

Fact sheet on the use of Molnupiravir in COVID-19 patients

跟據醫院管理局版本 (Ref: CCIDER-COVID 19-001 (V2.5)) (第3版, 2022年5月6日)

莫納皮拉韋 (Molnupiravir) 是一種有醫學實證能夠治療新冠肺炎的口服抗病毒藥物，用於輕度及中度病情有高風險未接種疫苗的新冠患者，能有效減低入院率及死亡率。雖然只有有限的安全性、效能及素質的資料，在公共衛生緊急事態以及本地的醫療需要下，莫納皮拉韋在本港已獲得有條件批准註冊。

From Hospital Authority (Ref: CCIDER-COVID 19-001 (v2.5)) (Version 3, 6 May 2022)

Molnupiravir is a nucleoside analogue that inhibits SARS-CoV-2 replication by viral mutagenesis. 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.

以下人士不可使用莫納皮拉韋 Contraindications	
<ul style="list-style-type: none"> 懷孕女性 (莫納皮拉韋對胚胎或胎兒有害) 哺乳女性 (莫納皮拉韋對胚胎或胎兒有害) 18 歲以下人士 (莫納皮拉韋可能會影響骨和軟骨的生長) 	<ul style="list-style-type: none"> Pregnancy Breastfeeding Patients less than 18 years of age
警告和注意事項 Warnings and precautions	
<ul style="list-style-type: none"> 莫納皮拉韋治療對胚胎及胎兒毒性 <ul style="list-style-type: none"> 建議有生育能力的女性，在莫納皮拉韋治療期間，和在服用最後一劑莫納皮拉韋後的 4 天內，正確和一致地使用有效的避孕方法 建議有生育能力的男性，在莫納皮拉韋治療期間，和在服用最後一劑莫納皮拉韋後的 3 個月內，正確和一致地使用有效的避孕方法 (註：直到目前為止，醫學界尚未清楚男性在服用最後一劑莫納皮拉韋 3 個月後，莫納皮拉韋會否對他們的子女產生胚胎或胎兒異常、傷害或毒性風險) 過敏、嚴重過敏反應、血管性水腫、紅斑、皮疹和蕁麻疹、化學 (ALT、AST、肌酐和脂肪酶) 和血液學 (血紅蛋白、血小板和白細胞) 的化驗報告異常等 	<ul style="list-style-type: none"> Embryo-fetal toxicity Allergic reactions: stop if it occurs. Bone and cartilage toxicity: molnupiravir should not be used in patients less than 18 years of age because it may affect bone and cartilage growth.
副作用 Adverse reactions	
<ul style="list-style-type: none"> 在醫學臨床研究中其副作用與安慰劑相約 較為可預見 (<2%) 的副作用包括：過敏反應、頭暈、嘔心、腹瀉等 	<ul style="list-style-type: none"> Diarrhea, dizziness, headache, skin itchiness, skin rash, nausea, vomiting. Laboratory abnormalities in kidney and liver functions tests and haematology (haemoglobin, platelets, and leukocytes)
劑量 Dosage and administration	
<ul style="list-style-type: none"> 每 12 小時 1 次，每次 800 毫克 (4 粒膠囊)，一個療程為期 5 天 	<ul style="list-style-type: none"> 800 mg (four 200 mg capsules) taken orally every 12 hours for 5 days, with or without food. Renal impairment: No dosage adjustment. Hepatic impairment: No dosage adjustment.

服用莫納皮拉韋應注意事項

- 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，每次服用 4 粒膠囊。
- 空肚或飽肚服用均可。
- 用水吞服整粒膠囊。請勿打開，破壞或壓碎膠囊。
- 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。
- 避免懷孕 - 由於莫納皮拉韋可能會對胎兒造成傷害，所以服藥期間應避免懷孕。如你在服用莫納皮拉韋期間懷孕或你認為可能懷孕，應立即通知醫生。

忘記服藥的處理方法

- 若你在預定服藥時間 10 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 10 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. 餵哺母乳**

- 在服藥期間和服用最後一劑莫納皮拉韋後 4 天內不建議餵哺母乳。如你正在餵哺母乳或計劃餵哺母乳，應在服藥前諮詢醫生的意見。

2. 具有懷孕能力的女士

- 不建議在懷孕期間服用莫納皮拉韋。在開始服用莫納皮拉韋之前，醫護人員可能會為你進行驗孕，以確認你是否懷孕。
- 在服藥期間和服用最後一劑莫納皮拉韋後 4 天內，應持續採取可靠的避孕措施。
- 如你在服用莫納皮拉韋期間懷孕或你認為可能懷孕，應立即通知醫生。

3. 與具有懷孕能力之伴侶有活躍性行為的男性

- 目前還未能確知莫納皮拉韋是否會對精子造成影響。雖然一般認為風險很低，但在服藥期間和服用最後一劑莫納皮拉韋後至少 3 個月內，應持續採取可靠的避孕措施。

4. 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 Molnupiravir, you should

- Take the drug as directed by your doctor.
- Take the medicine two times a day, every 12 hours. For each dose, take four capsules.
- This medicine can be taken with or without food.
- Swallow the capsule whole with water. Do not open, 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.
- Avoid getting pregnant as molnupiravir may cause fetal harm. If you become pregnant or think you might be pregnant while on molnupiravir, you should notify your doctor immediately.

What to do if you miss a dose

- Take the missed dose as soon as you remember if it's within 10 hours of the time it is usually taken.
- If the dose is missed by more than 10 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.

Other Precautions

1. Breast-feeding
 - Breastfeeding is not recommended during treatment and for 4 days after the last dose of molnupiravir. If you are breastfeeding or are planning to breastfeed, consult your doctor before taking this medicine.
2. Females of childbearing potential
 - Molnupiravir is not recommended for use during pregnancy. Your healthcare provider may do a pregnancy test to see if you are pregnant before starting treatment with molnupiravir.
 - You should use effective contraception consistently while on molnupiravir and for 4 days after the last dose of molnupiravir.
 - If you become pregnant or think you might be pregnant while on Molnupiravir, you should notify your doctor immediately.
3. Sexually active males with partners of childbearing potential
 - So far it is not known whether molnupiravir will affect sperm, although the risk is generally considered low. Sexually active males with partners of childbearing potential should use a reliable method of contraception during treatment and for at least 3 months after the last dose of molnupiravir.
4. 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); Keep it out of reach of children.

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.**