Therapeutics Today

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Paxlovid™ (PF-07321332+ritonavir [nirmatrelvir/ritonavir]): update on prescribing and access

Key safety points and useful resources:

Renal factors - A reduced dose of Paxlovid™ is required in patients with moderate renal impairment [eGFR (CrCl if >75 years) ≥ 30 to < 60 mL/min]; Paxlovid™ is contraindicated in patents with eGFR (CrCl if >75 years) <30 mL/min

Drug-drug interactions (DDIs) - Paxlovid™ is a potent inhibitor of cytochrome P450 3A (CYP3A) due to its ritonavir component; co-administration may lead to an increase in the plasma concentrations of a wide range of commonly prescribed medicines

Useful resources - the Paxlovid™ Summary of Product Characteristics (SmPC) and the University of Liverpool COVID-19 drug interaction checker give guidance on potential DDIs

Additional support - GPs who require assistance specifically relating to the potential for DDIs associated with Paxlovid™, can contact the National Medicines Information Centre (NMIC) by emailing the completed NMIC Template via secure email to nmic@stjames.ie, however **please note that contact with the NMIC is not mandatory in order to prescribe Paxlovid™.**

Paxlovid™ (PF-07321332+ritonavir [nirmatrelvir/ritonavir]) received a conditional marketing authorisation throughout the EU in January 2022 and became available for use in Ireland in specific circumstances, in April 2022. Full details of the authorisation process for Paxlovid™ are available on the European Medicines Agency website.

Eligibility and prescribing considerations

Paxlovid™ is now recommended by the HSE COVID-19 Therapeutic Advisory group (TAG) and the HSE clinical prioritisation subgroup for patients in Tier 1, 2 and 3 (*see appendix 2 of the HSE Interim Guidance*) who have a positive PCR, or during periods of high levels of community transmission of COVID-19, a positive self-administered antigen test.

Please consult the Summary of Product Characteristics (SmPC) available on the EMA website or www.medicines.ie,which contains full prescribing information including dose (reduced in renal impairment) and details of exclusion criteria such as severe renal impairment and certain interacting medicines, prior to initiating treatment with Paxlovid™.

Drug-drug interactions

Paxlovid™ is a potent inhibitor of cytochrome P450 3A (CYP3A) due to its ritonavir component and co-administration may lead to an increase in the plasma concentrations of a wide range of commonly prescribed medicines. **Due to the risk of drug-drug interactions a full review of patient medication history and interaction risk is required prior to initiating a prescription.**
In addition to the SmPC, the University of Liverpool COVID-19 drug interaction checker is a useful resource that provides practical guidance on the management of potential DDIs between Paxlovid™ and many commonly prescribed medicines. When using the University of Liverpool checker, please type in nirmatrelvir/ritonavir and then the potential co-administered medicine(s).

If a GP wishes to avail of assistance specifically relating to the potential for drug-drug interactions associated with Paxlovid™, the National Medicines Information Centre (NMIC) is available for support through their enquiry answering service. If required, drug-drug interaction enquiries should be emailed to the NMIC (nmic@stjames.ie) via secure email (e.g. Healthmail) with the patient's list of current medicines using the NMIC Template on the HSE – Medicines Management Programme website; please provide your telephone contact number on the form. However, **please note that contacting the NMIC is not a mandatory step in the Paxlovid™ prescribing process.**

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Prescriptions for Paxlovid™ should be sent by Healthmail to the community pharmacy of the patient's choice. Until practice IT systems have been updated, a prescription for Paxlovid™ may need to be typed or written manually and scanned, including all patient and prescriber details and identifiers. On receipt of a prescription, the community pharmacy will order Paxlovid™ from the wholesaler. **If the product is ordered by 5pm, it will be delivered to the community pharmacy by 5pm the next day.** Pharmacies will not hold a stock of Paxlovid™. This time needs to be considered in planning patient care to get the Paxlovid™ **first dose taken within 5 days of symptom onset**. There is a weekend/bank holiday ordering service available for pharmacies; the community pharmacy should be contacted for information relating to this.

To facilitate monitoring and stewardship of Paxlovid™ in the Irish context, the HSE-MMP has been requested to gather outcome data following the use of Paxlovid™. In the coming weeks, the MMP will be contacting an initial sample of prescribers for data relating to patients where Paxlovid™ was dispensed in the community setting.

The Irish College of General Practitioners (ICGP) has produced a number of Paxlovid™ resources including an ICGP Quick Reference Guide. This, along with other Paxlovid™ guidance, is available on the COVID-19 acute respiratory infection page of the HSE Antibiotic Prescribing website.

Every effort has been made to ensure that this information is correct and is prepared from the best available resources at our disposal at the time of issue. References are available on request. **This newsletter is produced by the National Medicines Information Centre, St James's Hospital (SJH) Dublin 8 and Dept. of Therapeutics Trinity College, Trinity Centre, SJH.** Tel: Direct Line (01) 473 0589 or 0818 727 727 Email: nmic@stjames.ie @NationalNmic