## 's COVID-19 Preparedness Plan



PAXLOVID has not been approved, but has been authorized for emergency use by FDA under an EUA, for the treatment of mild-to-moderate COVID-19 in pediatric patients 12 years of age and older weighing at least 88 pounds (40 kg) who are at high risk for progression to severe COVID-19, including hospitalization or death.

The emergency use of PAXLOVID is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.



# **Snapshot of Patient's Health**

Filling out this form now can help start a productive conversation with a healthcare professional if you notice COVID-19 symptoms in children over 12. The risk of becoming very sick from COVID-19 may be increased in people

COVID-19 may be increased in people who are not vaccinated or up to date with vaccinations. Those who have difficulty accessing healthcare because of where they live, work, or due to their race or ethnicity are also at increased risk.

Scan the QR code for the latest information on high-risk factors from the Centers for Disease Control and Prevention (CDC)\*



\*This link will take you to a website that is owned and operated by the CDC. Pfizer is not responsible for the content or services of this site.  $\bigcirc$ 

Cancer

Cerebrovascular disease or stroke

Chronic kidney problems

Chronic liver disease

Chronic lung disease, such as chronic obstructive pulmonary disease (COPD)—including emphysema and chronic bronchitis—and moderate-to-severe asthma

Cystic fibrosis

Dementia or other neurological conditions

Diabetes (type 1 or type 2)

Disabilities (including attention-deficit/hyperactivity disorder [ADHD], learning disabilities, and intellectual/developmental disabilities)

Heart conditions

Human immunodeficiency virus (HIV) infection

Immunocompromised condition or weakened immune system

Mental health conditions (schizophrenia spectrum disorders and mood disorders, including depression)

Obese or overweight

Physically inactive

Pregnant or recently pregnant

Sickle cell disease or thalassemia

Solid organ or blood stem cell transplant

Substance use disorders (such as alcohol, opioid, or cocaine use disorder)

Tuberculosis

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<sup>†</sup>This list does not include all possible conditions that may put someone at high risk of developing severe illness from COVID-19. If there are questions about a condition not included on this list, talk to a healthcare professional.

Continue to the next page

### **AUTHORIZED USE**

The FDA has authorized the emergency use of PAXLOVID for the treatment of mild-to-moderate COVID-19 in children 12 years of age and older weighing at least 88 pounds (40 kg) who are at high risk for progression to severe COVID-19, including hospitalization or death, under an EUA.

PAXLOVID is not FDA-approved or available under EUA for use in children younger than 12 years of age or weighing less than 88 pounds (40 kg). There is limited information about the safety and effectiveness of using PAXLOVID in these patients.

### **SELECTED SAFETY INFORMATION**

**Significant Drug Interactions.** PAXLOVID can interact with other medicines, causing severe or life-threatening side effects or death. It is important to know the medicines that should not be taken with PAXLOVID. See Important Safety Information on the following page to learn more.

Please see Important Safety Information throughout this resource and <u>Fact Sheets for Healthcare Providers</u> and for <u>Patients</u>, <u>Parents</u>, and <u>Caregivers</u> at <u>PAXLOVIDinformation.com</u>.

### **Medication Tracker**

It is very important to tell healthcare professionals about all the medicines being taken. Keep a list of the medicines being taken on the lines below, including prescription and over-the-counter medicines, vitamins, herbal supplements, and contraceptives. If unsure about medications being taken, speak with a pharmacist or healthcare professional for this information.

Kidney problei	ms?	
Note latest eGF	R* here:	
*Estimated glomerular	filtration rate.	
	o medications?	

Medications	Dose/Dosage	Medications	Dose/Dosage	

## **Next Steps if COVID-19 Symptoms Develop**

Keep this information somewhere to easily reference in case someone in your care develops COVID-19 symptoms and is at high risk for progression to severe COVID-19. This information may be helpful for a doctor or a healthcare professional from an urgent care, pharmacy, COVID-19 Test to Treat location, or telemedicine appointment to **determine if PAXLOVID is appropriate**.

If COVID-19 symptoms develop, talk to a healthcare professional about PAXLOVID. PAXLOVID can be taken at home and **must be started within the first 5 days of symptoms**, so it's important to act fast at the first signs of COVID-19.

Scan the QR code to find your nearest Test to Treat provider<sup>†</sup>



For more information about PAXLOVID, scan the QR code or visit PAXLOVIDinformation.com



†This link will take you to a website that is owned and operated by the U.S. Department of Health and Human Services. Pfizer is not responsible for the content or services of this site.





#### **IMPORTANT SAFETY INFORMATION**

**Significant Drug Interactions.** PAXLOVID can interact with other medicines, causing severe or life-threatening side effects or death. **Do not take PAXLOVID** if you are taking any of the following medicines:

- alfuzosin
- amiodarone
- apalutamide
- carbamazepine
- colchicine
- dihydroergotamine
- dronedarone
- eletriptan
- eplerenone
- ergotaminefinerenone

- flecainide
- flibanserin
- ivabradine
- lomitapide
- lovastatin
- lumacaftor/ivacaftor
- Iurasidone
- methylergonovine
- midazolam (oral)naloxegol
- naioxegoi
- phenobarbital

- phenytoin
- pimozide
- primidone
- propafenone
- quinidine
- ranolazinerifampin
- rifapentine
- St. John's Wort (hypericum perforatum)
- sildenafil (Revatio®) for pulmonary arterial hypertension
- silodosin
- simvastatin
- tolvaptan
- tolvaptar
- triazolamubrogepant
- voclosporin

Please see Important Safety Information throughout this resource and <u>Fact Sheets for Healthcare Providers</u> and for <u>Patients, Parents, and Caregivers</u> at <u>PAXLOVIDinformation.com</u>.

#### **IMPORTANT SAFETY INFORMATION (CONT'D)**

These are not the only medicines that may cause serious or life-threatening side effects if taken with PAXLOVID. PAXLOVID may increase or decrease the levels of other medicines. It is very important to tell your healthcare professional about all the medicines you are taking, including prescription and over-the-counter medicines, vitamins, and herbal supplements, because additional laboratory tests or changes in the dose of your other medicines may be necessary during treatment with PAXLOVID. Your healthcare professional may also tell you about specific symptoms to watch out for that may indicate that you need to stop or decrease the dose of some of your other medicines. Do not start taking a new medicine without telling your healthcare professional.

### Before taking PAXLOVID, tell your healthcare professional about all your medical conditions, including if you:

- have kidney or liver problems, including hepatitis.
- have Human Immunodeficiency Virus 1 (HIV-1) infection. PAXLOVID may lead to some HIV-1 medicines not working as well in the future.
- are pregnant, plan to become pregnant, breastfeeding, or plan to breastfeed.

**Tell your healthcare professional if you are taking combined hormonal contraceptive (birth control).** PAXLOVID may affect how your birth control works. People who can become pregnant should use another or an alternative effective form of birth control.

### PAXLOVID may cause serious side effects, including:

- Allergic reactions, including severe allergic reactions (anaphylaxis). Do not take PAXLOVID if you are allergic to nirmatrelvir, ritonavir, or any of the ingredients in PAXLOVID. Stop taking PAXLOVID and call your healthcare professional right away if you get any of the following symptoms of an allergic reaction:
  - o skin rash, hives, blisters, or peeling skin
  - o painful sores or ulcers in the mouth, nose, throat, or genital area
  - o trouble swallowing or breathing
  - o swelling of the mouth, lips, tongue, or face
  - o hoarseness
  - o throat tightness
- Liver problems. Tell your healthcare professional right away if you have any of the following signs and symptoms of liver problems during treatment with PAXLOVID:
  - o loss of appetite
  - o yellowing of your skin and the whites of your eyes
  - o dark-colored urine
  - o pale-colored stools
  - o itchy skin
  - o stomach-area (abdominal) pain

The most common side effects of PAXLOVID include: altered sense of taste and diarrhea.

Other possible side effects include:

- headache
- abdominal pain
- vomiting
- high blood pressure
- nausea
- feeling generally unwell

These are not all of the possible side effects of PAXLOVID. For more information, ask your healthcare professional or pharmacist.

There is limited experience treating pregnant women or breastfeeding mothers with PAXLOVID. For a mother and unborn baby, the benefit of taking PAXLOVID may be greater than the risk from the treatment. It is recommended that you use effective barrier contraception or do not have sexual activity while taking PAXLOVID. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare professional.

**Take PAXLOVID exactly as your healthcare professional tells you.** If you take too much PAXLOVID, call your healthcare professional or go to the nearest hospital emergency room right away. If you are taking a ritonavir- or cobicistat-containing medicine to treat hepatitis C or HIV-1 infection, you should continue to take your medicine as prescribed.

Talk to your healthcare professional if you do not feel better or if you feel worse after 5 days.

Contact your healthcare professional if you have any side effects that bother you or do not go away. Report side effects or problems with the appearance or packaging of PAXLOVID to FDA MedWatch at <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a> or call 1-800-FDA-1088, or you can report side effects to Pfizer Inc. at <a href="https://www.pfizersafetyreporting.com">www.pfizersafetyreporting.com</a>, by fax at 1-866-635-8337, or by calling 1-800-438-1985.

Please see <u>Fact Sheets for Healthcare Providers</u> and <u>Fact Sheet for Patients</u>, <u>Parents</u>, <u>and Caregivers</u> at <u>PAXLOVIDinformation.com</u>.

