

Paxlovid 孕婦使用說明單

台灣婦產科醫學會 2022/05/12 初版

- 成份: nirmatrelvir (150 mg/顆*2) + ritonavir (100 mg/顆*1)。
- 適應症: **確診或居隔、居檢、自主防疫時快篩陽性及症狀開始後 5 天內。**
(無法用在預防感染發生或已重症時治療用)
- 服法: 早晚各一次 連用 5 天。
(忘了吃! 8 小時內盡快補吃, 超過 8 小時則跳過一次, 可與食物一起或單獨服用, 直接吞服, 勿咬碎或打碎)
- 禁忌症: 對成分有嚴重過敏, 嚴重肝、腎功能異常, 未滿 12 歲、40 公斤, 未被診斷或控制不佳的 HIV 感染。
- 調整劑量: 中度的腎功能異常。
- 常見副作用: 比安慰劑發生率高的如下:
味覺失常 (6% vs.<1%), 腹瀉 (3% vs.2%), 高血壓 (1% vs.<1%), 肌肉疼痛 (1% vs.<1%).
停藥率 2% vs. 安慰劑的 4%。
- 好處: 使感染者重症率下降 **88%**
- 亞太先進地區感染 Omicron 重症、死亡率: 0.2%-3.1%、0.045%-0.69%, 而孕婦通常是同齡者的 1.5-2 倍, 高齡、懷孕後期、肥胖、慢性病、未完成疫苗接種為危險因子, 尤其同時有多項因子者更加危險。
- 台灣目前重症率&死亡率約為 0.04% & 0.02%, 但隨疫情發展預期會再上升, 且**一旦重症死亡率超過六成!**
至 2022/5/10 孕婦共確診 131 例, 中症 1 例, 重症 2 例(含死亡 1 例), 孕婦確診後重症以上比率約 1.5%。
- 懷孕相關安全性: **目前無人類懷孕相關資料**, 在動物身上使用 3 倍劑量無不良發展結果, 在兔子身上使用 10 倍劑量發現會減少胎兒體重。
- 哺乳: 非禁忌症。
- 藥物交互作用: 高達兩百多種 (使用前請參閱 Paxlovid EUA Fact Sheet 說明), **有其他科疾病尤其長期用藥者要特別小心, 建議例行 check 雲端藥歷**, 若有嚴重危害須回報。
- 屬緊急授權使用, 需告知風險及獲得病人同意後才能使用。
- 代替方案: Remdesivir, 得住院中用點滴注射三天。

不可併用藥物

影響下列藥物代謝, 可能引起嚴重後果

- Alpha1-adrenoreceptor antagonist: alfuzosin
- Analgesics: pethidine, propoxyphene
- Antianginal: ranolazine
- Antiarrhythmic: amiodarone, dronedarone, flecainide, propafenone, quinidine
- Anti-gout: colchicine
- Antipsychotics: lurasidone, pimozide, clozapine
- **Ergot derivatives:** dihydroergotamine, ergotamine, methylergonovine
- HMG-CoA reductase inhibitors: lovastatin, simvastatin
- PDE5 inhibitor: sildenafil (Revatio®) when used for pulmonary arterial hypertension (PAH)
- Sedative/hypnotics: triazolam, oral midazolam

可能導致抗病毒效果下降

- Anticancer drugs: apalutamide
- Anticonvulsant: carbamazepine, phenobarbital, phenytoin
- Antimycobacterials: rifampin
- Herbal products: St. John's Wort (*hypericum perforatum*)

附表：與婦產科常用藥物的交互作用

Drug Class	Drugs within Class	Effect on Concentration	Clinical Comments
Analgesics	pethidine, propoxyphene	↑ pethidine ↑ propoxyphene	Co-administration contraindicated due to potential for serious respiratory depression or hematologic abnormalities
Anticancer drugs	vinblastine, vincristine	↑ anticancer drug	Co-administration of vincristine and vinblastine may lead to significant hematologic or gastrointestinal side effects.
Anticoagulants	warfarin rivaroxaban dabigatran	↑↓ warfarin ↑ rivaroxaban ↑ dabigatran	Closely monitor INR if co-administration with warfarin is necessary. Increased bleeding risk with rivaroxaban. Avoid concomitant use. Increased bleeding risk with dabigatran. Depending on dabigatran indication and renal function, reduce dose of dabigatran or avoid concomitant use. Refer to the dabigatran product label for further information.
Antifungals	voriconazole, ketoconazole, isavuconazonium sulfate itraconazole	↓ voriconazole ↑ ketoconazole ↑ isavuconazonium sulfate ↑ itraconazole ↑ nirmatrelvir/ritonavir	Avoid concomitant use of voriconazole. Refer to ketoconazole, isavuconazonium sulfate, and itraconazole product labels for further information.
Antiinfective	clarithromycin, erythromycin	↑ clarithromycin ↑ erythromycin	Refer to the respective prescribing information for anti-infective dose adjustment.
Calcium channel blockers	amlodipine, diltiazem, felodipine, nicardipine, nifedipine	↑ calcium channel blocker	Caution is warranted and clinical monitoring of patients is recommended. A dose decrease may be needed for these drugs when co-administered. If co-administered, refer to individual product label for calcium channel blocker for further information.
Ergot derivatives	dihydroergotamine, ergotamine, methylergonovine	↑ dihydroergotamine ↑ ergotamine ↑ methylergonovine	Co-administration contraindicated due to potential for acute ergot toxicity characterized by vasospasm and ischemia of the extremities and other tissues including the central nervous system
Hormonal contraceptive	ethinyl estradiol	↓ ethinyl estradiol	An additional, non-hormonal method of contraception should be considered during the 5 days of treatment and until one menstrual cycle after stopping.
Systemic corticosteroids	betamethasone , budesonide, ciclesonide, dexamethasone , fluticasone, methylprednisolone mometasone, prednisone, triamcinolone	↑ corticosteroid	Increased risk for Cushing's syndrome and adrenal suppression. Alternative corticosteroids including beclomethasone and prednisolone should be considered.