MSD
Merck Sharp & Dohme (Australia) Pty Limited
ABN: 14 000 173 508
Level 1 - Building A, 26 Talavera Road
Macquarie Park NSW 2113
North Ryde Post Business Centre
Locked Bag 2234 North Ryde, NSW, 1670
T 02 8988 8000
F 02 8988 8001
msd-australia.com.au

Monday 4th April 2022

LAGEVRIO® (molnupiravir) Oral Treatment for COVID-19 was listed on PBS as of 1st March 2022[1-3]

Dear Valued Pharmacist,

I am writing to inform you that on the 1st March, LAGEVRIO® became the first oral COVID-19 treatment to be listed on the Pharmaceutical Benefits Scheme (PBS) as a Streamlined Authority. You can now order LAGEVRIO from your preferred wholesaler with a 'sale or return' offer that commenced on 1st March 2022 and now has been extended to the 31st August 2022, see below conditions*.

*CONDITIONS:

- You must purchase LAGEVRIO by the 31st August 2022 to receive the 'sale or return' offer from your preferred wholesaler
- 'sale or return' offer is only valid for the "return" of one pack of LAGEVRIO when stock expires at the end of January 2023

Order Requirement	Min. Qty	Supplier PDE numbers				
		API	CH2	Sigma	Symbion	CHS
LAGEVRIO® (molnupiravir) 200mg / 40 capsules	1	74221	2571481	10029790	074632	1046689
		Barrett's	National Pharmacy			
		108405	2138589			

For further information contact your local FarmaForce representative via +61 2 8239 5400 or email Charles George (Charles.george@farmaforce.com.au).

Bec Cadd
Business Manager, Infectious Diseases
Merck Sharpe & Dohme (Australia)

Richard Gooderham
Commercial Trade Channel Manager
Merck Sharpe & Dohme (Australia)

If you wish to opt out from future messages, please notify the Privacy Officer at Locked Bag 2234, North Ryde, NSW 1670, T +61 2 8988 8000, E msd_privacy_office@msd.com. If you require further information on MSD's privacy policy please visit https://www.msdprivacy.com/au/en/index.html .

Please review the Product Information available at www.msdinfo.com.au/lagevriopi.

PBS Information: LAGEVRIO® is listed on the PBS (Streamlined Authority).
Please refer to www.pbs.gov.au for eligibility criteria.

▼ This medicine is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

LAGEVRIO® SELECTED SAFETY INFORMATION[2]

INDICATION:

LAGEVRIO® (molnupiravir) has provisional approval for the treatment of adults with COVID-19 who do not require initiation of oxygen due to COVID-19 and who are at increased risk for hospitalisation or death. The decision to approve this indication was based on efficacy and safety data from a Phase 3 trial. Continued approval of this indication depends on additional data.

PRECAUTIONS:

Pregnancy and contraception: Pregnancy Category D: The use of LAGEVRIO® is not recommended during pregnancy. In women of childbearing potential, health care providers should discuss the chance that they may be pregnant and consider the need for a pregnancy test. Advise women of childbearing potential to use effective contraception for the duration of treatment and for 4 days after the last dose of LAGEVRIO®. Sexually active men with a partner of childbearing potential should use contraception during and for 3 months after treatment. Based on animal data, LAGEVRIO® may cause fetal harm when administered to pregnant women.

Breastfeeding: 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®.

Paediatric patients: Use in children is not recommended.

Use in elderly: No dose adjustment of LAGEVRIO® is recommended based on age. In the MOVe-OUT study there was no difference in the safety and tolerability between patients >65 years of age and younger who were treated with LAGEVRIO®.

INTERACTIONS:

No drug interactions have been identified based on the limited available data.

CONTRAINDICATIONS:

Hypersensitivity to the active substance or any of the excipients.

ADVERSE REACTIONS:

The most common adverse reactions occurring in ≥1% of subjects in the LAGEVRIO® treatment group in the Phase 3 double-blind MOVe-OUT study were diarrhoea (2% versus placebo at 2%), nausea (1% versus placebo at 1%), and dizziness (1% versus placebo at 1%) all of which were Grade 1 (mild) or Grade 2 (moderate). Serious adverse events occurred in 7% of subjects receiving LAGEVRIO® and 10% receiving placebo; most serious adverse events were COVID-19 related. Adverse events leading to death occurred in <1% of the subjects receiving LAGEVRIO® and 2% of subjects receiving placebo.

References: 1. Australian Government Department of Health, Pharmaceutical Benefits Scheme (PBS). Available at www.pbs.gov.au accessed 1 March 2022. 2. LAGEVRIO® Approved Product Information. 20 January 2022. 3. MSD, Data on File.