Program (ChAMP)

## MONOGRAPH

## Nirmatrelvir with ritonavir (Paxlovid®) Monograph -**Paediatric**

Scope (Staff):	Medical, Pharmacy, Nursing
Scope (Area):	All Clinical Areas

## **Child Safe Organisation Statement of Commitment**

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

## This document should be read in conjunction with this DISCLAIMER

QUICKLINKS				
<u>Dosage/Dosage</u> <u>Adjustments</u>	Administration	Compatibility	<u>Monitoring</u>	

## **DRUG CLASS**

Antiviral with activity against severe acute respiratory syndrome coronavirus (SARS-CoV-2) also known as COVID-19.(1)

## INDICATIONS AND RESTRICTIONS

- Nirmatrelvir with ritonavir (Paxlovid®) may be considered in exceptional circumstances for the treatment of COVID-19 in children and adolescents ≥12 years and ≥40 kg who:
  - o are within 5 days of symptom onset
  - o do not require oxygen
  - are at high risk of deterioration
  - o are not up to date with vaccination OR are immunosuppressed (regardless of immunisation status)(2)

Further information regarding high risk patients can be found in the Australian guidelines for the clinical care of people with COVID-19.(2)

## Oral: Restricted (red) antiviral

ChAMP approval is required prior to prescription.

## **CONTRAINDICATIONS**

- Hypersensitivity to nirmatrelvir, ritonavir or any component of the formulation.<sup>(3)</sup>
- Nirmatrelvir with ritonavir (Paxlovid®) is contraindicated in patients with severe renal impairment, severe hepatic impairment and in combination with other medications that are dependent on CYP3A4 for clearance where elevated concentrations are associated with harm.<sup>(3-5)</sup> Further information regarding potential interactions for nirmatrelvir with ritonavir (Paxlovid®) can be found on the Liverpool COVID-19 interaction checker.

#### **PRECAUTIONS**

- For patients with renal impairment who require dose reduction, the additional tablets of nirmatrelvir should be removed prior to providing to the patient. (1, 4)
- Sexually active adolescent females should use effective contraception whilst taking nirmatrelvir with ritonavir (Paxlovid®).<sup>(3)</sup>

## **FORMULATIONS**

Listed below are products available at PCH, other formulations may be available, check with pharmacy if required:

Nirmatrelvir 150 mg tablets with ritonavir 100 mg tablets – co-packaged

Imprest location: Not on imprest, contact Pharmacy for individual patient stock

#### **DOSAGE & DOSAGE ADJUSTMENTS**

## Children <12 years of age and/or <40 kg:

 Not recommended for this age group. Contact Infectious Diseases to discuss alternative options.

## Children and adolescents ≥12 years and ≥40 kg:

 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet) twice daily for a total of five days.<sup>(1)</sup>

## **Renal impairment:**

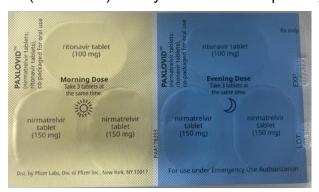
- eGFR calculator
- No dosage adjustment is required in patients with an eGFR of 60 mL/minute or greater.
- eGFR 30 to 59 mL/minute: 150 mg nirmatrelvir (one 150mg tablet) with 100 mg ritonavir (one 100 mg tablet) twice daily for a total of five days. (1, 4)
- eGFR < 30 mL/minute: Contact Infectious Diseases to discuss alternative options.</li>

## Hepatic impairment:

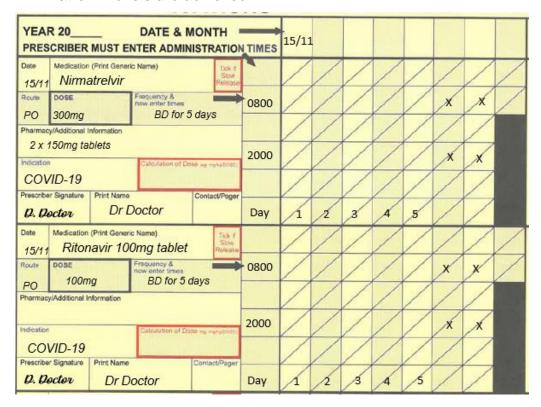
No dose adjustment is required for patients with a Child-Pugh score of A and B. There is no data on use in patients with severe hepatic impairment (Child-Pugh score C) and nirmatrelvir with ritonavir (Paxlovid®) should not be used in these patients. (1, 4)

## Prescribing recommendations for inpatient use:

Nirmatrelvir with ritonavir (Paxlovid®) is only available as separate, co-packaged tablets.



- The patient must be charted for both agents separately on the medication chart as per the guide below:
  - Nirmatrelvir and ritonavir must be taken at the same time to ensure adequate nirmatrelvir levels are achieved.<sup>(1, 3, 5)</sup>



#### **ADMINISTRATION**

- Nirmatrelvir and ritonavir must be taken at the same time to ensure adequate nirmatrelvir levels are achieved.<sup>(1, 3, 5)</sup>
- Nirmatrelvir and ritonavir tablets are co-packaged with 5 daily blister cards. Each daily blister card contains a morning dose (two 150 mg nirmatrelvir tablets and one 100 mg ritonavir tablet) and evening dose (two 150 mg nirmatrelvir tablets and one 100 mg ritonavir tablet.<sup>(4)</sup>
- Nirmatrelvir and ritonavir (Paxlovid®) may be taken with or without food and should not be

cut, crushed or chewed. (1, 3, 4)

• If a dose of nirmatrelvir with ritonavir is missed by ≤8 hours, the dose should be taken as soon as possible. If the dose is missed by >8 hours, the subsequent dose should be taken at the next scheduled time. There is no need to given an additional dose to replace the missed dose. (4, 5)

## COMPATIBILITY (LIST IS NOT EXHAUSTIVE)

Not applicable

## **MONITORING**

Consider monitoring liver function tests and serum creatinine during treatment. (1)

## **ADVERSE EFFECTS**

**Common:** diarrhoea, vomiting, alteration in taste, headache<sup>(1, 3, 5)</sup>

Infrequent: Hypertension, myalgia<sup>(1, 3)</sup>

Rare: Toxic epidermal necrolysis, Stevens-Johnson syndrome, hypersensitivity reactions,

angioedema(1, 5)

## **STORAGE**

Store below 25°C(3)

## **INTERACTIONS**

This medication may interact with other medications; consult PCH approved references (e.g. Clinical Pharmacology), a clinical pharmacist or PCH Medicines Information Service on extension 63546 for more information.

## Related CAHS internal policies, procedures and guidelines

Antimicrobial Stewardship Policy

ChAMP Empiric Guidelines and Monographs

**KEMH Neonatal Medication Protocols** 

## References

- 1. Clinical Pharmacology [Internet]. Elsvier BV. 2022 [cited 23/06/2022]. Available from: <a href="https://www-clinicalkey-com.pklibresources.health.wa.gov.au/pharmacology/">https://www-clinicalkey-com.pklibresources.health.wa.gov.au/pharmacology/</a>
- 2. Paediatric and Adolescent Care Panel. National COVID-19 Clinical Evidence Taskforce Melbourne2022 [Available from: <a href="https://covid19evidence.net.au/">https://covid19evidence.net.au/</a>.
- 3. MIMS Australia. MIMS online [full product information]. St Leonards, N.S.W: CMP Medica

<sup>\*\*</sup>Please note: The information contained in this guideline is to assist with the preparation and administration of **nirmatrelvir with ritonavir (Paxlovid®)**. Any variations to the doses recommended should be clarified with the prescriber prior to administration\*\*

Australia.; 2022. p. 1v. (various pagings).

- McEvoy G, editor. AHFS Drug Information. Maryland: American Society of Health-System Pharmacists: 2022.
- IBM Micromedex [Internet]. Truven Health Analytics. 2022 [cited 09/06/2022]. Available from: http://www-micromedexsolutions-com.pklibresources.health.wa.gov.au/micromedex2/librarian.

## **Useful resources (including related forms)**

National COVID-19 Clinical Evidence Taskforce - living guidelines

Patient Consent form

Patient medicines information leaflet

This document can be made available in alternative formats on request for a person with a disability.

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