Molnupiravir (Lagevrio®)

Information sheet for Barwon Health staff

BH Reference Number 22/124: Barwon Health Staff Access to Molnupiravir

Barwon Health

BACKGROUND

- Molnupiravir (Lagevrio®) is an oral antiviral therapy that is currently provisionally approved by the Therapeutic Goods Administration (TGA) for the treatment of symptomatic COVID-19 in people who have risk factors for severe disease.
- Molnupiravir reduces the risk of hospitalisation or death due to COVID-19 by 30% in this patient demographic.
- Additionally, the use of Molnupiravir may reduce the severity and duration of your symptoms, as well as reduce your infectiousness meaning that you are less likely to transmit the virus to your household members.
- It is well tolerated, with few side effects, and easily prescribed due to no drug-drug interactions or dosing issues with those who have organ dysfunction.

BARWON HEALTH STAFF ACCESS TO MOLNUPIRAVIR

- Given the enormous impact that this COVID-19 Pandemic has had on the healthcare system, Barwon Health is currently looking into various ways in which we can help support our staff.
- We believe that Molnupiravir is likely to bring benefit to everyone, even those who do not have risk factors for severe disease; namely by reducing the length and severity of illness and reducing the spread of the virus within a household. We also feel it may allow staff to feel more secure at work knowing they have access to treatment if they become infected.
- It is important to understand that the use of Molnupiravir in this setting is "off-label" meaning that it is not currently approved by the TGA for those not at risk of severe disease.
- Furthermore, being a new medication, it is unknown whether there are any long-term adverse effects of the treatment.

HOW TO PARTICPATE

- You are receiving this handout as you are a member of University Hospital Geelong Staff, and have enquired about antiviral therapy to treat your COVID-19 illness.
- If you agree to take the medication; following your appointment with a medical practitioner, you will receive the medication as well as instructions on how to take it. You are advised to take the medication as directed for five days.
- Prior to commencing treatment you will be provided with Rapid Antigen Tests (RATs) and we ask that those living in your household who are not already infected with COVID undertake a RAT.
- On the 5th day of treatment you will be asked to perform a RAT on yourself and any household members who remain un-infected with COVID.

- Following completion of treatment, you will receive three follow up surveys at different time points; two weeks, three months and six months post the start of treatment. Each survey should not take longer than five minutes to complete.
- You are asked to complete those surveys when you receive each of them. The researchers will be able to see whether you have responded to your survey, as an individualised link is sent to each participant. If you do not complete a survey within one week of receiving it, you will receive an email reminding you to complete the survey. If you still have not completed the survey after receiving a reminder, you may receive a follow up phone call from a member of the research team.
- All survey responses are entered into a computer database where they are securely stored. The responses are stored in a de-identified manner, meaning that your sensitive health information cannot be linked back to you in any way.

PRECAUTIONS

- Pregnancy / Reproduction
    - The effect of Molnupiravir on an unborn child is not known and thus this drug should be avoided if you are pregnant or planning to become pregnant
    - Women taking Molnupiravir should use effective contraception for the five day course, as well as an additional four days after completion.
    - Men taking Molnupiravir should use effective contraception for the five day course, as well as an additional three months after completion.
- Breastfeeding
    - It is not known whether Molnupiravir enters breastmilk so women who are breastfeeding should not do so for the five days of treatment, as well as the following four days after completion of the course

HOW TO TAKE THE MEDICATION

- Take 4 capsules of Molnupiravir every 12 hours for five days (with or without food)

SIDE EFFECTS

- Diarrhoea / nausea
- Dizziness

DATA MANAGEMENT

- Your email address and contact number will be stored in a password protected RedCap database
- The researchers will be able to see whether you have completed your survey, and if you have not completed the survey within one week of receiving it, you will receive a reminder email. If you still have not completed the survey following the reminder, you may receive a follow up phone call from a member of the research team.
- Please note however, that when your survey is returned, it is delivered to a RedCap database in a de-identified manner, meaning the researchers cannot identify which set of responses are yours.

WITHDRAWAL

- Should you have any concerns, or wish to withdraw from the treatment, please contact a member of the research team (see the list of contacts below).

If you wish to withdraw from the study, this will not impact your ongoing care at StaffCare.

QUESTIONS AND CONTACTS

Should you have any concerns or issues whilst taking Molnupiravir, please contact

StaffCare Reception 4215 3220

Principal Investigator: Dr Jessica O'Keeffe via switchboard 4215 0000

DETAILS OF RESEARCH TEAM

Principal Investigator: Dr Jessica O'Keeffe

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Co-investigators: A/Prof Daniel O'Brien, Dr Arvind Yerramilli, Ms Janice Chaing, Dr Greg Weeks, Dr Ross Nolan, Dr Jeff Urquhart, Dr Margaret Somerville

ETHICS APPROVAL AND COMPLAINTS

This study has been approved by the HREC of Barwon Health.

If you have any questions, please contact the Principal investigator using the above details.

If you have any complaints about the conduct of the research, please contact the Manager of the Barwon Health Research Ethics, Governance & Integrity (REGI) Unit on 4215 3372.

Thank you for your interest in this study.