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MSD

Lagevrio® molnupiravir

1st February 2022

Dear Health Care Provider,

RE: LAGEVRIO® (molnupiravir) is now registered and included on the ARTG.

MSD is proud to announce that 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[1]. The decision to approve this indication is based on the efficacy and safety data from a Phase 3 trial. Continued approval of this indication depends on additional data[1].

MSD is working hard with the Australian Government to help make LAGEVRIO® available in Australia. MSD will be in a position to provide further information about how LAGEVRIO® will be accessed by prescribing clinicians once confirmed by the Australian Government.

In the meantime, please see below for further information on LAGEVRIO®.

To stay up to date on the availability of LAGEVRIO®, as well as on-going medical education and clinical resources, please register at the myMSD Portal at www.mymsd.com.au

LAGEVRIO® oral treatment to be initiated within 5 days of symptom onset[1]. Key features include:

Contains full course in one bottle[1]
Dosing: 4 x 200mg capsules every 12 hours for 5 days[1]

Can be taken with or without food[1]

No drug interactions identified based on the limited available data[1]
NHC (n-hydroxycytidine) is not a substrate of major drug metabolising enzymes or transporters. Neither LAGEVRIO® nor NHC are inhibitors or inducers of major drug metabolising enzyme or transporters[1].

No dose adjustments required for elderly patients or those with hepatic or renal impairment[1]

Please review full Product Information before prescribing, available at msdinfo.com.au/lagevriopi or via QR code below

▼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.

Selected Safety Information LAGEVRIO® (molnupiravir) Capsules[1]

PRECAUTIONS: 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.

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.

Kind regards,
MSD Infectious Disease Team

ARTG = Australian Register of Therapeutic Goods

References: 1. LAGEVRIO® Approved Product Information. 18 January 2022.