

**Important Information on Shortage
of BICILLIN® L-A Injection (penicillin G benzathine) 2 mL Single Use
Syringe and Replacement with Australian Labelled Stock**



2016/05/12

Audience

Healthcare professionals including physicians, infectious disease specialists, pharmacists and nurses, public health officials and sexual health clinics

Please distribute this communication to appropriate personnel within your facility who are using this product.

Key messages

- **Pfizer Canada is currently experiencing a supply disruption of BICILLIN L-A (penicillin G benzathine) sterile injection due to a production issue.**
- **To alleviate the temporary shortage (expected resupply date of early July 2016), Health Canada, per the conditions agreed upon by Pfizer Canada, has facilitated the importation of Pfizer Australian labelled BICILLIN L-A, lot 72453.**
- **The Australian BICILLIN L-A is the same as the Canadian product with respect to composition, packaging (syringes), specification and expiry period (shelf life).**
- **Healthcare professionals should refer to the BICILLIN L-A Canadian Product Monograph for prescribing information. If administering Australian BICILLIN L-A in children under 2 years of age, it may be necessary to do dosage conversions.**

What is the issue?

During the temporary supply disruption of BICILLIN L-A (penicillin G benzathine) in Canada, Pfizer will be filling orders of the product with BICILLIN L-A, lot 72453, from Pfizer Australia. In light of this situation, Health Canada, per the conditions agreed upon by Pfizer Canada, facilitated the importation of Pfizer Australian labelled BICILLIN L-A, lot 72453. The Australian BICILLIN L-A is the same as Canadian product with respect to composition, packaging (syringes), specification and expiry period (shelf life). However, healthcare professionals need to be aware of the need to do dosage conversions when administering Australian BICILLIN L-A due to the difference in the expression of product strength as well as differences in the labelling of the syringe. The strength of the drug is expressed in "international units (I.U.)" in the Canadian BICILLIN L-A product label and in "mg" in the Australian BICILLIN product label (1.2 million I.U.= 900 mg).

Products affected

Pfizer Canada BICILLIN L-A (penicillin G benzathine) sterile injection, available as a 2 mL disposable syringe containing 1.2 million I.U. penicillin G benzathine (as an aqueous suspension) and supplied in packages of 10 syringes.

BICILLIN L-A (benzathine benzylpenicillin) from Pfizer Australia, Lot 72453, has an expiry date of 2018.

Background information

Pfizer Canada is currently experiencing a supply disruption for BICILLIN L-A (penicillin G benzathine) sterile injection. This situation is caused by a production issue at the manufacturing plant. Pfizer is currently completing an investigation and will remedy the situation as soon as possible. The expected resupply date of the Canadian labelled product from Pfizer Canada Inc. is early July 2016.

BICILLIN L-A (penicillin G benzathine) intramuscular injection is indicated in the treatment of infections due to penicillin-G-sensitive microorganisms that are susceptible to the low and very prolonged serum levels common to this particular dosage form.

In Canada, BICILLIN L-A (penicillin G benzathine) is the main drug used in adults for the treatment of syphilis caused by the bacterium *Treponema pallidum*.

Information for Health care professionals

Healthcare professionals should consult the "Interim Syphilis Treatment Guidelines during the Benzathine Penicillin G (BICILLIN L-A) Shortage 2016" developed by the Public Health Agency of Canada (<http://www.phac-aspc.gc.ca/std-mts/sti-its/cgsti-lcdcits/assets/pdf/syphilis-eng.pdf>).

Healthcare professionals should be aware of the differences in the syringe labelling of the Canadian BICILLIN L-A product and the Australian BICILLIN L-A product that is being supplied temporarily in its place. The Australian product is the same as the Canadian product with respect to composition, packaging (syringes), specification and expiry period (shelf life). There are differences in the nomenclature used on the label, however, the active ingredient and the non-medicinal ingredients in the Canadian and Australian BICILLIN L-A are the same. The volume of the two products is the same (i.e., 2.3 mL), except that the Canadian product is rounded down to 2mL.

Differences in the Canadian and Australian BICILLIN L-A Syringe Labelling		
	Canadian Product Labelling	Australian Product Labelling
Language	English and French	English
Product Name (same but different nomenclature)	penicillin G benzathine	benzathine benzylpenicillin
Strength (1.2 million I.U. = 900 mg)	1.2 million I.U./2 mL	900 mg/2.3 mL
Warning	Deep IM only (not IV)	Deep IM only (not IV)
Storage Conditions	Refrigerate (between 2 and 8°C). Protect from freezing.	Not included on label. The Australian product should also be refrigerated. Refer to Canadian product labelling.
Use information	Single use only	Single use only
Bar code	3 60793 00366 5	Not included
Drug Identification Number	02291924	Not included
Address	Included	Not included

In the BICILLIN L-A (penicillin G benzathine) Canadian Product Monograph (CPM), the dosage is expressed as I.U./mL. As the strength of the Australian BICILLIN L-A product is expressed as mg/mL, a dosage conversion is necessary in children under 2 years of age. The equivalent doses of the products for the treatment of syphilis are provided in the following table as an example. For the calculation of partial doses using the Australian product, a value of 442 mg/mL should be used.

Dosage Conversion from the Canadian to Australian BICILLIN L-A for Treatment of Syphilis (based on 1.2 million I.U. = 900 mg)		
	Canadian Dosage¹	Australian Dosage
Primary, secondary and early latent	2.4 million I.U. (2 syringes)	1,800 mg (2 syringes)
Late Latent and tertiary (not involving central nervous system)	2.4 million I.U. (2 syringes) at 7-day intervals for 3 doses	1,800 mg (2 syringes) at 7-day intervals for 3 doses
Congenital (with normal CSF): under 2 years of age	50,000 I.U./kg body weight (0.095 mL/kg body weight)	37.5 mg/kg body weight (0.095 mL/kg body weight)
Congenital (with normal CSF): ages 2-12 years	Adjust dosage based on adult dosage schedule	Adjust dosage based on adult dosage schedule

For complete prescribing information, including Dosage and Administration, please refer to the BICILLIN L-A Canadian package insert, which is provided with the Australian labelled BICILLIN L-A (penicillin G benzathine) stock, rather than the enclosed Australia labelling information. The BICILLIN L-A CPM is available at the following link: <http://www.pfizer.ca/products>. The Australian product will be accompanied by this risk communication and the Canadian package insert.

Action taken by Health Canada

As per the *Protocol for the Notification and Communication of Drug Shortages*, Health Canada and the Provinces and Territories Drug Shortages Task Team have classified this situation as a Tier 3 shortage, which indicates a national shortage with the greatest potential impact. In light of the temporary situation, Health Canada, per the conditions agreed upon by Pfizer Canada, facilitated the importation of Pfizer Australian labelled BICILLIN L-A, lot 72453.

Report health or safety concerns

Managing health product-related side effects depends on health care professionals and consumers reporting them. Any serious or unexpected side effects in patients receiving BICILLIN L-A should be reported to Pfizer Canada Inc. or Health Canada.

Pfizer Canada Inc. Contact Information

**17300 Trans-Canada Highway
Kirkland, QC
H9J 2M5**

Telephone: If you have an inquiry of a medical nature related to Bicillin L-A, please contact our Medical Information Group at 1-800-463-6001. For all other inquiries, please contact our Customer Service Group at 1-800-387-4974.

To report an adverse event (or suspected side-effect) experienced with a Pfizer medication (prescription, non-prescription or a vaccine) please contact Pfizer at 1 866 723-7111 or by fax at 1 855 242-5652.

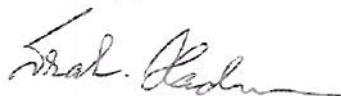
You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

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

Regulatory Operations and Regions Branch
E-mail: dcviu_uvcm@hc-sc.gc.ca
Telephone: 1-800-267-9675

Sincerely,



Vratislav Hadrava M.D., Ph.D.
Vice-President and Medical Director
Pfizer Canada Inc.