

## Palbociclib

【O8063】 Ibrance® 125mg Cap

ATC Code : L01XE33

中文名： 愛乳適膠囊 125 毫克 «Pfizer»

【O8064】 Ibrance® 100mg Cap

ATC Code : L01XE33

中文名： 愛乳適膠囊 100 毫克 «Pfizer»

適應症： 1. 對於荷爾蒙受體為陽性、第二型人類表皮生長因子接受體(HER2)呈陰性之局部晚期或轉移性乳癌之停經後婦女，IBRANCE 可與芳香環轉化酶抑制劑 (aromatase inhibitor)合併使用。  
2. 對於荷爾蒙受體為陽性、第二型人類表皮生長因子接受體(HER2)呈陰性之局部晚期或轉移性乳癌之婦女，IBRANCE 可合併 fulvestrant 用於先前曾接受過內分泌治療者。

藥理分類： **Antineoplastic Agent, Cyclin-Dependent Kinase Inhibitor.**

用法用量： **Administration:**

- Orally taken **with food**. Administer at approximately the same time each day.
- Swallow the capsules whole, do not crush or chew; do not open capsules prior to swallowing.

**Indications and regimens:**

**Breast cancer, advanced, initial endocrine-based therapy:**

- HER-2 negative: 125 mg QD x 21 days, followed by 7 days off, repeat every 28 days (in combination with continuous aromatase inhibitor therapy); continue until disease progression or unacceptable toxicity.
- For males receiving palbociclib in combination with an aromatase inhibitor, also consider treatment with a luteinizing hormone-releasing hormone (LHRH) agonist.

**Breast cancer, advanced (with disease progression following endocrine therapy):**

HER-2 negative: 125 mg QD x 21 days, followed by 7 days off, repeat every 28 days (in combination with fulvestrant [and an LHRH/gonadotropin-releasing hormone agonist (eg, goserelin) if pre- or perimenopausal female]); continue until disease progression or unacceptable toxicity.

**Dosage adjustment for Toxicity:**

Grade 1 or 2: No dosage adjustment required.

Grade 3:

**Day 1 of cycle:** Withhold palbociclib therapy and repeat CBC with differential within 1 week. When improved to  $\leq$  grade 2, initiate the next cycle at the same dose.

**Day 15 of first 2 cycles:** If at grade 3, continue palbociclib therapy at current dose to complete the cycle. Repeat CBC with differential on day 22. If at grade 4 on day 22, withhold palbociclib treatment until resolved to  $\leq$  grade 2. After resolution, resume at next lower dose. Consider dose reduction in future cycles if recovery from grade 3 neutropenia is prolonged ( $>1$  week) or for recurrent grade 3 neutropenia on day 1 of subsequent cycles.

**Grade 3 (ANC  $500/\text{mm}^3$  to  $<1,000/\text{mm}^3$ ) plus fever  $\geq 38.5^\circ\text{C}$  and/or infection at any time:** Withhold palbociclib treatment until resolved to  $\leq$  grade 2. Resume at next lower dose upon restarting.

**Grade 4 at any time:** Withhold palbociclib treatment until resolved to  $\leq$  grade 2. After resolution, resume at next lower dose.

**不良反應：** 嗜中性白血球減少症、感染、白血球減少症、疲倦、噁心、口腔炎、貧血、禿髮、以及腹瀉。

**交互作用：**

1. **strong CYP3A4 inhibitor** (clarithromycin, itraconazole, ketoconazole, voriconazole, indinavir, lopinavir/ritonavir, nelfinavir, ritonavir, saquinavir, nefazodone, grapefruit): ↑ Palbociclib exposure。
2. **CYP3A4 inducer** (phenytoin, rifampin, carbamazepine, St John's Wort): ↓ Palbociclib exposure。

**注意事項：**

1. 建議依據個人安全性及耐受性表現或不良反應發生程度調整劑量。
2. 某些藥品可能影響(增強或減弱)本藥作用。
3. 服此藥期間，請勿吃葡萄柚或喝葡萄柚汁。
4. 建議每天於大約相同的時間服藥，**與食物一起服用**。如果嘔吐或漏服一劑藥物，當天**不可額外再服一劑**。應按照平常的時間服用下一個處方劑量。
5. Ibrance<sup>®</sup>膠囊應整顆吞服(吞服前請勿咀嚼、咬碎或打開膠囊)。如果膠囊破損、有裂痕或殘缺不完整，請不要服用。
6. 本品含有乳糖成分。有半乳糖不耐症、Lapp 乳糖酶缺乏症或葡萄糖半乳糖吸收不良等罕見遺傳問題的患者不可使用本藥。

**懷孕期：** 目前僅有有限的孕婦使用 palbociclib 的資料。動物研究顯示具有生殖毒性。不建議懷孕期間使用，也不建議用於具生育能力但未採取避孕措施的婦女。

**授乳期：** 目前並不確知 palbociclib 是否會分泌進入人類的乳汁。接受 palbociclib 治療的患者不可餵哺母乳。

**儲存：** 於 30°C 以下乾燥處儲存。