Feidhmeannacht na Seirbhíse Sláinte, Seirbhís Aisíocaíochta Cúraim Phríomhúil
Bealach amach 5, M50, An Bóthar Thuaidh, Fionnghlas
Baile Átha Cliath 11, D11 XKF3
Fón: (01) 864 7100 Facs: (01) 834 3589

Health Service Executive, Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas, Dublin 11, D11 XKF3
Tel: (01) 864 7100 Fax: (01) 834 3589

17th February 2023

Circular 010/23

RE: Shelf-life extension of PAXLOVID® (nirmatrelvir 150 mg/ritonavir 100 mg), film-coated tablets

Dear Pharmacist,

Please find attached communication issued from Pfizer Healthcare Ireland in relation to the shelf-life extension of PAXLOVID® (nirmatrelvir 150 mg/ritonavir 100 mg), film-coated tablets.

The new expiry date for a pack must be determined by identifying the specific batch number in the list below:

Batch Number	Printed Expiry Date	New Expiry Date
GC0763	02/2023	10/2023
GC0765	02/2023	10/2023
GJ5809	04/2023	01/2024
GN6222	10/2023	02/2024

Ongoing stewardship for this product remains in place. Therefore, pharmacies are still required to forward by Healthmail a copy of the Paxlovid® prescription to pharmacy.response@hse.ie. Please include the pharmacy GMS contract number in the email correspondence to ensure payment of the patient care fee.

Administrative Code	Drug Name	Pack Size	Pharmaceutical Form
89181	Paxlovid 150mg/100mg	30	Film Coated Tabs

The HSE Medicines Management Programme would like to remind pharmacists that there are a number of resources available to support the prescribing of Paxlovid® including:

- Paxlovid® Prescribing Guidance Summary for Community Settings, available on www.antibioticprescribing.ie which outlines the eligibility criteria and other important considerations for prescribing Paxlovid®.
- HSE Interim Guidance for the Pharmacological Management of patients with COVID-19 which outlines more detailed information regarding Paxlovid®.

The following resources are available to support the review of a medication list for drug-drug interactions involving Paxlovid®:

- University of Liverpool drug interaction checker
- Paxlovid™ Summary of Product Characteristics

Yours faithfully,

Shaun Flanagan
Assistant National Director
Primary Care Reimbursement Service

Pfizer Healthcare Ireland
9 Riverwalk, National Digital Park,
Citywest Business Campus, Dublin 24
Telephone: 01 4676500 Facsimile 01 4676501
Freephone: 1800 460 900
www.pfizer.ie

16-02-2023

Dear Healthcare Professional – Hospital Pharmacists, Community Pharmacists, GPs, Hospital Group Clinical Directors

Shelf-life extension of PAXLOVID® (nirmatrelvir 150 mg/ritonavir 100 mg), film-coated tablets

European Marketing Authorisation number EU/1/22/1625/001

Pfizer Healthcare Ireland is writing to inform you that on the 24th of January 2023, a new shelf-life for PAXLOVID was approved in the European Union (EU).

The Product Information for PAXLOVID film-coated tablets has now been updated with the new shelf-life, which has been **extended to 24 months.**

This extension applies to batches manufactured after this approval date.

In addition, this extension of the shelf-life is being applied retrospectively to all PAXLOVID batches manufactured prior to this approval, including those batches that were temporarily authorised for distribution at national level before the granting of marketing authorisation.

Packs with an expiry date of 11/2022 through to 12/2023 printed on their outer cartons or blisters may remain in use for a longer period beyond the printed date.

Paxlovid is a co-packaged product consisting of nirmatrelvir and ritonavir tablets, which sometimes have different production dates. For this reason, the updated expiry date cannot simply be calculated by adding 6 months or 12 months (some packs have the previous approved shelf-life of 18 months and others the initial shelf-life of 1 year) to the printed expiry date. The new expiry date for a pack must be determined by identifying the specific batch number in the list below:

Batch number	Printed Expiry Date	New expiry date
GC0763	02/2023	10/2023
GC0765	02/2023	10/2023
GJ5809	04/2023	01/2024
GN6222	10/2023	02/2024

In consequence of the extension of the shelf-life, the handling of the EU-serialisation data for this medicinal product according to the delegated Regulation (EU) 2016/161 relating to Falsified Medicinal Products must also be considered.

Please be aware that during the verification/decommissioning of the unique identifiers that are on the packs of the above batches, alerts for the affected batches will appear, indicating that the packs have expired. These 'expired pack' alerts should be ignored. The alerts will appear because the labelled expiration date on the packs of the above batches and the stored expiration date in the National Medicines Verification System (NMVS) repository system do not reflect the extended shelf-life now assigned to the product. Kindly share this information with the central pharmacy, wholesalers and persons authorised or entitled to supply Paxlovid.

Pfizer Healthcare Ireland
9 Riverwalk, National Digital Park,
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Telephone: 01 4676500 Facsimile 01 4676501
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www.pfizer.ie

Please review the current Product Information before prescribing or dispensing.

This medicine has been given 'conditional approval'. This means that there is more evidence to come about this medicine. The European Medicines Agency will review new information on this medicine at least every year and this leaflet will be updated as necessary.

Call for reporting

You can assist us with monitoring the safety of Paxlovid by reporting suspected adverse reactions. Suspected adverse drug reactions (ADRs) should be reported to the Health Products Regulatory Authority (HPRA):

- Online Reporting via the HPRA Website www.hpra.ie
- Using downloadable form from the HPRA website. An adverse reaction report form can be downloaded from the HPRA Website. This can be sent by Freepost to the HPRA or by email to medsafety@hpra.ie.
- By telephoning the Pharmacovigilance Section of the HPRA, (01) 676 4971

Suspected adverse drug reactions may also be reported to Pfizer Medical Information on 1800 633 363.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website. Scan the code with a mobile device to get the package leaflet in different languages.

URL: https://pfi.sr/c19oralrx

For more information about Paxlovid, please contact Pfizer Medical Information at https://www.pfizer.com/products/product-contact-information

Yours sincerely,

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Dr Kate O'Keeffe, PhD

Medical Advisor, COVID and Vaccines

Pfizer Healthcare Ireland

PP-PAX-IRL-0129

Date of Prep: Feb 2023