

Nintedanib

【OFEV】Ofev® Soft Capsules 150mg

ATC Code : L01EX09

中文名：抑肺纖軟膠囊 150 毫克 《百靈佳》

適應症：特發性肺纖維化、與全身性硬化症有關之間質性肺病、慢性漸進性纖維化間質性肺病。

藥理分類：Tyrosine Kinase Inhibitor.

用法用量：**Administration:**

Orally, taken with food. Swallow capsules whole with liquid; do not chew or crush (bitter taste).

Indications and dosage regimens:

Idiopathic pulmonary fibrosis (IPF):

150 mg Q12H (Max: 300 mg/day)

Systemic sclerosis-associated interstitial lung disease (SSc-ILD):

150 mg Q12H (Max: 300 mg/day).

Progressive pulmonary fibrosis (PF-ILD):

150 mg Q12H (Max: 300 mg/day).

Dosage adjustment for concomitant therapy:

Significant drug interactions exist, requiring dose/frequency adjustment or avoidance.

Missed dose:

If a dose is missed, the next dose should be taken at the next scheduled time. Do not make up a missed dose.

Dosing in Hepatic Impairment: Adult

Mild impairment (Child-Pugh class A): 100 mg Q12H.

If a patient does not tolerate 100 mg every 12 hours, consider treatment interruption or discontinue treatment to manage adverse reactions.

Moderate to severe impairment (Child-Pugh class B or C): Not recommended.

不良反應：腹瀉、噁心、腹痛、嘔吐、體重減輕、食慾減少、頭痛、血壓升高

交互作用：

- Warfarin: ↑ risk of bleeding.
- Phenytoin, carbamazepine, phenobarbital, rifampin, St. John's wort: ↓ Nintedanib exposure.
- Clarithromycin, Itraconazole, Ketoconazole, Ritonavir: ↑ the serum concentration of Nintedanib.
- Tobacco (Smoked) may ↓ the serum concentration of Nintedanib.

注意事項：1.服用時請搭配食物和足量的水。

2.因為味道很苦，請勿咀嚼或咬碎膠囊。

3.如果漏服 OFEV，請忽略該劑，直接於下一次排定的時間服用下一劑，不要補服漏掉的劑量。

4.若有持續腹瀉或嚴重副作用時，請立即就醫。

懷孕期：懷孕女性使用 Ofev®可對胎兒造成傷害。應告知 Ofev®治療可能會對懷孕婦女的胎兒具潛在風險。

授乳期：不建議哺乳婦女接受 Ofev®治療。目前沒有 Nitendanib 存在人類乳汁、對母乳餵養嬰兒或乳汁分泌影響的相關資訊，Nintedanib 及／或其代謝物可能存在於授乳大鼠的乳汁內。由於 Ofev®治療可能引起乳兒嚴重不良反應，因此不建議哺乳婦女接受 Ofev®治療。