Important Safety Information on PAXLOVID (nirmatrelvir and ritonavir) Dosing and Dispensing in Renal Impairment due to Shortage of the Moderate Renal Impairment Pack

2024/09/30

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

Key messages

Paxlovid is supplied in two different Dose Packs. The Dose Packs differ in the number of nirmatrelvir tablets they contain:

- **Regular dose pack (300 mg nirmatrelvir (150 mg x 2); 100 mg ritonavir) for patients with normal renal function or mild renal impairment (eGFR ≥60 mL/min). Each carton of PAXLOVID contains 30 tablets divided in 5 daily-dose blister cards. Each daily blister card contains 4 nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each), which are separated into morning and evening doses. Drug Identification Number (DIN): 02524031.**
- **Moderate renal impairment pack (150 mg nirmatrelvir; 100 mg ritonavir) for patients with moderate renal impairment (eGFR ≥30 to <60 mL/min). Each carton of PAXLOVID contains 20 tablets divided in 5 daily-dose blister cards. Each daily blister card contains 2 nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each), which are separated into morning and evening doses. Drug Identification Number (DIN): 02527804.**

Pfizer is experiencing a shortage of PAXLOVID™ moderate renal impairment pack (150 mg nirmatrelvir; 100 mg ritonavir).

Healthcare professionals are advised that:

- **Patients with moderate renal impairment require a nirmatrelvir dose reduction. Healthcare professionals who dispense PAXLOVID should remove two nirmatrelvir tablets (one morning tablet and one evening tablet) from the daily blister cards of the regular dose pack for patients with moderate renal impairment.**

Please refer to PAXLOVID (nirmatrelvir and ritonavir) - Dosing and Dispensing in Renal Impairment, Risk of Serious Adverse Reactions Due to Drug Interactions, and English-Only Labels - Canada.ca and July 6, 2022 Important Safety Information on Paxlovid (nirmatrelvir and ritonavir) for more information on Dosing and Dispensing in Renal Impairment, Risk of Serious Adverse Reactions Due to Drug Interactions, and English-Only Labels.

What is the issue?
Pfizer is experiencing a shortage of PAXLOVID™ moderate renal impairment pack (150 mg nirmatrelvir; 100 mg ritonavir).

Information for healthcare professionals
Healthcare professionals are advised that:

- **PAXLOVID is not recommended in patients with severe renal impairment. Patients with moderate renal impairment require a nirmatrelvir dose reduction.**

  When dispensing PAXLOVID, healthcare professionals should ensure that patients with moderate renal impairment receive additional support and instructions given the risk of dosing errors. This includes removing two nirmatrelvir tablets from daily blister cards of the regular dose pack (i.e., one of the 150 mg nirmatrelvir tablets from the morning dose and one of the 150 mg nirmatrelvir tablets from the evening dose) prior to dispensing, notifying patients that blister cards have been altered at the pharmacy and counselling patients about renal dosing instructions.

  Please refer to PAXLOVID (nirmatrelvir and ritonavir) - Dosing and Dispensing in Renal Impairment, Risk of Serious Adverse Reactions Due to Drug Interactions, and English-Only Labels - Canada.ca and July 6, 2022 Important Safety Information on Paxlovid (nirmatrelvir and ritonavir) for more information on Dosing and Dispensing in Renal Impairment, Risk of Serious Adverse Reactions Due to Drug Interactions, and English-Only Labels.

For all inquiries including medical information, allocations and general information related to this product, please contact 1-800-387-4974.

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.

Sincerely,

Vratislav Hadrava M.D., Ph.D.
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Pfizer Canada ULC