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Lagevrio® (molnupiravir) 200 mg Capsules for Oral Treatment of COVID-19

Dear Healthcare Professional

Lagevrio (molnupiravir) 200 mg capsules have been granted provisional consent by Medsafe, for the treatment of mild to moderate coronavirus disease (COVID-19) in adults aged 18 years and older who are at increased risk of progressing to severe COVID-19, hospitalisation and death. Molnupiravir is the prodrug of the nucleoside analogue N-hydroxycytidine (NHC).

The purpose of this letter is to inform you of important safety information regarding the usage of Lagevrio, and that Medsafe has granted approval to supply Lagevrio in the United Kingdom (UK) packaging which includes the UK Patient Information Leaflet (PIL) as a pack insert.

Safety Information Regarding Usage in Pregnancy and Lactation

Pregnancy

The use of Lagevrio is not recommended during pregnancy. Consider the need for a pregnancy test before initiating treatment in women of childbearing potential who are sexually active. Based on animal data, Lagevrio may cause fetal harm when administered to pregnant women. There are no available data on the use of Lagevrio in pregnant women to evaluate the risk of major birth defects, miscarriage or adverse maternal or fetal outcomes.

In an animal reproduction study, oral administration of molnupiravir to pregnant rats during the period of organogenesis resulted in embryofetal lethality and teratogenicity at 8 times the human NHC exposures at the recommended human dose (RHD) and reduced fetal growth at 3 times the human NHC exposure at the RHD. Oral administration of molnupiravir to rabbits during the period of organogenesis resulted in reduced fetal body weights at 18 times the human NHC exposure at the RHD.

In a pre- and post-natal developmental study in female rats, no effects were observed in offspring at exposures 2 times the human NHC exposure at the RHD.

Breast-feeding

It is unknown whether molnupiravir or any of the metabolites of molnupiravir are present in human milk, affect human milk production, or have effect on the breastfed infant. NHC was detected in the plasma of nursing pups from lactating rats administered molnupiravir.

Based on the potential for adverse reactions on the infant from Lagevrio, breastfeeding is not recommended during treatment and for 4 days after the last dose of Lagevrio.

Contraception in Individuals of Reproductive Potential

Women

Advise women of childbearing potential to use effective contraception for the duration of treatment and for 4 days after the last dose of Lagevrio.

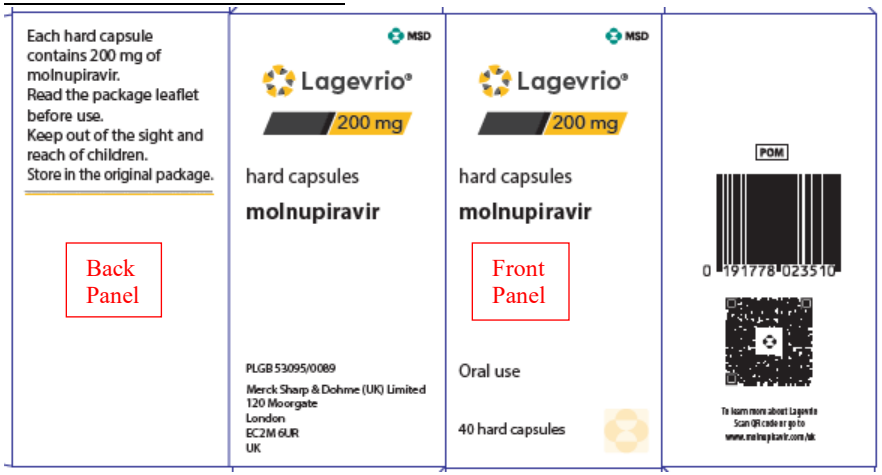
Men

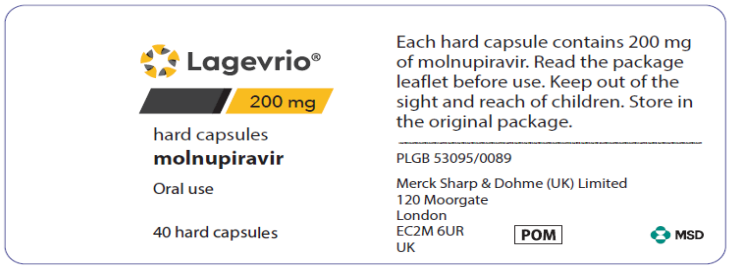
It is recommended that men who are sexually active with a partner of childbearing potential use an adequate form of contraception during and 3 months after treatment with Lagevrio.

Presentation of Lagevrio Packs to be Supplied in New Zealand

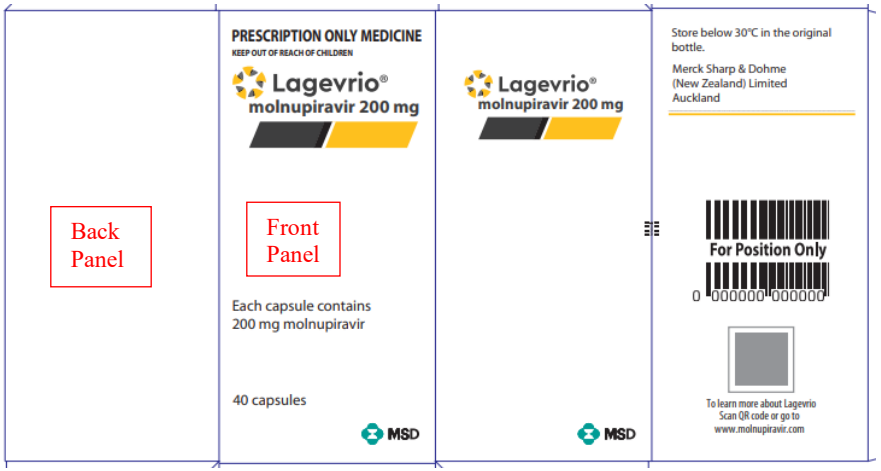
Lagevrio will be supplied to the New Zealand market in a 40-count HDPE bottle (representing a full 5-day treatment regimen of 800 mg (4x 200 mg capsules) twice daily) within an outer carton. The bottle and carton each bear a label compliant with UK regulations. Images of the UK bottle and carton labels to be supplied in New Zealand, as well as the New Zealand-specific registered labels (not supplied at this time) are outlined on the following page.

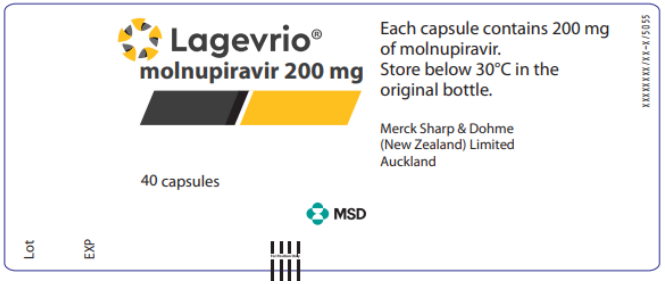
UK Carton and Bottle Label:





New Zealand Carton and Bottle Label:





UK Pack	New Zealand Pack
A black box containing the text: 'POM' (carton and bottle)	'PRESCRIPTION ONLY MEDICINE' (carton only)
'Keep out of the sight and reach of children' (carton and bottle)	'KEEP OUT OF REACH OF CHILDREN' (carton only)
UK registration number 'PLGB 53095/0089'	No registration number (carton or bottle)
'Store in the original package.'	'Store below 30°C in the original bottle.'
No space is assigned for a pharmacy dispensing label*	Space is provided for affixation of a pharmacy dispensing label on the back panel (carton only)
Address details for the UK sponsor	Address details for the New Zealand sponsor
The active ingredient quantity (200 mg) is displayed immediately beneath the brand name, and 'molnupiravir' is displayed beneath the quantity and dosage form (carton and bottle)	Active ingredient name and quantity presented as a cohesive unit beneath the brand name: 'molnupiravir 200 mg' (carton and bottle)

***The affixation of a pharmacy dispensing label should not obscure the QR code. Please see below for further information.**

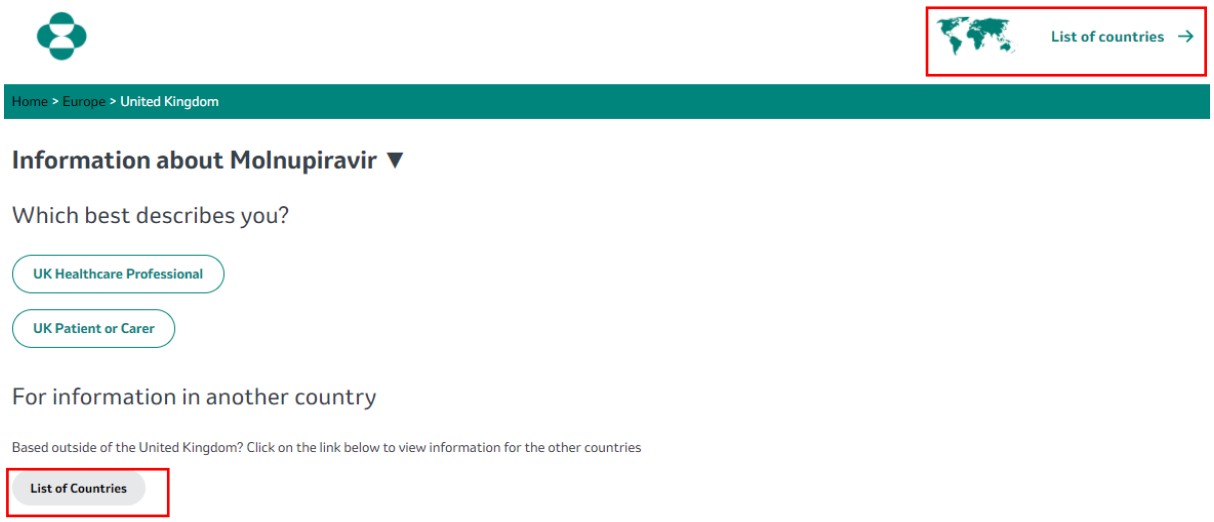
As the pack contains the UK PIL, please provide patients with the New Zealand CMI.

New Zealand DS and CMI Can be Accessed via the Following:

Option 1

1. Scan the QR code on the carton or the leaflet. This links to a landing page (shown in *Figure 1* below)
2. From the landing page, click 'List of Countries' (shown in red boxes)
3. Select 'New Zealand' to access the approved New Zealand Data Sheet and CMI.

Figure 1: Landing Page from QR Code (UK Carton/PIL)



Option 2

1. Go to the Medsafe website Product/Application Search page: https://www.medsafe.govt.nz/regulatory/dbsearch.asp
2. Search for 'Lagevrio'

Should you require any further information, please contact MSD Medical Information on 0800 500 673 or DPOC.australia@msd.com.

Yours sincerely,

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