

**Health Canada Endorsed Important Safety Information on  
Fluoroquinolone antibiotics (AVELOX<sup>®</sup>, CIPRO<sup>®</sup>, CIPRO<sup>®</sup> XL, and LEVAQUIN<sup>®</sup>)**



Bayer HealthCare



March 9, 2012

Dear Health Care Professional:

**Subject: Association of fluoroquinolone antibiotics (AVELOX<sup>®</sup>, CIPRO<sup>®</sup>, CIPRO<sup>®</sup> XL, and LEVAQUIN<sup>®</sup>) with worsening of symptoms of myasthenia gravis in patients with myasthenia gravis**

The manufacturers of the fluoroquinolone innovator products (Bayer Inc. and Janssen Inc.) in consultation with Health Canada would like to inform you of important updates to the labelling for fluoroquinolone antibiotics (AVELOX<sup>®</sup>, CIPRO<sup>®</sup>, CIPRO<sup>®</sup> XL, and LEVAQUIN<sup>®</sup>).

Fluoroquinolone antibiotics are indicated for the treatment of adults with various bacterial infections caused by susceptible strains of bacteria, such as respiratory tract infections, skin infections and urinary tract infections.

Health professionals should be aware that the Canadian Product Monographs (PM) for all the innovator fluoroquinolone antibiotics were updated by January 2012 to reflect the potential for the exacerbation of myasthenia gravis symptoms in patients with myasthenia gravis.

- Fluoroquinolones have neuromuscular blocking activity and may exacerbate muscle weakness in patients with myasthenia gravis.
- Exacerbation of myasthenia gravis symptoms in patients with myasthenia gravis can lead to a requirement for respiratory support in some patients.
- Fluoroquinolone antibiotics should be avoided in patients with a known history of myasthenia gravis.

The association between the exacerbation of myasthenia gravis and fluoroquinolone use has been established based on the review of post-marketing reports. Cases of serious adverse events, including deaths and requirement for ventilatory support have been associated with fluoroquinolone use in patients with myasthenia gravis.

Exacerbation of symptoms of myasthenia gravis was already included as an undesirable effect in earlier versions of the Product Monographs of Avelox<sup>®</sup>, Cipro<sup>®</sup>, Cipro<sup>®</sup> XL and LEVAQUIN<sup>®</sup>. To reinforce the warning, the Product Monographs for the innovator fluoroquinolone antibiotics have been revised under the Warnings and Precautions section to include information that they may exacerbate muscle weakness in patients with myasthenia gravis. The corresponding generic Product Monographs are in the process of being updated to reflect these warnings.

This information has been summarized for patients in a related Public Communication that can be accessed at [http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/public/\\_2012/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/public/_2012/index-eng.php), <http://www.bayer.ca/?q=en/node/62>, and <http://www.janssen.ca>.

Managing marketed health product-related adverse reactions depends on healthcare professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any case of serious adverse reactions related to exacerbation of symptoms of myasthenia gravis in patients with myasthenia gravis or other serious or unexpected adverse reactions in patients receiving fluoroquinolone antibiotics should be reported to Bayer Inc., Janssen Inc. or Health Canada.

**For AVELOX<sup>®</sup>, CIPRO<sup>®</sup> and CIPRO<sup>®</sup> XL:**

Bayer Inc.  
77 Belfield Road  
Toronto, Ontario  
M9W 1G6  
Toll-free telephone: 1-800-265-7382  
E-mail: [Canada.medinfo@bayer.com](mailto:Canada.medinfo@bayer.com)

**For LEVAQUIN<sup>®</sup>:**

Janssen Inc.  
19 Green Belt Drive  
Toronto, Ontario  
M3C 1L9  
Toll-free at telephone: 1-866-825-7122  
E-mail to [dssc@jica.jnj.com](mailto:dssc@jica.jnj.com)  
Fax to 1-866-767-5865

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- Call toll-free at 1-866-234-2345
- Complete a Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 0701E  
Ottawa, Ontario K1A 0K9

The Reporting Forms, postage paid labels, and Guidelines can be found on the MedEffect<sup>™</sup> Canada Web site in the Adverse Reaction Reporting section (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>). The Reporting Form is also in the *Canadian Compendium of Pharmaceuticals and Specialties*.

**For other health product inquiries related to this communication, please contact Health Canada at:**

Marketed Health Products Directorate  
E-mail: [mhpd\\_dpssc@hc-sc.gc.ca](mailto:mhpd_dpssc@hc-sc.gc.ca)  
Telephone: 613-954-6522  
Fax: 613-952-7738

**To change your mailing address or fax number, contact the Market Authorization Holder (Industry).**

Sincerely,



Shurjeel Choudhri, MD FRCPC  
Senior Vice President & Head,  
Medical & Scientific Affairs  
Bayer HealthCare Pharmaceuticals



Cathy Lau, PhD.  
Vice President,  
Regulatory and Quality  
Janssen Inc.

**References:**

1. AVELOX Product Monograph, January 20, 2012.
2. CIPRO Product Monograph, January 23, 2012.
3. CIPRO XL Product Monograph, January 23, 2012.
4. LEVAQUIN Product Monograph, July 20, 2011.