

## Important Safety Information on Methylphenidate Products and Priapism



April 21, 2015

### Audience

Consumers, caregivers and healthcare professionals working in the following settings: psychiatrists, pediatricians, family medicine and general practitioners, emergency physicians, urologists, and pharmacists.

### Key messages

- **Prolonged and painful erections (called priapism) have been very rarely reported in patients, including children, taking methylphenidate products.**
- **Priapism is a very rare condition that has been reported during treatment with methylphenidate products, after increasing the dose, or stopping the product even for a short period of time. The prescribing information for methylphenidate products has been updated to include this information.**
- **Patients who develop priapism should seek immediate medical attention to prevent potential long-term effects on the penis.**

### What is the issue?

The manufacturers of methylphenidate products, in consultation with Health Canada, would like to inform healthcare professionals, parents/caregivers and patients that reports of priapism have been received from the worldwide and Canadian experience.

Drugs can be a cause of priapism. Priapism has been reported very rarely in patients treated with methylphenidate products even though they are frequently prescribed. From January 1, 1965 to December 31, 2014, 2 cases of suspected priapism in association with methylphenidate products were reported in Canada.

Priapism is considered a medical emergency. For this reason, it is important that patients, parents/caregivers and healthcare professionals be aware of this rare risk of priapism and seek immediate medical attention for priapism to prevent potential long-term effects on the penis.

## Products affected

BIPHENTIN<sup>®</sup> (methylphenidate hydrochloride controlled release capsules)  
CONCERTA<sup>®</sup> (methylphenidate hydrochloride, extended-release tablets)  
RITALIN<sup>®</sup> (methylphenidate hydrochloride)  
RITALIN<sup>®</sup> SR (methylphenidate hydrochloride extended release tablets)  
All generic versions of methylphenidate hydrochloride

## Background information

Methylphenidate products are among the medicines that can be used to treat Attention Deficit Hyperactivity Disorder (ADHD). While the condition is common in childhood, ADHD can continue through adolescence and adulthood. RITALIN<sup>®</sup> and RITALIN<sup>®</sup> SR are also indicated for the treatment of narcolepsy, a disorder affecting control of sleep-wake cycles.

Priapism occurs when blood in the penis becomes trapped, leading to an abnormally prolonged (greater than 4 hours) and sometimes painful erection. Priapism is considered a medical emergency. Immediate medical attention is recommended to prevent potential long-term effects on the penis.

Priapism can occur at any age. Identifying the condition in children may be more difficult. Younger patients, especially those who have not yet reached puberty, may not recognize the problem or may be embarrassed to tell anyone if it occurs.

The prescribing information for methylphenidate products has been updated to include information on priapism.

## Information for consumers

If you have or if you notice that your child has symptoms of prolonged (greater than 4 hours in duration) and/or painful erections, it is recommended to seek immediate medical attention in order to prevent potential long-term effects on the penis.

Patients and parents/caregivers should discuss with their healthcare professional if they need further information or have questions about methylphenidate therapy.

Additional Information about BIPHENTIN<sup>®</sup> is provided in Part III: Consumer Information section of BIPHENTIN<sup>®</sup> Product Monograph at

<http://www.purdue.ca/en/products-research/prescription-medication>

Additional Information about CONCERTA<sup>®</sup> is provided in Part III: Consumer Information section of CONCERTA<sup>®</sup> Product Monograph at

<http://www.janssen.ca/product/98>

Additional Information about RITALIN<sup>®</sup> and RITALIN<sup>®</sup> SR is provided in Part III: Consumer Information section of RITALIN<sup>®</sup> and RITALIN<sup>®</sup> SR Product Monograph at:

<http://www.novartis.ca/en/products/pharmaceuticals/index.shtml>

## Information for health care professionals

Physicians are advised to talk to patients and parents/caregivers about the symptoms and risk of priapism and about the need for immediate medical attention should it occur.

For full prescribing information consult the Product Monographs as follows:

BIPHENTIN<sup>®</sup>: <http://www.purdue.ca/en/products-research/prescription-medication>

CONCERTA<sup>®</sup>: <http://www.janssen.ca/product/98>

RITALIN<sup>®</sup> and RITALIN<sup>®</sup> SR:

<http://www.novartis.ca/en/products/pharmaceuticals/index.shtml>

and on Health Canada's Web page: <http://webprod5.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp>

### **Action taken by Health Canada**

The prescribing information, called Product Monographs, for BIPHENTIN<sup>®</sup>, CONCERTA<sup>®</sup>, RITALIN<sup>®</sup> and RITALIN<sup>®</sup> SR have been updated with this new safety information.

### **Report health or safety concerns**

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any case of priapism or other serious or unexpected side effects in patients receiving methylphenidate products should be reported to the manufacturers of those products or Health Canada.

Contact information for manufacturer of BIPHENTIN®  
Drug Safety Group  
Purdue Pharma  
575 Granite Court  
Pickering, ON  
L1W 3W8  
Or call toll free at 1-800-387-4501 or (905) 420-4955  
Or email to [productinfo@purdue.ca](mailto:productinfo@purdue.ca)  
Or fax to (905) 420-6342

Contact information for manufacturer of CONCERTA®  
Drug Safety Department  
Janssen Inc.  
19 Green Belt Drive  
Toronto, ON  
M3C 1L9  
Or call toll free at 1-866-825-7122  
Or email to [dsscan@joica.inj.com](mailto:dsscan@joica.inj.com)  
Or fax to 1-866-767-5865

Contact information for manufacturer of RITALIN® and RITALIN® SR  
Novartis Pharma Canada Inc.  
385 Bouchard Blvd.,  
Dorval, (QC) H9S 1A9  
Or call toll free at: 1-800-363-8883 (Medical Information)  
[http://www.novartis.ca/en/util/contact\\_product.shtml](http://www.novartis.ca/en/util/contact_product.shtml)

**For change of address, fax number or transmission difficulties regarding this notification please email [info@ptm-health.com](mailto:info@ptm-health.com) or fax 1-888-780-4268.**

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect™ Canada's Web page on [Adverse Reaction Reporting \(http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php\)](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax


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

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

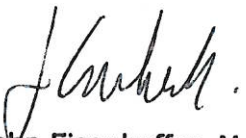
Sincerely,



Cathy Lau, Ph.D.  
Vice President  
Regulatory Affairs and  
Quality Management  
Janssen Inc.



for: Jean Godin, M.D.,  
Vice-President and Chief  
Scientific Officer  
Novartis Pharmaceuticals  
Canada Inc.



John Eisenhoffer, M.D.,  
Director  
Pharmacovigilance &  
Medical Liaison  
Purdue Pharma Inc.

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