2023/01/17

Important Safety Information on PAXLOVID (nirmatrelvir and ritonavir): 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 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).**
- **The approved storage conditions remain unchanged.**
- **Healthcare professionals are advised that:**
  - **The expiration date of Paxlovid Tablets must be verified prior to dispensing.**
  - **The Canadian Paxlovid Product Monograph in French and English is available on Health Canada's Drug Product Database.**

What is the issue?
On January 17, 2022, PAXLOVID (150 mg nirmatrelvir; 100 mg ritonavir) co-packaged tablets for oral use, was authorized by Health Canada with an approved shelf-life of 12 months. To provide earlier access to PAXLOVID in the context of the global pandemic, Pfizer initially supplied Canada with US Emergency Use labels with 9 months shelf-life, that was subsequently extended to 12, and then 18 months shelf-life. 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, Pfizer has extended the expiration dates of PAXLOVID lots currently in the market. Health Canada has been notified and has no objection with this proposition as summarized below:

- Blisters and cartons with an expiry date of August 2022 printed on the label may remain in use for an additional 15 months beyond the printed date.
- Blisters and cartons with an expiry date of January 2023 through May 2023 printed on the label may remain in use for an additional 12 months beyond the printed date.
- Blisters and cartons with an expiry date of November 2023 through January 2024 printed on the label may remain in use for an additional 6 months beyond the printed date.

Please refer to 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).
- The approved storage conditions remain unchanged.
- The expiration date of Paxlovid tablets must be verified prior to dispensing.

Dose Pack	Lot(s)#	Labelled Expiry Date	Extended Expiry Date
PAXLOVID (300 mg nirmatrelvir (2 x 150 mg); 100 mg ritonavir)	FT3540	2022-08-31[a]	2023-11-30
	FX7185, FX4437, FX4444, FX8106	2023-01-31[b]	2024-01-31
	GC8177, GC2133, GC2886, GA6769, GA6205, GA6761	2023-02-28[b]	2024-02-28
	GD1181, GD1183, GC5723, GC5720, GA3793, GD4585	2023-03-31[b]	2024-03-31
	GD8407, GC8182, GC8181, GD8410, GD8409, GD4673, GD4670, GD4671, GD4669, GD4677, GC5733, GD4678	2023-04-30[b]	2024-04-30
	GG2189, GG2190, GG2191, GG2187, GG2185	2023-05-31[b]	2024-05-31
	GK4940, GK4941, GK4942	2023-11-30[c]	2024-05-31
	GK4943, GJ2964, GK1234, GJ7300, GJ7303, GL0349, GL6161, GL0350, GL0351, GL0352, GJ2965	2023-12-31[c]	2024-06-30
	GM7360, GM7359, GM7358, GM7357, GR2928	2024-01-31[c]	2024-07-31
PAXLOVID (150 mg nirmatrelvir; 100 mg ritonavir)	GJ4599	2023-03-31[b]	2024-03-31
	GG3564	2023-05-31[b]	2024-05-31
	GP9562, GP9563	2023-11-30[c]	2024-05-31

[a] Lots to remain in use for an additional 15 months beyond the printed expiry date
[b] Lots to remain in use for an additional 12 months beyond the printed expiry date
[c] Lots to remain in use for an additional 6 months beyond the printed expiry date

- 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,

Original signed by
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Vice President & Medical Director
Pfizer Canada ULC