

**Importation of South Korean-Authorized BONKY Injection, 1 mcg/mL
Calcitriol, due to the Current Shortage of Canadian-Authorized Calcitriol
Injection USP, 1 mcg/mL**



2026/08/24

Audience

Healthcare professionals at hospitals and units such as dialysis clinics and renal units.

Key messages

- **Due to a shortage of Calcitriol Injection USP, 1 mcg/mL in Canada, and given the medical necessity of this drug, Health Canada has permitted the exceptional, temporary importation and sale of South Korean-authorized BONKY Injection, 1 mcg/mL Calcitriol with Korean-only labels.**
- **This South Korean-authorized product has the same active ingredient (calcitriol), strength (1 mcg/mL), dosage form (injection), and route of administration (intravenous) as the Canadian-authorized product. However, there are differences between these products.**
- **Healthcare professionals are advised that:**
 - **The South Korean-authorized product has a different brand name, carton and ampoule label, and pack size (10 x 1 mL ampoules instead of 25 x 1 mL ampoules) than the Canadian-authorized product (see Appendix 1).**
 - **The expression of strength displayed on the South Korean-authorized product carton appears as "1 µg", whereas the South Korean-authorized ampoule displays the strength as "1 mcg/mL". Please note that "µg" denotes microgram (mcg). Refer to the expression of strength displayed on the ampoule label when verifying the product strength. The Canadian-authorized product displays the strength as "1 mcg/mL" on both the carton and ampoule.**

- **Although the South Korean-authorized product has differences in carton and ampoule labelling, healthcare professionals should continue to consult the Indications, Contraindications, Warnings and Precautions, Adverse Reactions, Dosage and Administration, and Storage Conditions sections of the Canadian Product Monograph for Calcitriol Injection USP, 1 mcg/mL by SteriMax Inc. (DIN 02399334), available in English and French on Health Canada's Drug Product Database.**
- **Pharmacies/hospitals are advised to generate a sticker or auxiliary label for the outer carton label (and ampoules, if feasible) to ensure proper identification of the product and access to safe use information (including the active ingredient and strength using mcg/mL).**

What is the issue?

There is a shortage of Calcitriol Injection USP in Canada. Given the medical necessity of Calcitriol Injection USP, 1 mcg/mL and the need to maintain continuity of supply in Canada, Health Canada has authorized the exceptional, temporary importation and sale of South Korean-authorized BONKY Injection, 1 mcg/mL Calcitriol, with Korean-only labels to mitigate the shortage.

Healthcare professionals should be aware that there are differences between the South Korean-authorized and Canadian-authorized products (see Information for healthcare professionals section).

Products affected

Brand name	Dosage form and route of administration	Country of authorization and identifying code	Marketed By	Importer in Canada
BONKY Injection, 1 mcg/mL Calcitriol	Injection Intravenous	Republic of Korea 199801831	YuYu Pharma Inc.	Septa Pharmaceuticals Inc.

Background information

In Canada, Calcitriol Injection USP is indicated for the management of hypocalcemia in patients undergoing chronic renal dialysis. It has also been shown to help with the improvement of renal osteodystrophy by reducing elevated parathyroid hormone levels. Calcitriol Injection USP is NOT recommended for use in pediatric patients.

Currently, there is a critical shortage of Canadian-authorized Calcitriol Injection USP, 1 mcg/mL in Canada. To help mitigate the shortage, Health Canada has

permitted the exceptional, temporary importation and sale of South Korean-authorized BONKY Injection, 1 mcg/mL Calcitriol, with Korean-only labels.

Information for healthcare professionals

The South Korean-authorized product has the same active ingredient (calcitriol), strength (1 mcg/mL), dosage form (injection), and route of administration (intravenous) as the Canadian-authorized product. However, there are differences between these products.

Healthcare professionals are advised that:

- The South Korean-authorized product has a different brand name, carton and ampoule label, and pack size (10 x 1 mL ampoules instead of 25 x 1 mL ampoules) than the Canadian-authorized product (see Appendix 1). Proper selection of the intended product must be verified to avoid confusion with other products and to prevent medication errors.
- The expression of strength displayed on the South Korean-authorized product carton appears as "1 µg", whereas the South Korean-authorized ampoule displays strength as "1 mcg/mL". Please note that "µg" denotes microgram (mcg). Refer to the expression of strength displayed on the ampoule label when verifying the product strength. The Canadian-authorized product displays the strength as "1 mcg/mL" on both the carton and ampoule.
- The labelling of the Canadian-authorized product includes the statement "NOT recommended for use in children". While this information is not stated on the labels or in the translated prescribing information, the same applies to the South Korean-authorized product.
- The South Korean-authorized product label includes a serious warning that when opening an ampoule, glass fragments may enter the solution and cause adverse effects. The ampoule should be opened carefully to minimize contamination by glass fragments.
- The Canadian Product Monograph for Calcitriol Injection USP, 1 mcg/mL from SteriMax Inc. (DIN 02399334), available in English and French on [Health Canada's Drug Product Database](#), should be consulted for information on the appropriate use of the product, including the Indications, Contraindications, Warnings and Precautions, Adverse Reactions, Dosage and Administration, and Storage Conditions.
- The product labels of the Canadian-authorized Calcitriol Injection USP identify that the product is preservative free, sterile and for single use. While this information is not stated on the labels or in the translated prescribing information, the same applies to the South Korean-authorized product.
- A sticker or auxiliary label should be generated at pharmacies/hospitals for the outer carton label (and ampoules, if feasible) to ensure proper identification of the product and access to safe use information (including the active ingredient name and strength using mcg/mL).
- The South Korean-authorized product 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.

- Additional information about South Korean-authorized BONKY Injection, 1 mcg/mL Calcitriol, for reference by healthcare professionals can be found in the English- and French-translated prescribing information at [Septa's Pharmaceuticals Inc. website](https://septalife.com/posts/resources/) (<https://septalife.com/posts/resources/>).

Action taken by Health Canada

To help mitigate the shortage of Calcitriol Injection USP, 1 mcg/mL in Canada, Health Canada has permitted the exceptional, temporary importation and sale of South Korean-authorized BONKY Injection, 1 mcg/mL Calcitriol and has added this product to the [List of Drugs for Exceptional Importation and Sale](#).

Health Canada has worked with Septa Pharmaceuticals Inc. to prepare this alert for South Korean-authorized BONKY Injection, 1 mcg/mL Calcitriol. 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 update 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 healthcare professionals and consumers reporting them. Any case of any serious or unexpected side effects in patients receiving South Korean-authorized BONKY Injection, 1 mcg/mL Calcitriol should be reported to Septa Pharmaceuticals Inc. and/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

Image of South Korean-authorized BONKY Injection, 1 mcg/mL Calcitriol, ampoule and carton:



Appendix 2

a) Image of South Korean-authorized BONKY Injection, 1 mcg/mL Calcitriol, outer carton and translation:

BONKY Injection, 1 mcg/mL Calcitriol , outer carton:



Carton dimension: 145mm (H) x 68mm x 19mm (L)

BONKY Injection, 1 mcg/mL Calcitriol , outer carton translation:

[Left]

[분류번호] 311

[Classification Code] 311

[원료약품 및 그 분량] 이 약 1mL 중

[Composition] Each 1ml contains

유효성분 : 칼시트리올(별규)..... 1.0μg

Active ingredient : Calcitriol

기타 첨가제 : 무수인산수소나트륨, 아스코르브산나트륨, 에데트산
나트륨, 염화나트륨, 인산이수소나트륨일수화물, 주사용수, 폴리소
르베이트 20

Excipients : Sodium hydrogen phosphate anhydrous, sodium ascorbate, sodium edetate,
sodium chloride, sodium dihydrogen phosphate monohydrate, water for injection,
polysorbate 20

[성상]

무색 내지 미황색의 투명한 액이 충전된 갈색 앰플 주사제

[Appearance]

Colorless to light yellow transparent solution in a brown glass ampoule

[효능·효과], [용법·용량], [사용상의 주의사항] 등 자세한 내용은 첨부

문서를 참조하십시오. (주의-이상반응)

Please refer to the attached document for detailed information on [Indications and
Effects], [Dosage and Administration], [Precautions], and other details. (Caution—
Adverse Reactions)

[저장방법] 차광밀봉용기, 상온보관

[Storage] Store in a light-proof, airtight container at room temperature

[제조사] 아주약품(주) / 경기도 평택시 산단로 121번길 23

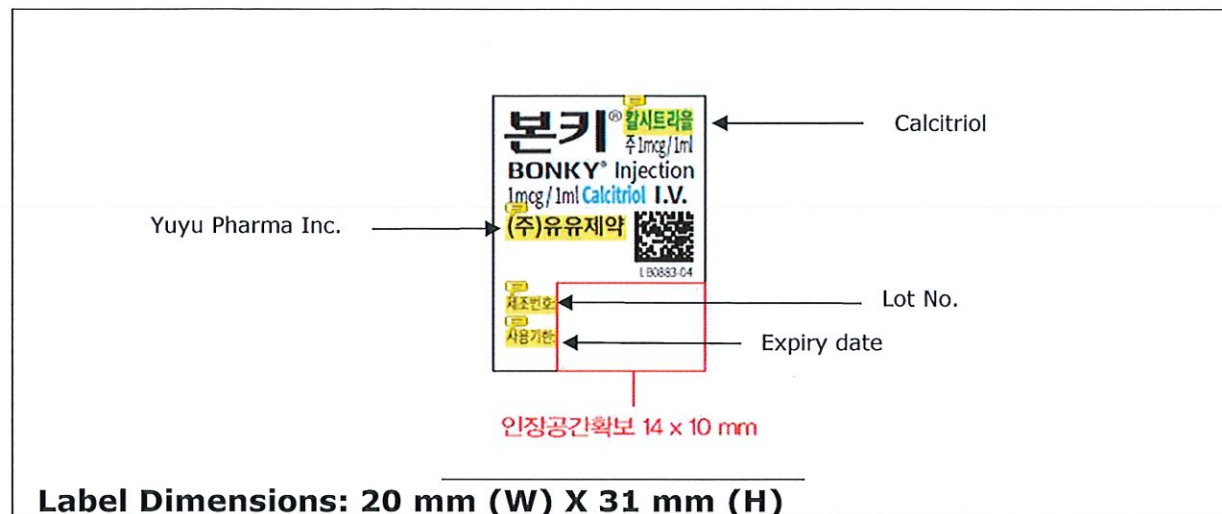
[Manufacturer] Aju Pharm Co., Ltd. / 23, Sandan-ro 121beon-gil, Pyeongtaek-si,
Gyeonggi-do, Republic of Korea

[Right]

[제조의뢰자] (주)유유제약 / 충북 제천시 바이오밸리1로 94

[MAH] Yuyu pharma, Inc. / 94 Bio valley 1-ro, Jecheon-si, Chungcheongbuk-do, Republic
of Korea

b) Image of South Korean-authorized BONKY Injection, 1 mcg/mL Calcitriol, ampoule label (Original) and translation:



BONKY Injection, 1 mcg/mL Calcitriol, Ampoule Label English translation (Mock-up label)

