets may remain on the market until May 2020 and as such, may still be available at some points of sale.