



2022/11/11

Important Safety Information on PAXLOVID (nirmatrelvir and ritonavir): Extension of Shelf-Life from 12 months to 18 months

Audience

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

Key messages

- **On September 26, 2022, Health Canada has issued a Notice of Compliance (NOC) for the shelf-life extension of PAXLOVID (nirmatrelvir and ritonavir) from 12 months to 18 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 supplied US Emergency Use label with 9 months and 12 months shelf-life in Canada. On September 26, 2022, Health Canada has issued a Notice of Compliance (NOC) for an extension of the shelf-life (from 12 months to 18 months) for PAXLOVID as summarized below:

- Blisters and cartons with an expiry date of August 2022 printed on the label may remain in use for an additional 9 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 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 September 26, 2022, Health Canada has issued a Notice of Compliance (NOC) for the shelf-life extension of PAXLOVID (nirmatrelvir and ritonavir) from 12 months to 18 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	2023-05-31
	FX7185, FX4437, FX4444, FX8106	2023-01-31	2023-07-31
	GC8177, GC2133, GC2886, GA6769, GA6205, GA6761	2023-02-28	2023-08-31
	GD1181, GD1183, GC5723, GC5720, GA3793, GD4585	2023-03-31	2023-09-30
	GD8407, GC8182, GC8181, GD8410, GD8409, GD4673, GD4670, GD4671, GD4669, GD4677, GC5733, GD4678	2023-04-30	2023-10-31
	GG2189, GG2190, GG2191, GG2187, GG2185	2023-05-31	2023-11-30
PAXLOVID (150 mg nirmatrelvir); 100 mg ritonavir)	GJ4599	2023-03-31	2023-09-30
	GG3564	2023-05-31	2023-11-30

- 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 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,

A handwritten signature in dark ink, appearing to read "Vratislav Hadrava", with a long horizontal flourish extending to the right.

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