Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA provisionally approves two oral COVID-19 treatments, molnupiravir (LAGEVRIO) and nirmatrelvir + ritonavir (PAXLOVID)

The TGA has granted provisional approval to two oral COVID-19 treatments.

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The Therapeutic Goods Administration (TGA) has granted provisional approval to two oral COVID-19 treatments:

- PAXLOVID (nirmatrelvir + ritonavir) - Pfizer Australia Pty Ltd
- LAGEVRIO (molnupiravir) - Merck Sharp & Dohme (Australia) Pty Ltd

Both of these products, which are the first oral treatments to be approved for COVID-19 in Australia, have been granted provisional approval for the treatment of adults with COVID-19 who do not require initiation of oxygen and who are at increased risk of progression to hospitalisation or death. Neither product is intended to be used as a substitute for vaccination against COVID-19.

Either medicine should be administered as soon as possible after diagnosis of COVID-19 and within 5 days of the start of symptoms. LAGEVRIO is available as capsules, while PAXLOVID comprise separate tablets of nirmatrelvir and ritonavir. In both cases, the medicines are taken twice a day for 5 days.

Molnupiravir (LAGEVRIO) works by inhibiting replication of the SARS-CoV-2 virus. The use of LAGEVRIO is not recommended in pregnancy and breastfeeding. It is recommended that sexually active women of childbearing potential use contraception and men also use contraception during and 3 months after treatment with LAGEVRIO.

Regarding PAXLOVID, the nirmatrelvir component blocks the activity of a protease enzyme that

the coronavirus needs in order to replicate. Nirmatrelvir is administered in combination with low-dose ritonavir to maintain plasma levels of nirmatrelvir for the duration of the treatment.

The use of PAXLOVID is also not recommended in pregnancy or breastfeeding, and in women of childbearing potential. It is recommended that sexually active women of childbearing potential use contraception. PAXLOVID must also not be used with a number of other commonly used medicines, either because for some medicines this may lead to potentially harmful increases in their blood levels, or in the case of some other medicines they may reduce the activity of PAXLOVID. The list of medicines that must not be used with PAXLOVID is included in the Product Information (/node/288206#pi). PAXLOVID must also not be used in patients with severely reduced kidney or liver function.

Both PAXLOVID and LAGEVRIO have received conditional marketing authorisation from the UK Medicines and Healthcare products Regulatory Agency and emergency use authorization from the US Food and Drug Administration, and PAXLOVID was authorised by Health Canada earlier this week.

Provisional approval of these treatments in Australia is subject to certain strict conditions, such as the requirement for the sponsors to continue providing information to the TGA on longer-term efficacy and safety from ongoing clinical trials and post-market assessment.

Australians can be confident that the TGA's review process of both medicines was rigorous. The decision to provisionally approve the medicine was informed by expert advice from the Advisory Committee on Medicines (https://www.tga.gov.au/node/285047) (ACM), an independent committee with expertise in scientific, medical and clinical fields including consumer representation.

The Australian Government has secured access to 500,000 treatment courses of PAXLOVID and 300,000 courses of LAGEVRIO for supply during 2022, with the first deliveries of both medicines anticipated in the coming weeks.

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