



2023/06/14

Important Safety Information on PAXLOVID (nirmatrelvir and ritonavir): Correction of the Expiry Dates following the Extension of Shelf-Life from 18 months to 24 months

Audience

Healthcare professionals including physicians, pharmacists, nurse practitioners, nurses and public health officials.

Key messages

- **On December 1, 2022, Health Canada has issued a Notice of Compliance (NOC) for an extension of the shelf-life (from 18 months to 24 months) for PAXLOVID.**
- **On January 17, 2023, Pfizer extended the expiration dates of PAXLOVID (nirmatrelvir and ritonavir) lots currently in the market for the authorized Standard Dose Pack (DIN: 02524031) and the Moderate Renal Impairment Dose Pack (DIN: 02527804).**
- **Pfizer is now correcting the expiry dates provided in the January 17, 2023 letter for PAXLOVID lots currently in the market to ensure that appropriate action is taken. Please refer to the below table in section [Information for healthcare professionals](#) for the corrected expiry dates.**
- **The approved storage conditions remain unchanged.**
- **Healthcare professionals are advised that:**
 - **The expiry dates in the January 17, 2023 letter must be disregarded.**
 - **The expiration date of Paxlovid Tablets must be verified prior to dispensing.**
 - **The Canadian Paxlovid Product Monograph in French and English are available on Health Canada's [Drug Product Database](#).**

What is the issue?

On December 1, 2022, Health Canada has issued a Notice of Compliance (NOC) for an extension of the shelf-life (from 18 months to 24 months) for PAXLOVID. Accordingly, on January 17, 2023, Pfizer had extended the expiration dates of PAXLOVID lots currently in the market. Following further review, Pfizer is correcting the expiry dates provided in the January 17, 2023 letter for PAXLOVID lots currently in the market to ensure that appropriate action is taken. Health Canada has been notified with the correction of the expiration dates and has no objection with this proposition as summarized in the below table in section [Information for healthcare professionals](#).

Products affected

- PAXLOVID (300 mg nirmatrelvir (as two 150 mg pink tablets); 100 mg ritonavir (white tablet)) co-packaged tablets for oral use. Standard Dose Pack Drug Identification Number (DIN): 02524031.
- PAXLOVID (150 mg nirmatrelvir (pink tablet); 100 mg ritonavir (white tablet)) co-packaged tablets for oral use. Moderate Renal Impairment Dose Pack Drug Identification Number (DIN): 02527804.

Background information

PAXLOVID is indicated for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

PAXLOVID is not authorized for:

- the initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19;
- pre-exposure or post-exposure prophylaxis for prevention of COVID-19;
- use for longer than 5 consecutive days.

Information for healthcare professionals

Healthcare professionals are advised that:

- On December 1, 2022, Health Canada issued a Notice of Compliance (NOC) for the shelf-life extension of PAXLOVID (nirmatrelvir and ritonavir) from 18 months to 24 months for the authorized Standard Dose Pack (DIN: 02524031) and the Moderate Renal Impairment Dose Pack (DIN: 02527804).
- On January 17, 2023, Pfizer extended the expiration dates of PAXLOVID (nirmatrelvir and ritonavir) lots currently in the market for the authorized Standard Dose Pack (DIN: 02524031) and the Moderate Renal Impairment Dose Pack (DIN: 02527804).
- Pfizer is now correcting the expiry dates provided in the January 17, 2023, letter for the PAXLOVID lots currently in the market to ensure that appropriate action is taken.
- The expiry dates in the January 17, 2023, letter must be disregarded.
- The expiration date of Paxlovid tablets must be verified prior to dispensing and healthcare professionals should contact patients who may have unused packages of PAXLOVID to advise them of the corrected expiry dates.
- The approved storage conditions remain unchanged.

Dose Pack	Lot(s)#	Labelled Expiry Date	Corrected Extended Expiry Date
PAXLOVID (300 mg nirmatrelvir (2 x 150 mg); 100 mg ritonavir)	FT3540	2022-08-31	2023-07-31
	FX4437, FX4444	2023-01-31	2023-07-31
	FX8106	2023-01-31	2023-08-31
	FX7185	2023-01-31	2023-09-30
	GA6769, GA6205, GA6761	2023-02-28	2023-12-31
	GC2133, GC2886	2023-02-28	2024-01-31
	GC8177	2023-02-28	2024-02-29
	GD4585, GC5723, GC5720	2023-03-31	2024-01-31
	GA3793, GD1181	2023-03-31	2023-11-30
	GD1183	2023-03-31	2024-02-29
	GD4677, GD8410, GD8409, GC8182, GC8181	2023-04-30	2024-03-31
	GD8407, GD4673, GD4670, GD4671, GD4669, GC5733, GD4678	2023-04-30	2024-02-29
	GG2189, GG2190, GG2191, GG2187, GG2185	2023-05-31	2024-03-31
	GK4940, GK4941, GK4942	2023-11-30	2024-03-31
	GK4943, GJ2964, GK1234, GJ7300, GJ7303, GL0349, GL6161, GL0350, GL0351, GL0352, GJ2965	2023-12-31	2024-03-31
	GM7360, GM7359, GM7358, GM7357	2024-01-31	2024-03-31
GR2928	2024-01-31	2024-05-31	

PAXLOVID (150 mg nirmatrelvir; 100 mg ritonavir)	GJ4599	2023-03-31	2024-03-31
	GG3564	2023-05-31	2024-01-31
	GP9562, GP9563	2023-11-30	2024-05-31

- The Canadian Paxlovid Product Monograph in French and English is available on Health Canada’s Drug Product Database.
- This communication in both French and English, as well as the French-translated Canadian Product Monograph are available at [PAXLOVID \(nirmatrelvir tablets; ritonavir tablets\) | Pfizer Canada](#).

Report health or safety concerns

Adverse drug reactions associated with the use of Paxlovid should be reported to Pfizer Canada ULC by calling 1-866-723-7111, online at [Pfizer's Adverse Event Reporting Portal \(pfizersafetyreporting.com\)](#) or to Health Canada at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html> or by calling toll-free at 1-866-234-2345.

For Medical Inquiries, please contact Medical Information at 1-800-463-6001 or you can also access Medical Information via www.pfizermedinfo.ca. For Allocation Inquiries please contact our Allocation Specialist via email: allocation@pfizer.com, or by phone at 1-888-999-8750. For General Inquiries: Please contact our Customer Service Group at 1-888-888-9221.

Sincerely,



Vratislav Hadrava M.D., Ph.D.
 Vice President & Medical Director
 Pfizer Canada ULC