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NEWS

What GPs need to know about the new COVID antivirals

Matt Woodley

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Important information has been released on the drugs' specific indications and contraindications, as well as how global supply issues will impact distribution.





Initial supplies of COVID-19 antiviral oral treatments will be available through the National Medical Stockpile.

Nirmatrelvir in combination with ritanovir (sold as Paxlovid) and molnupiravir (sold as Lagevrio) will soon be available in Australia for the treatment of COVID-19.

However, according to the Department of Health (DoH), initial supplies will be limited due to international supply chain constraints and will therefore be prioritised to highest clinical need.

'The initial supplies of COVID-19 antiviral oral treatments ... will be made available through the National Medical Stockpile [NMS], as occurs with the current treatments, to ensure the most vulnerable Australians can access them as soon as possible,' a spokesperson told *newsGP*.

'In addition, this includes delivering treatments of Lagevrio directly to residential aged care facilities [RACFs], as these are oral treatments designed to be taken by those not in hospital.

'Additional supplies [can] be requested from the National Medical Stockpile as required.'

The DoH also indicated that the medications will likely be made available through the Pharmaceutical Benefits Scheme (PBS) but did not provide a timeline as to when this would occur.

'By law medicines can only be listed on the PBS following a positive recommendation from the Pharmaceutical Benefits Advisory Committee [PBAC],' the spokesperson said.

'The [Federal] Government is working with the manufacturers of these treatment to seek PBS listing, allowing broad-based community prescribing through general practice and dispensing under arrangements that all Australians are familiar with as soon as possible.'

Aside from RACFs, the antivirals will also be made available to rural and remote communities, particularly in regions with high Aboriginal and Torres Strait Islander populations, via 'state and territory distribution arrangements'.

Deputy Chief Medical Officer Professor Michael Kidd will host a webinar for GPs and other primary care providers at 11.30 (AEDT) on Monday 7 February, alongside RACGP President Dr Karen Price and ACRRM President Dr Sarah Chalmers, which will feature more details on the new oral treatments.

The link can be watched live but is also being recorded.

Lagevrio

Consumer Medical Information and Product Information.

The DoH declined to clarify how many doses of Lagevrio will be available initially, nor when shipments are anticipated, but once they have arrived the drugs will be placed directly into RACFs before being listed on the PBS.

Indications

The National COVID-19 Clinical Evidence Taskforce has said Lagevrio should be prescribed:

- within five days of symptom onset in adults with COVID-19 who do not require oxygen; and
- who are unvaccinated and have one or more risk factors for disease progression; or
- who are over 60 or have chronic health conditions; or
- who are immunosuppressed or not immunocompetent regardless of vaccination status; or
- who have received one or two doses of vaccine and are at high risk of severe disease on the basis of age and multiple risk factors; and
- where other treatments (such as sotrovimab or nirmatrelvir plus ritonavir) are not suitable or available.

Dosage

Four capsules every 12 hours (for example, at 8 am and at 8 pm),

for five days. Lagevrio can be taken with or without food, but patients should not open, break, or crush the capsules.

Contraindications

Whilst not considered a high risk in RACFs, it is especially important to note that Lagevrio is not recommended in pregnancy.

Patients must use effective birth control while taking Lagevrio and for four days after stopping if there is a possibility of them getting pregnant.

Male patients who are sexually active with a partner who could become pregnant should use a reliable method of contraception during treatment and for three months after their last dose.

Likewise, breastfeeding is not recommended during treatment and for four days after the last dose of Lagevrio.

If there are contraindications to Lagevrio then Paxlovid may be considered, however; there are also many significant drug interactions to note with Paxlovid and GPs must make a special application to state and territory authorities to gain access.

There are no known drug interactions identified with Lagevrio based on the limited data that is currently available. The most common side effects are diarrhoea, nausea and dizziness

Paxlovid

Consumer Medical Information and Product Information.

Paxlovid is a medicine that has two different tablets; one containing the active ingredient, nirmatrelvir (pink oval tablet) and the other containing the active ingredient, ritonavir, (white oval tablet). They must be taken as instructed in order to be effective against COVID-19.

It is indicated for patients with one or more risk factors, including people who:

- are aged over 60
- have diabetes
- are obese
- have cardiovascular disease
- have hypertension
- have chronic lung disease.

Contraindications

There are a number of potential complex and serious drug—drug interactions that can result in severe or life—threatening side effects, or reduce the drugs' effectiveness against COVID—19.

Paxlovid is contraindicated with the following drugs:

- Alfuzosin, medicine to treat an enlarged prostate
- Ranolazine, medicine to treat chronic chest pain (angina)
- Pethidine, and Piroxicam, medicine to relieve pain
- **Amiodarone**, and **Flecainide**, medicine to correct or change heart rhythm or lower blood pressure
- Neratinib, Apalutamide, and Venetoclax, medicine to treat certain types of cancers
- Colchicine, medicine to treat gout
- **Lurasidone**, and **Clozapine** medicine to treat certain mental and emotional health conditions
- Ergometrine, medicine to stop excessive bleeding that may occur following childbirth, miscarriage or termination of pregnancy
- Simvastatin, medicine to lower blood cholesterol
- Sildenafil, Avanafil, Vardenafil, and Tadalafil medicines for erectile dysfunction;
 - **Sildenafil**, medicine to treat high blood pressure in the lungs;
 - Tadalafil, medicine for urinary difficulties due to an enlarged prostate
- **Diazepam**, medicine to assist anxiety, agitation or muscle spasms, spasticity
- Carbamazepine, Phenobarbital, Phenytoin medicine to treat epilepsy to prevent convulsions, fits
- **Rifampicin**, medicine to treat tuberculosis
- St. John's Wort (hypericum perforatum), a herbal remedy used for depression and anxiety

In addition, the following drugs have the potential for complex and serious drug—drug interactions that can result in severe or life—threatening side effects, or reduce the drugs' effectiveness against COVID—19:

- Fentanyl, and Methadone, medicine to treat pain
- Digoxin, medicine to treat certain heart conditions
- Lidocaine, medicine to correct or change heart rhythm
- Atinib, Abemaciclib, Ceritinib, Dasatinib, Nilotinib, Encorafenib, Ibrutinib, Vinblastine, and Vincristine, medicine to treat certain types of cancer
- **Haloperidol, Risperidone**, and **Quetiapine**, medicine to treat certain mental and emotional conditions
- **Rivaroxaban**, and **Warfarin**, medicine to treat or prevent blood clots
- Lamotrigine, medicine to prevent or treat convulsions, fits
- Amitriptyline, Fluoxetine, Imipramine, Nortriptyline, Paroxetine, and Sertraline, medicine to treat depression
- Loratadine, medicine to treat allergies
- Atovaquone, Clarithromycin, Erythromycin, Rifabutin, Ketoconazole, Isavuconazonium Sulfate, Voriconazole, and Itraconazole, medicine to treat infections
- Atazanavir, Darunavir, Efavirenz, Fosamprenavir,
 Maraviroc, Nevirapine, Saquinavir, Tipranavir,
 Raltegravir, Zidovudine,
 Bictegravir/Emtricitabine/Tenofovir, medicine to treat
 HIV
- Glecaprevir/Pibrentasviror,
 Sofosbuvir/Velpatasvir/Voxilaprevir, medicine to treat hepatitis C
- Salmeterol, medicine to treat severe lung conditions, including asthma and chronic obstructive pulmonary disease (COPD)
- Amlodipine, Diltiazem, Felodipine, and Nifedipine, medicine to treat angina or lower blood pressure
- **Bosentan**, and **Riociguat**, medicine to treat high blood pressure in the lungs
- **Ethinylestradiol**, medicine to treat hormone deficiency or for contraception
- Ciclosporin, Everolimus, Tacrolimus, and Sirolimus,

medicine to suppress the immune system

- Atorvastatin, and Rosuvastatin, medicine to lower cholesterol
- Alprazolam, Midazolam, and Zolpidem, medicine to help you sleep
- Bupropion, a medicine to assist in giving up smoking
- Betamethasone, Budesonide, Dexamethasone,
 Prednisone, Methylprednisolone, and Triamcinolone,
 medicine to treat various inflammatory conditions

The combination treatment should also not be prescribed to patients who are allergic to nirmatrelvir and/or ritonavir, nor any of the ingredients listed in the CMI.

There is no available clinical data on Paxlovid in pregnancy or with breast feeding. In animal studies, reduced fetal body weights were seen at around 10 times the nirmatrelvir exposure seen in humans with the authorised dose; no other adverse developmental effects were seen.

Paxlovid is not recommended for patients with severe liver or kidney disease, but can be prescribed at a lower dose for patients with moderate kidney disease.

Dosage

The standard dose of Paxlovid is two 150 mg tablets of nirmatrelvir, together with one 100 mg tablet of ritonavir. Patients with reduced kidney function can be prescribed a lower dose of one 150 mg tablet of nirmatrelvir with one 100 mg tablet of ritonavir.

Both tablets must be taken together with or without food. The tablets should be swallowed whole and not chewed, broken, or crushed.

Paxlovid dose
300 mg nirmatrelvir with 100
mg ritonavir, taken twice daily
for five days

≥30 to ≥60 mL/min (moderate renal impairment)	150 mg nirmatrelvir with 100 mg ritonavir, taken twice daily for five days
<30mL/min (severe renal impairment)	Paxlovid is not recommended (the appropriate dose has not been determined)

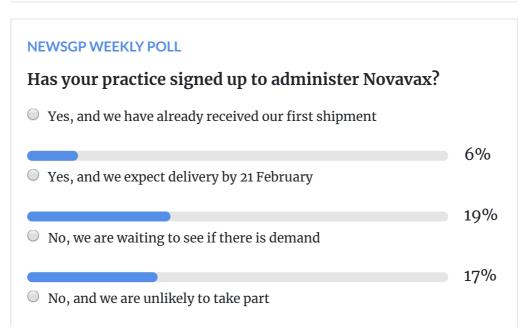
^{*}eGFR = estimated glomerular filtration rate based on the Chronic Kidney Disease-Epidemiology Collaboration (CKD-EPI) formula

Pronunciation

Mol-nu-pir-a-veer or La-gev-rio Nirma-trel-vir and rit-on-a-vir or Pax-Lovid

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Dr Daniel Peter Ewald 8/02/2022 12:45:54 PM

The piece on use of the new antivirals has misrepresented the recommendations from the Covid evidence taskforce. E.g for molnupiravir; There is only consensus recommendation for use in those partially vaccinated if they are at very high clinical risk and other treatment options are not available. - Sorry but this is poor health journalism.

Dr Ragupathy Renganathan 9/02/2022 10:13:20 AM

Considering the contraindications with the "LONG LIST OF DRUGS" there appears a very narrow window to use PAXLOVID.

It means perhaps in the" inclusion criteria" - a male of less than 45 yrs not using Viagra and of sound health is only one fit for Paxlovid

Dr Sandra 12/02/2022 11:24:03 AM

So molnupiravir is the new (expensive) drug Merck sidelined it's old (cheap) drug ivermectin for to sell for Covid treatment.



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