Use of nirmatrelvir and ritonavir (Paxlovid™) for the treatment of COVID-19 in adults

This information leaflet includes important information about the medicine nirmatrelvir and ritonavir (Paxlovid™) when used to treat COVID-19.

What is the potential benefit of Paxlovid[™] for COVID-19?

Paxlovid[™] belongs to a group of medicines called antivirals. Paxlovid[™] works by targeting the virus that causes COVID-19 and preventing it from infecting healthy cells. Paxlovid[™] has been shown to reduce the risk of severe infection and hospitalisation in those with mild to moderate COVID-19 with one or more risk factors.

Paxlovid[™] has been provisionally approved in Australia to treat COVID-19 in people who do not need oxygen but are at risk of severe illness and hospitalisation. This medicine is not intended to be a replacement for vaccination against COVID-19.

Paxlovid[™] contains 2 medicines, nirmatrelvir and ritonavir.

What should be considered when using PAXLOVID™ in COVID-19?

Paxlovid[™] is a new medicine and provisionally (not fully) registered to treat COVID-19 in Australia, information about how well it works and how safe it is, is being collected. It is important that patients and their carers understand when and why Paxlovid[™] may be useful. Your doctors will provide more information about how well it works and how safe it is in your condition.

The use of Paxlovid[™] for COVID-19 is new and it is important you provide your formal consent before Paxlovid[™] treatment begins. You can always change your mind about treatment with Paxlovid[™] and withdraw consent at any time.

What should your doctor know before Paxlovid™ is used in COVID-19?

Your doctor should know about:

- · any medical conditions you have
- any kidney or liver problem
- · previous allergic reactions to any medicine
- all medicines including over-the-counter and complementary medicines e.g. vitamins, minerals, herbal or naturopathic medicines that you are taking or have recently taken
- the possibility of pregnancy or plans for pregnancy
- · if you are breastfeeding or plan to breastfeed

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How is Paxlovid[™] taken? (Pharmacist to tick relevant regimen)

□ **STANDARD DOSE** – Take 2 pink tablets of nirmatrelvir with 1 white tablet of ritonavir by mouth every 12 hours at the same time each morning and evening. Use this calendar to help keep track of your doses. Note, if your first dose was in the evening on Day 1 your last dose may be in the morning on Day 6.

	Day 1	Day 2	Day 3	Day 4	Day 5
	Date:	Date:	Date:	Date:	Date:
Morning 2 x nirmatrelvir 1 x ritonavir Time:					
Evening 2 x nirmatrelvir 1 x ritonavir Time:					

□ REDUCED DOSE (if you have reduced kidney function) – Take 1 pink tablet of nirmatrelvir with 1 white tablet of ritonavir by mouth every 12 hours at the same time each morning and evening. The pharmacy will modify the packaging of the medication to ensure you have the correct number of tablets for your dose. Use this calendar to help keep track of your doses. Note, if your first dose was in the evening on Day 1 your last dose may be in the morning on Day 6.

	Day 1	Day 2	Day 3	Day 4	Day 5
	Date:	Date:	Date:	Date:	Date:
Morning 1 x nirmatrelvir 1 x ritonavir Time:					
Evening 1 x nirmatrelvir 1 x ritonavir Time:					

- Take Paxlovid[™] with or without food.
- Take Paxlovid[™] for 5 days. Do not stop taking Paxlovid[™] without talking to your doctor first, even if you feel better.
- Paxlovid[™] must be swallowed whole. Do not chew, break, or crush the tablets. If you cannot swallow tablets whole, please inform your doctor or pharmacist.
- Paxlovid[™] is most effective when commenced as soon as possible after a diagnosis of COVID-19 has been made and within five days of symptom onset.

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What to do if you miss a dose

- If it has been less than 8 hours since the missed dose, take it as soon as you remember.
- If it has been more than 8 hours since the missed dose, skip the missed dose and take your dose at the next scheduled time.
- Do not double the dose of PaxlovidTM to make up for a missed dose.

If you take too much Paxlovid™

If you think you have taken too much PaxlovidTM, you may need urgent medical attention. You should immediately:

- Contact your doctor, OR
- Phone the Poisons Information Centre (by calling 13 11 26), OR
- · Go to the Emergency Department of your nearest hospital

You should do this even if there are no signs of discomfort or poisoning.

Are there special precautions with Paxlovid™ treatment?

Reduced kidney or liver function – tell your doctor if you have kidney or liver problems, as how much $Paxlovid^{TM}$ you take may need to be adjusted. $Paxlovid^{TM}$ may not be suitable in people with severe kidney or liver disease.

<u>Use with other medicines</u> – PaxlovidTM may increase or decrease the effects of multiple medicines. It is important that your doctor and other health professionals (such as the pharmacist or nurse) are informed about all medications normally taken or planned. This includes over-the-counter and complementary medicines, e.g. vitamins, minerals, herbal or naturopathic medicines that you are taking or have recently taken. The doctor and pharmacist will check for potential medicine interactions before PaxlovidTM is started and when it is stopped.

Do not take PaxlovidTM if you are taking any of the following medicines and inform your healthcare provider immediately. Taking PaxlovidTM with any of these medicines may cause serious or life-threatening side effects or affect how well PaxlovidTM works:

Specific medicines	Medicines used for
Alfuzocin	To treat enlarged prostate
Ranolazine	To treat chronic chest pain (angina)
Amiodarone and flecainide	To correct heart rhythm
Neratinib, apalutamide, venetoclax, vincristine and vinblastine	To treat certain types of cancer
Colchicine	To treat gout
Lurasidone, clozapine	To treat certain mental health conditions

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Information for patients, family and carers Use of nirmatrelvir and ritonavir (Paxlovid™) for the treatment of COVID-19 in adults

Ergometrine	To stop excessive bleeding	
	that may occur following childbirth, miscarriage	
	or termination of pregnancy	
Simvastatin	To lower blood cholesterol level	
Sildenafil, avanafil, vardenafil, tadalafil	To treat erectile dysfunction	
Diazepam	To treat anxiety, agitation or muscle spasms, spasticity	
Carbamazepine, phenobarbital, phenytoin	To prevent convulsions and fits	
Rifampicin	To treat tuberculosis	
St. John's Wort (Hypericum perforatum)	Herbal remedy used for depression and anxiety	

If you are taking any of the following medicines, you must contact your healthcare provider before starting Paxlovid[™]. Taking Paxlovid[™] with any of these medicines may require additional monitoring by your healthcare provider:

Specific medicines	Medicines used for
Fentanyl, methadone	To treat pain
Digoxin	To treat certain heart conditions
Lidocaine	To correct or change heart rhythm
Afatinib, abemaciclib, ceritinib, dasatinib, nilotinib, encorafenib, ibrutinib, vinblastine, vincristine	To treat certain types of cancer
Haloperidol, risperidone, quetiapine	To treat certain mental and emotional conditions
Rivaroxaban, warfarin	To treat or prevent blood clots
Lamotrigine	To prevent or treat convulsions, fits
Amitriptyline, fluoxetine, imipramine, nortriptyline, paroxetine, sertraline	To treat depression
Loratadine	To treat allergies
Atovaquone, clarithromycin, erythromycin, rifabutin, ketoconazole, isavuconazonium sulfate, voriconazole, itraconazole	To treat infections

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Atazanavir, darunavir, efavirenz, fosamprenavir, maraviroc, nevirapine, saquinavir, tipranavir, raltegravir, zidovudine, bictegravir/ emtricitabine/ tenofovir	To treat HIV
Glecaprevir/pibrentasviror, sofosbuvir/velpatasvir/voxilaprevir	To treat hepatitis C
Salmeterol	To treat severe lung conditions, including asthma and chronic obstructive pulmonary disease (COPD)
Amlodipine, diltiazem, felodipine, nifedipine	To treat angina or lower blood pressure
Bosentan, riociguat	To treat high blood pressure in the lungs
Ethinylestradiol	To treat hormone deficiency or for contraception
Ciclosporin, everolimus, tacrolimus, sirolimus	To suppress the immune system
Atorvastatin, rosuvastatin	To lower cholesterol
Alprazolam, midazolam, zolpidem	To help you sleep
Bupropion	To assist in giving up smoking
Betamethasone, budesonide, dexamethasone, prednisone, methylprednisolone, triamcinolone	To treat various inflammatory conditions including allergies, asthma or eczema

Fertility, pregnancy and breastfeeding

For women who are pregnant:

 As the effect of Paxlovid[™] on fertility is unknown, it is not recommended that Paxlovid[™] is taken during pregnancy. Tell your doctor if you are pregnant or plan to become pregnant.

For women who can become pregnant:

- Your doctor may do a pregnancy test to see if you are pregnant before starting treatment with Paxlovid™.
- A reliable form of contraception should be used during treatment with Paxlovid[™] and for 7 days after the last dose of Paxlovid[™]. If you are taking a combined hormonal contraceptive ("the pill"), please inform your doctor as Paxlovid[™] may affect how well your hormonal contraceptive works. Consult your doctor or pharmacist about reliable contraception methods.

For women who are breastfeeding:

You should not breastfeed your baby while taking Paxlovid[™]. If you are breastfeeding or planning to breastfeed, discuss options and your specific situation with your doctor before taking Paxlovid[™].

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What are the side effects of Paxlovid[™]?

All medicines have side effects. Sometimes they are serious, but most of the time they are not, and many of them disappear with time or when treatment is stopped. Medical treatment may be needed with some side effects. Side effects may not be experienced. Some side effects that might be experienced during treatment with PaxlovidTM are shown below. Other, currently unknown, side effects with PaxlovidTM may occur when it is used in people with COVID-19. Because PaxlovidTM is a new medicine, patients who receive it will be monitored closely.

Possible side effects of Paxlovid™	What to do			
Side effects which may appear after receiving Paxlovid™	Immediately tell your doctor if these			
may include:	symptoms occur.			
Vomiting				
Diarrhoea				
Headache				
High blood pressure				
Aching muscle, muscle tenderness or weakness				
not due to exercise				
 Changes in taste or metallic taste in the mouth 				
Loss of appetite				
 Yellowing of the skin and whites of eyes 				
Dark-coloured urine				
Pale-coloured stools				
Itchy skin				
Abdominal Pain				
Allergic reactions, symptoms may include:	Contact 000 or go straight to the			
Shortness of breath	Emergency Department at your nearest			
Swelling of the face, lips, tongue or any parts of the	hospital.			
body				
Severe skin rash, itching, hives				

Please note: This is not a complete list of all side effects. Because Paxlovid™ is a new medicine, it is important to report side effects to the doctor directly and/or to the Therapeutic Goods Administration at www.tga.gov.au/reporting-problems

If you are experiencing any side effects, including any of the ones listed above or are feeling unwell, please call the healthcare worker on the phone number below for advice.

Name of healthcare worker to call:	
Telephone number:	

For more information about PaxlovidTM.

- refer to the Australian Consumer Medicines Information
- call the NPS Medicines Line 1300 633 424

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