PAXLOVID[™]

nirmatrelvir and ritonavir

Consumer Medicine Information

This medicine has **provisional approval** in Australia to treat COVID-19 in adults who are at increased risk of progression to hospitalisation or death. This approval has been granted on the basis of short-term efficacy and safety data. Evidence of efficacy and safety from ongoing trials continues to be gathered and assessed.

This leaflet provides important information about taking PAXLOVID. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking PAXLOVID.

Where to find information in this leaflet:

- 1. Why am I taking PAXLOVID?
- 2. What should I know before I take PAXLOVID?
- 3. What if I am taking other medicines?
- 4. How do I take PAXLOVID?
- 5. What should I know while taking PAXLOVID?
- 6. Are there any side effects?
- 7. Product details

1. Why am I taking PAXLOVID?

PAXLOVID contains the active ingredients nirmatrelvir and ritonavir. PAXLOVID is used to treat COVID-19 in adults who are at increased risk of progression to hospitalisation or death.

2. What should I know before I take PAXLOVID?

Warnings

Do not take PAXLOVID if:

- You are allergic to nirmatrelvir and/or ritonavir or any of the ingredients listed at the end of this leaflet.
- Do not take PAXLOVID if you are taking any of these medicines. Taking PAXLOVID with these medicines may cause serious or life-threatening side effects or affect how PAXLOVID work:
 - alfuzosin, medicine to treat an enlarged prostate
 - ranolazine, medicine to treat chronic chest pain (angina)
 - pethidine, piroxicam medicine to relieve pain
 - amiodarone, flecainide medicine to correct or change heart rhythm or lower blood pressure
 - neratinib, apalutamide, venetoclax, medicine to treat
 - certain types of cancers - colchicine, medicine to treat
 - gout
 - lurasidone, 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, 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, spasicity
- 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.

Check with your doctor if you:

- Have or have had problems with your liver.
- Have or have had problems with your kidneys.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Tell your doctor if you become pregnant or plan to become pregnant, breastfeeding or plan to breast feed. You should not breastfeed your baby while taking PAXLOVID.