

Important Safety Information - Importation of Portuguese-authorized Lentocilin S 1200; 1 200 000 IU / 4 mL, due to the current shortage of Canadian-authorized Bicillin L-A 1 200 000 IU / 2 mL

2026/02/18



UPDATED INFORMATION – March 3, 2026

Further to the Health Canada communication below, issued on February 18, 2026, additional supply of the Portuguese-authorized Lentocilin S 1200; 1 200 000 IU / 4 mL has been made available to mitigate the ongoing shortage. This new supply is available with bilingual (English and French) labels (see images in Appendix 2 below).

Audience

Healthcare professionals including physicians, nurses, hospital pharmacists, public health and sexual health clinics, group purchasing organizations, and wholesalers.

Key messages

- **Due to a critical shortage of the antibiotic Bicillin L-A 1 200 000 IU / 2 mL in Canada, and given the medical necessity of this drug, Health Canada has permitted the exceptional, temporary importation and sale of Portuguese-authorized Lentocilin S 1200; 1 200 000 IU / 4 mL with English-only labels.**
- **Lentocilin S has the same active ingredient, strength (1 200 000 IU) and route of administration (intramuscular) as Bicillin L-A. However, Lentocilin S has a different formulation, dosage form, reconstitution requirement, and presentation than Bicillin L-A (see Appendix 1).**
- **Healthcare professionals are advised to:**
 - **Be aware that the active ingredient (benzathine benzylpenicillin) in Lentocilin S is identical to the active ingredient (penicillin G benzathine) in Bicillin L-A. The products use different nomenclature on their labels.**
 - **Be aware that Lentocilin S is supplied as a powder in a vial, to be reconstituted with the co-packaged diluent containing lidocaine hydrochloride 1.5% (final volume 4 mL), whereas Bicillin L-A is supplied as a suspension in a ready-to-use pre-filled syringe and does not contain lidocaine (final volume 2 mL) (see the Information for healthcare professionals section).**
 - **Be aware that Lentocilin S contains soy phospholipids and may cause hypersensitivity reactions (urticaria, anaphylactic shock) in patients with a history of allergy to soybeans.**
 - **Refer to the indications and the Serious Warnings and Precautions Box, including information related to severe cutaneous adverse**

reactions (SCAR) associated with penicillin G benzathine, in the Canadian Product Monograph for Bicillin L-A from Pfizer Canada ULC, available in English and French on [Health Canada's Drug Product Database](#).

- Refer to the [Lentocilin S Summary of Product Characteristics \(SmPC\)](#) in English and French for product specific information on dosing, preparation and administration, warnings and precautions, and storage and handling.

What is the issue?

Given the medical necessity of Bicillin L-A 1 200 000 IU / 2 mL and the need to maintain continuity of supply in Canada, Health Canada has authorized the exceptional, temporary importation and sale of Portuguese-authorized Lentocilin S 1200; 1 200 000 IU / 4 mL, manufactured by Laboratórios Atral, S.A. with English-only labels, by Septa Pharmaceuticals Inc., to mitigate the shortage.

Lentocilin S has the same active ingredient, strength (1 200 000 IU), and route of administration (intramuscular) as Bicillin L-A. However, there are differences in the formulation, dosage form, reconstitution requirement, and presentation between Lentocilin S and Bicillin L-A. Healthcare professionals are advised to enhance the safety monitoring of the imported drug, including monitoring for potential adverse effects.

Products affected

Brand name	Dosage form and route of administration	Country of authorization and identifying code	Manufactured By	Importer in Canada
Lentocilin S 1200 1 200 000 IU / 4 mL	Powder and solvent for suspension for injection. Intramuscular	Portugal 9908301	Laboratórios Atral, S.A.	Septa Pharmaceuticals Inc.

Background information

Bicillin L-A (intramuscular penicillin G benzathine) 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. Therapy should be guided by bacteriological studies (including sensitivity tests) and by clinical response.

Currently, there is a critical shortage of Canadian-authorized Bicillin L-A 1 200 000 IU / 2 mL in Canada. To help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation and sale of Portuguese-authorized Lentocilin S 1200; 1 200 000 IU / 4 mL, with English-only labels.

Information for healthcare professionals

Lentocilin S has the same active ingredient, strength (1 200 000 IU), and route of administration (intramuscular) as Bicillin L-A. However, there are differences in the formulation, dosage form, reconstitution requirement, and presentation among other characteristics, which are important to note (see Table 1).

Table 1: Key differences between Lentocilin S 1200; 1 200 000 IU / 4 mL and Bicillin L-A 1 200 000 IU / 2 mL

	Portuguese drug product for importation	Canadian drug product
Product Brand Name, Dosage Form and Strength	Lentocilin S 1200 (Laboratórios Atral, S.A., Portugal) Each vial contains 1 200 000 IU of benzathine benzylpenicillin 1 200 000 IU / 4 mL, Powder and solvent for suspension.	Bicillin L-A (Pfizer Canada ULC) penicillin G benzathine 1 200 000 IU per 2 mL suspension for injection.
Identifying Code	9908301	DIN 02291924
Product Presentation	Each unit consists of a clear glass vial for injection (powder) and an amber glass ampoule with diluent.	2 mL ready-to-use pre-filled syringe.
Reconstitution	Reconstitute immediately prior to use. Refer to Lentocilin S SmPC for instructions.	None
Administration	In infants younger than 2 years, and if considered necessary, the dosage may be divided and administered in two separate sites. A needle with a minimum 18 gauge is required to administer Lentocilin S.	No reference to divided dosage in infants.
Additional Medicinal and Non-Medicinal Ingredients	Lidocaine hydrochloride (present in the ampoule containing the diluent) is identified as a non-medicinal ingredient in the Lentocilin S SmPC -	None

requiring caution	it should be used with caution in specific populations such as the presence of cardiovascular, hepatic or renal dysfunction, inflammation and/or infection at the injection site or sensitivity to local anesthetics of the amide type; children, the elderly and patients with acute illnesses or debilitated; and patients on concomitant central nervous system (CNS) depressant drugs.	
	Soy phospholipids - may cause hypersensitivity reactions (urticaria, anaphylactic shock) in patients with a history of allergy to soybeans.	
Storage	Store below 25°C. Store in the original package in order to protect from light and moisture.	Store under refrigeration (2°-8°C). May be removed from refrigerator and stored for 7 days at a temperature not exceeding 30°C. Protect from freezing.

Healthcare professionals are advised that:

- Due to the different product formulation, enhanced monitoring of the safety of the imported drug for the intended disease condition is recommended, including monitoring for potential adverse effects.
- Lentocilin S contains soy phospholipids and may cause hypersensitivity reactions (urticaria, anaphylactic shock) in patients with a history of allergy to soybeans. The co-packaged diluent contains lidocaine hydrochloride and should be used with caution in specific populations, including those with sensitivity to local anesthetics of the amide type.
- The reconstituted Lentocilin S product should be administered immediately after reconstitution. Note that there is a difference in the volume for injection of the reconstituted Lentocilin S (4 mL) compared to Bicillin L-A (2 mL).
- A needle with a minimum 18 gauge is required to administer Lentocilin S.
- Refer to the indications and the Serious Warnings and Precautions Box, including information related to severe cutaneous adverse reactions (SCAR), in the Canadian Product Monograph for Bicillin L-A from Pfizer Canada ULC, available in English and French on [Health Canada's Drug Product Database](#).
- Refer to the [Lentocilin S Summary of Product Characteristics \(SmPC\)](#) in English and French for product specific information on dosing, preparation and administration, warnings and precautions, and storage and handling.
- Aspects of the labels of Lentocilin S may differ from Bicillin L-A (see images of Lentocilin S in Appendix 1). **Proper selection of the intended product must**

be verified to avoid confusion with other products and to prevent medication errors.

- Lentocilin S does not have a Drug Identification Number (DIN) or a barcode that scans in medication management systems in Canada. A facility-generated sticker may be required to enable barcode scanning and allow the product being dispensed and administered to be properly identified.

Action taken by Health Canada

Health Canada has worked with Septa Pharmaceuticals Inc. to prepare this alert for Portuguese-authorized Lentocilin S 1200; 1 200 000 IU / 4 mL. Health Canada is communicating this important safety information to healthcare professionals and Canadians via the [Recalls and Safety Alerts Database](#) on the Healthy Canadians Web Site. This communication will be further distributed through the MedEffect™ e-Notice email notification system.

Report health or safety concerns

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any case of serious or unexpected side effects in patients receiving Lentocilin S should be reported to Septa Pharmaceuticals Inc. or Health Canada.

Septa Pharmaceuticals Inc.
7035 Maxwell Road, Unit 2
Mississauga, ON
L5S 1R5
Canada

Telephone: +1 905-564-5665
Fax: +1 905-564-1291

To correct your mailing address or fax number, contact Septa Pharmaceuticals Inc.

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:

Regulatory Operations and Enforcement Branch
E-mail: hpce-cpsal@hc-sc.gc.ca
Telephone: 1-800-267-9675

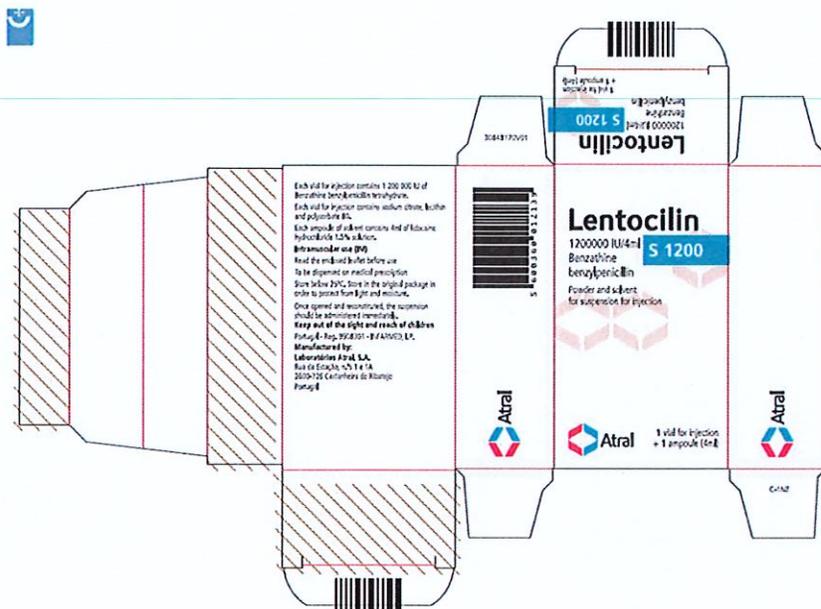


Devinder Kumar
President & CEO
Septa Pharmaceuticals Inc.

Appendix 1

Portuguese-authorized Lentocilin S 1200; 1 200 000 IU / 4 mL, **carton, vial, and ampoule labels:**

Lentocilin S 1200; 1 200 000 IU / 4 mL, Carton Label:



Each vial for injection contains 1 200 000 IU of Benzathine benzylpenicillin tetrahydrate.

Each vial for injection contains sodium citrate, lecithin and polysorbate 80.

Each ampoule of solvent contains 4ml of lidocaine hydrochloride 1.5% solution.

Intramuscular use (IM)

Read the enclosed leaflet before use

To be dispensed on medical prescription

Store below 25°C. Store in the original package in order to protect from light and moisture.

Once opened and reconstituted, the suspension should be administered immediately.

Keep out of the sight and reach of children

Portugal – Reg. 9908301 – INFARMED, I.P.

Manufactured by:

Laboratórios Astral, S.A.

Rua da Estação, n.ºs 1 e 1A

2600-726 Castanheira do Ribatejo

Portugal

30848170V01

Atral

Lentocilin

S 1200

1 200 000 IU/4ml

Benzathine

benzylpenicillin

1 vial for injection
+ 1 ampoule (4ml)

Lentocilin

S 1200

1 200 000 IU/4ml

Benzathine

benzylpenicillin

Powder and solvent
for suspension for injection

Atral

1 vial for injection
+ 1 ampoule (4ml)

Atral

Lentocilin S 1200; 1 200 000 IU / 4 mL, Vial and Ampoule Image:



Lentocilin S 1200; 1 200 000 IU / 4 mL, Vial Label:

R-27-A
Lentocilin S 1200
 1 200 000 IU
 benzathine benzylpenicillin
 Powder for suspension for injection

Intramuscular use (IM)
 Each vial contains 1 200 000 IU of benzathine benzylpenicillin.
 Store below 25°C. Store in the original package in order to protect from the light and moisture.
 Once opened and reconstituted, the suspension should be administered immediately.

35848170V01


Lentocilin **S 1200**
 1 200 000 IU
 benzathine benzylpenicillin

Powder for suspension for injection

Atral

Intramuscular use (IM)

Each vial contains 1 200 000 IU of benzathine benzylpenicillin.

Store below 25°C. Store in the original package in order to protect from the light and moisture.

Once opened and reconstituted, the suspension should be administered immediately.

Lentocilin S 1200; 1 200 000 IU / 4 mL, Ampoule Label:

Cloridrato de lidocaína 1,5%
Clorhidrato de lidocaína 1,5%
Lidocaine hydrochloride 1.5%
IM
 Lab. Atral, S.A. PORTUGAL **4ml**

Lote:
 Prep.:
 EXP:



220 • 311185.V01

Cloridrato de lidocaína 1,5%
Clorhidrato de lidocaína 1,5%
Lidocaine hydrochloride 1.5%
IM
 Lab. Atral, S.A. PORTUGAL

4ml

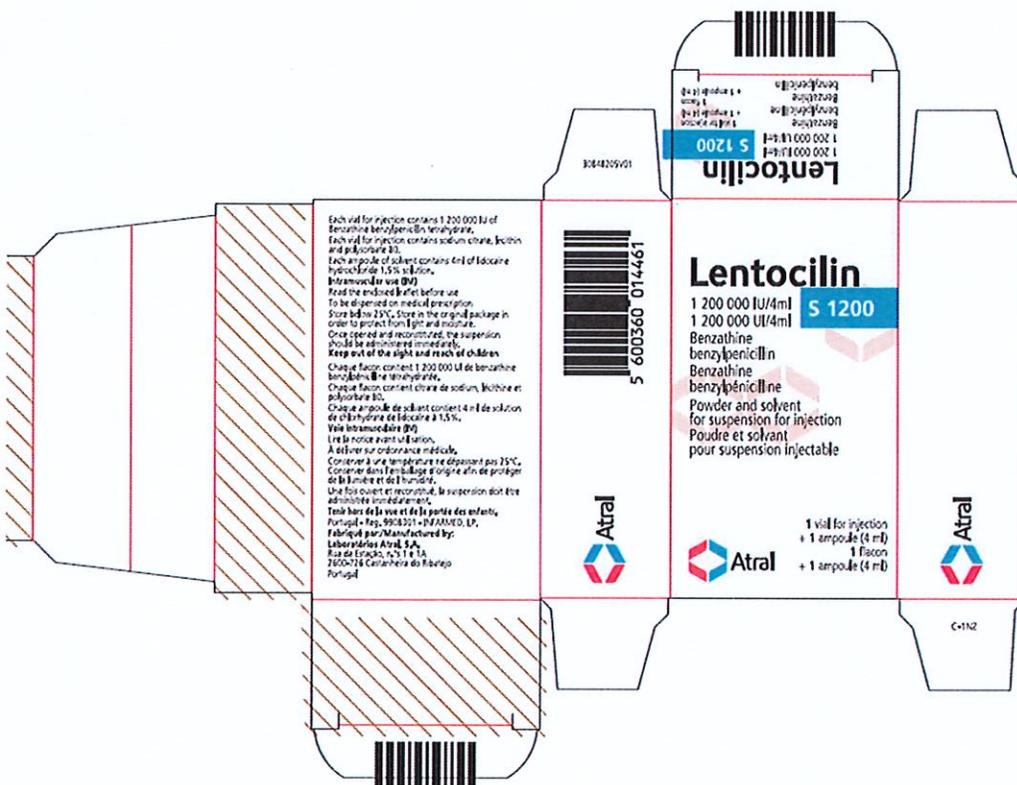
Lote:
Prep.:
EXP:

220 . 311185.V01

Appendix 2:

Portuguese-authorized Lentocilin S 1200; 1 200 000 IU / 4 mL, carton, vial, and ampoule labels with bilingual labelling (English and French):

Lentocilin S 1200; 1 200 000 IU / 4 mL, Carton Label:



Each vial for injection contains 1 200 000 IU of Benzathine benzylpenicillin tetrahydrate.
Each vial for injection contains sodium citrate, lecithin and polysorbate 80.
Each ampoule of solvent contains 4ml of lidocaine hydrochloride 1.5% solution.

Intramuscular use (IM)

Read the enclosed leaflet before use
To be dispensed on medical prescription
Store below 25°C. Store in the original package in order to protect from light and moisture.
Once opened and reconstituted, the suspension

should be administered immediately.

Keep out of the sight and reach of children

Chaque flacon contient 1 200 000 UI de benzathine benzylpénicilline tétrahydratée.

Chaque flacon contient citrate de sodium, lécithine et polysorbate 80.

Chaque ampoule de solvant contient 4 ml de solution de chlorhydrate de lidocaïne à 1,5%

Voie intramusculaire (IM)

Lire la notice avant utilisation.

A délivrer sur ordonnance médicale.

Conserver à une température ne dépassant pas 25°C

Conserver dans l'emballage d'origine afin de protéger de la lumière et de l'humidité.

Une fois ouvert et reconstituée, la suspension doit être administrée immédiatement.

Tenir hors de la vue et de la portée des enfants.

Portugal – Reg. 9908301 – INFARMED, I.P.

Fabriqué par:/Manufactured by:

Laboratórios Astral, S.A.

Rua da Estação, n.ºs 1 e 1A

2600-726 Castanheira do Ribatejo

Portugal

30848170V01

Atral

Lentocilin

S 1200

1 200 000 IU/4ml

Benzathine

benzylpenicillin

Benzathine

benzylpénicilline

Powder and solvent

for suspension for injection

Poudre et solvant

pour suspension injectable

1 vial for injection

+ **1** ampoule (4ml)

1 flacon

+ **1** ampoule (4 ml)

Lentocilin

1 200 000 IU/4ml

S 1200

Benzathine

benzylpenicillin

Benzathine

benzylpénicilline

Powder and solvent

For suspension for injection

Poudre et solvant

Pour suspension injectable

1 vial for injection

+ **1** ampoule (4ml)

1 flacon

+ **1** ampoule (4 ml)

Lentocilin S 1200; 1 200 000 IU / 4 mL, Vial and Ampoule Image:



Lentocilin S 1200; 1 200 000 IU / 4 mL, Vial Label:

R-27-A	Lentocilin S 1200	Intramuscular use (IM)	
		Voie intramusculaire (IM)	
35848215V01	1 200 000 IU	Each vial contains 1 200 000 IU of benzathine benzylpenicillin	
	1 200 000 UI	Chaque flacon contient 1 200 000 UI de benzathine benzylpénicilline	
	Benzathine benzylpenicillin	Once opened and reconstituted, the suspension should be administered immediately	
	Benzathine benzylpénicilline	Une fois ouvert et reconstitué, la suspension doit être administrée immédiatement	
	Powder for suspension for injection		
	Poudre pour suspension injectable		
			

35848215V01

R-27-A

Lentocilin**S 1200**

1 200 000 IU

1 200 000 UI

Benzathine benzylpenicillin

Benzathine benzylpénicilline

Powder for suspension for injection

Poudre pour suspension injectable

Atral

Intramuscular use (IM)

Voie intramusculaire (IM)

Each vial contains 1 200 000 IU
of benzathine benzylpenicillin.Chaque flacon contient 1 200 000 UI
de benzathine benzylpénicillineOnce opened and reconstituted, the
suspension should be administered
immediately.Une fois ouvert et reconstitué, la
suspension doit être administrée
immédiatementLentocilin S 1200; 1 200 000 IU / 4 mL, Ampoule Label:**Cloridrato de lidocaína 1,5%**
Clorhidrato de lidocaína 1,5%
Lidocaine hydrochloride 1.5%**IM**

Lab. Atral, S.A. PORTUGAL

4ml

Lote:

Prep.:

EXP:



220 • 311185.V01

Cloridrato de lidocaína 1,5%
Clorhidrato de lidocaína 1,5%
Lidocaine hydrochloride 1.5%**IM**

Lab. Atral, S.A. PORTUGAL

4ml**Lote:****Prep.:****EXP:**

220 . 311185.V01