

# 新冠肺炎口服抗病毒治療藥物須知 奈瑪特韋(nirmatrelvir)/利托那韋(ritonavir)

跟據醫院管理局版本 (Ref: CCIDER-COVID 19-001 (V2.5)) (修訂於 2024 年 3 月)

帕克斯洛維德(Paxlovid<sup>TM</sup>)包裝內含有兩種藥物,奈瑪特韋(nirmatrelvir)和利托那韋(ritonavir)。 Nirmatrelvir 是一種 SARS-CoV-2 主要蛋白酶(Mpro)的擬肽抑制劑,而 ritonavir 是一種 HIV-1 蛋白酶抑制劑。雖然只有有限的安全性、效能及素質的資料,在公共衞生緊急事態以及本地的醫療需要下,帕克斯洛維德在本港已獲得有條件批准註冊。

## 以下人士不可使用帕克斯洛維德 (Paxlovid<sup>TM</sup>)

- 12歲以下或體重少於40公斤的病人 (適用於12-17歲)
- 曾對帕克斯洛維德中的任何成分有嚴重過敏史

#### 警告和注意事項

- 肝臟毒性: 出現肝轉氨酶升高、臨床肝炎和黃疸
- 對 HIV 藥物的抗藥性:在未受控制或未經治療的 HIV 感染情况下,帕克斯洛維德可能會影響 某些 HIV 藥物在未來發揮作用
- 以下藥物相互作用例子可能會導致嚴重副作用或影響帕克斯洛維德的藥效(如有需要,請查閱詳細藥物資料)

**副作用** 味覺改變、腹痛、噁心、腹瀉、高血壓、肌肉疼痛、身體不適、過敏反應

#### 劑量

- 每 12 小時一次,每次 300 毫克 nirmatrelvir (兩粒 150 毫克藥丸)和 100 毫克 ritonavir (一粒 100 毫克藥丸),空肚或飽肚服用均可,整個療程為期五天。
  - 中度腎功能不全病人(eGFR 30 to <60 mL/min): 每 12 小時一次,每次 150 毫克 nirmatrelvir (一粒 150 毫克藥丸)和 100 毫克 ritonavir (一粒 100 毫克藥丸),空肚或飽肚服用均可,整個療程為期五天。
  - 嚴重腎功能不全病人(eGFR < 30 mL/min): 詳情請諮詢您的主診醫生。

┷嚴重肝功能不全病人(Child-Pugh Class C): 不建議使用

222 亞皆老街,九龍 Argyle Street, Kowloon

₹ 2711 5222 ♣ 2761 1469 info@evanhosp.org.hk www.evangel.org.hk

caringorganisation



# Fact sheet on the use of nirmatrelvir/ritonavir (Paxlovid) Use of nirmatrelvir/ritonavir in COVID-19 patients

From Hospital Authority (Ref: CCIDER-COVID 19-001 (v2.5)) (Revised March 2024)

Paxlovid<sup>TM</sup> is nirmatrelvir tablets co-packaged with ritonavir tablets. Nirmatrelvir is a SARS-CoV-2 main protease (Mpro) inhibitor, and ritonavir is an HIV-1 protease inhibitor and CYP3A inhibitor. The product is conditionally approved with limited safety, efficacy, and quality data for public health emergency to satisfy local unmet medical need in Hong Kong.

#### **Contraindications**

- Patients less than 12 years of age or weighing below 40kg (for 12-17 years of age)
- History of clinically significant hypersensitivity reactions to the ingredients or components of the product.

#### Warnings and precautions

- Hepatotoxicity: Hepatic transaminase elevations, clinical hepatitis, and jaundice
- Risk of developing drug resistance to HIV protease inhibitors in individuals with uncontrolled or undiagnosed HIV-1 infection
- Examples of significant/potentially significant drug interactions [consult full prescribing information if needed]

Antianginal: ranolazine
Anti-gout: colchicine (in patients with renal and/or
hepatic impairment)
Benign prostatic hyperplasia agents: silodosin
• Ergot derivatives: dihydroergotamine, ergotamine, methylergonovine
Immunosuppressants: voclosporin
Microsomal triglyceride transfer protein inhibitor: lomitapide
Mineralocorticoid receptor antagonists: finerenone
PDE5 inhibitor: sildenafil (Revatio®) when used for pulmonary arterial hypertension (PAH)
• Serotonin receptor 1A agonist/serotonin receptor 2A antagonist: flibanserin

#### Adverse reactions

• Dysgeusia (altered sense of taste), abdominal pain, nausea, diarrhoea, hypertension (high blood pressure), myalgia (muscle aches), malaise (feeling of weakness), hypersensitivity reactions

#### Dosage and administration

- 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet) taken orally every 12 hours for 5 days, with or without food
  - Moderate renal impairment (eGFR ≥30 to <60 mL/min):</li>
     150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet) taken orally every 12 hours for 5 days, with or without food
  - Severe renal impairment (*eGFR* < 30 *mL/min*): Please consult your attending doctor for details.

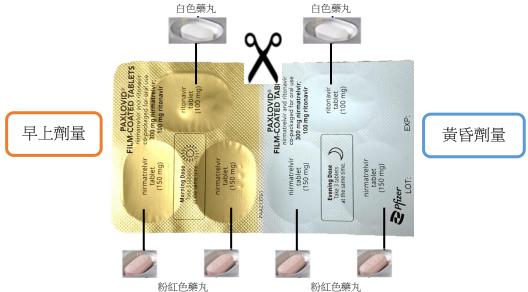
Severe hepatic impairment (Child-Pugh Class C): NOT recommended

# 用藥指南 Information Leaflet 2019 冠狀病毒病□服藥 - 帕克斯洛維德 COVID-19 Oral Medication - Paxlovid

#### 服用帕克斯洛維德應注意事項

- 帕克斯洛維德由兩種藥物組成:尼馬瑞韋 (Nirmatrelvir) 和利托那韋(Ritonavir)。粉紅色藥丸為 尼馬瑞韋,白色藥丸為利托那韋。
- 請按照醫生指示服用適當的劑量。

• 每天服用 2 次,每劑量相隔 12 小時。每次同時服用 3 粒藥丸(2 粒粉紅色藥丸和 1 粒白色藥丸)。



- 注意中度腎功能不全的病人可能會服用減量的劑量。
- 空肚或飽肚服用均可。
- 用水吞服整粒藥丸,請勿咀嚼,破壞或壓碎藥丸。
- 必須服完整個為期5天的療程。在服藥期間,即使感到病情好轉,在未經醫生許可的情況下, 不能停服此藥。
- 請依照指示接受隔離。這對提高病毒的清除率及避免冠狀病毒的傳播非常重要。

## 忘記服藥的處理方法

- 若你在預定服藥時間8小時內忘記服藥,應盡快補服一個劑量。
- 若漏服的藥物已超過預定服藥時間 8 小時,就不應補服,等待下一個預定的時間才服藥。
- 切勿服用兩倍劑量。
- 記錄錯過的劑量供醫生參考,並尋求醫生的建議。
- 如服用了錯誤的劑量,而所服的劑量超出正常劑量時,必須盡快通知醫生。

#### 其他注意事項

- 1. 如你正在懷孕
  - 目前還沒有服用帕克斯洛維德治療孕婦的相關資料。對於母親和未出生的嬰兒服用帕克斯 洛維德的益處可能大於治療的風險。如你正在懷孕,請與醫生商討你服藥的效益和風險。 一般建議你在服用帕克斯洛維德時使用有效可靠的屏障避孕方法或避免進行性行為。
- 2. 如你正在餵哺母乳
  - 目前還沒有服用帕克斯洛維德治療哺乳期女士的相關資料。如果你正在餵哺母乳,請與醫生商討你的選擇和具體情況。
- 3. 帕克斯洛維德可能會減低複方激素避孕藥的效果。正在服用複方激素避孕藥且具有懷孕能力的女士,應使用另一種有效可靠的替代避孕方式或額外的屏障避孕方法。





# 用藥指南 Information Leaflet 2019 冠狀病毒病□服藥 - 帕克斯洛維德 COVID-19 Oral Medication - Paxlovid

- 4. 如你正在服用含有利托那韋(Ritonavir)或考比司他 (Cobicistat) 的藥物來治療丙型肝炎或人類免疫缺乏病毒 (HIV),你應該繼續按照醫生的處方服藥。對 HIV 藥物的抗藥性 如果你有未經治療的人類免疫缺乏病毒感染 (HIV),帕克斯洛維德可能會導致某些人類免疫缺乏病毒藥物在未來使用時效用減低。
- 5. 帕克斯洛維德不適用於治療患有嚴重肝臟或腎臟疾病的病人。如你有肝臟或腎臟問題,服藥 前請告知醫生。
- 6. 如有需要請攜同此藥到治療地點(如醫院或社區隔離設施)繼續服用。

## 貯存方法

• 請把藥物存放於室溫 20-25°C;勿讓兒童接觸。

## 此藥物指引只供參考之用

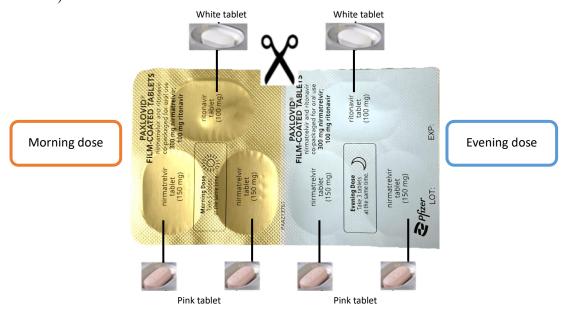
 用藥應按醫生指示;如有疑問請向主診醫生或藥劑師查詢; 切勿將自己的藥物給予他人服用。





### While taking Paxlovid, you should

- Paxlovid consists of two medicines: Nirmatrelvir and Ritonavir. The pink tablets are nirmatrelvir and the white tablets are ritonavir.
- Take the drug as directed by your doctor.
- Take the medicine two times a day, every 12 hours. Take all three tablets (two pink tablets and one white tablet) at the same time.



- Note that there is a dose reduction in patients with moderate kidney impairment.
- This medicine can be taken with or without food.
- Swallow the tablets whole with water. Do not chew, break, or crush.
- You should complete the whole 5-day treatment course. Do not stop taking this medicine even if you feel better, unless your doctor told you to do so.
- Please follow instructions for isolation. This is very important to maximise viral clearance and limit transmission of SARS-CoV-2.

#### What to do if you miss a dose

- Take the missed dose as soon as you remember if it's within 8 hours of the time it is usually taken.
- If the dose is missed by more than 8 hours, skip the missed dose, and take the next dose at your regular time.
- Do not double the dose.
- Record the missed dose for your doctor's reference. Seek advice from your doctor for the missed dose.
- If you took a wrong dose by mistake and the dose you took exceeded your normal dose, you should contact your doctor immediately.



# 用藥指南 Information Leaflet 2019 冠狀病毒病口服藥 - 帕克斯洛維德 COVID-19 Oral Medication - Paxlovid

#### **Other Precautions**

- 1. If you are pregnant
  - There is no experience treating pregnant women with Paxlovid. For a mother and an unborn baby, the benefit of taking Paxlovid may be greater than the risk from the treatment. If you are pregnant, discuss your benefit and risk for treatment with your doctor. It is recommended to use effective barrier contraception or do not have sexual activity while on Paxlovid.
- 2. If you are breast-feeding
  - There is no experience treating breastfeeding mothers with Paxlovid. If you are breastfeeding, discuss your options and specific situation with your doctor.
- 3. Paxlovid may reduce the combined hormonal contraceptive efficacy. Females of childbearing potential should use another effective alternative form of contraception or an additional barrier method of contraception.
- 4. If you are taking a ritonavir- or cobicistat-containing medicine to treat hepatitis C or Human Immunodeficiency Virus (HIV), you should continue to take your medicine as prescribed by your doctor.
- 5. Resistance to HIV medicines If you have untreated HIV infection, Paxlovid may lead to some HIV medicines not working as well in the future.
- 6. Paxlovid is not suitable for use in patients with severe liver or kidney disease. Before taking Paxlovid, you should notify your doctor if you have any liver or kidney problems.
- 7. Please bring along this medicine to treatment facilities (e.g. hospital or community isolation facilities) for continuing treatment if needed.

#### Storage of the drug

• Keep the medicine at room temperature, 20-25°C.

#### This information leaflet is for reference only

- Medicine should be used as directed by the doctor.
- For enquiry, please consult your doctor or pharmacist.
- Do not share your medicine with others.