Perampanel

【OFYC2】Fycompa® 2 mg/Tab *ATC Code：N03AX22*

中文名： 癲控達膜衣錠 2 毫克 《衛采》

【OFYC4】Fycompa® 4 mg/Tab *ATC Code：N03AX22*

中文名： 癲控達膜衣錠 4 毫克 《衛采》

適應症： 適用於 4 歲以上病人局部癲癇發作併有或未併有續發型全身發作之治療。適用於 7 歲以上病人原發型全身性強直陣攣癲癇發作併有原發性全身發作之輔助治療。

藥理分類： **AMPA Glutamate Receptor Antagonist; Antiseizure Agent, Miscellaneous**

用法用量： **Administration:** Orally administer at bedtime without regard to food.

Indications and dosage regimens:

Adult:

Partial-onset seizures:

- **Patients not receiving enzyme-inducing AED regimens:**
  Initial: 2 mg QD at bedtime; may increase daily dose by 2 mg QD no more frequently than at weekly intervals based on response and tolerability.
  Maintenance dose: 8 to 12 mg QD at bedtime.

- **Patients receiving enzyme-inducing AED regimens (eg, phenytoin, carbamazepine, oxcarbazepine):**
  Initial: 4 mg QD at bedtime; may increase daily dose by 2 mg QD no more frequently than at weekly intervals based on response and tolerability.
  Maintenance dose: has not been established;
  Highest dose used in clinical trials was 12 mg QD.

Primary generalized tonic-clonic seizures (adjunct):

- **Patients not receiving enzyme-inducing AED regimens:**
  Initial: 2 mg QD at bedtime; may increase dose by 2 mg QD no more frequently than at weekly intervals based on response and tolerability.
  Maintenance dose: 8 mg QD at bedtime; if tolerated and further seizure control is needed, may increase up to 12 mg once daily (maximum dose: 12 mg once daily).

- **Patients receiving enzyme-inducing AED regimens (eg, phenytoin, carbamazepine, oxcarbazepine):**
  Initial: 4 mg QD at bedtime; may increase daily dose by 2 mg QD no more frequently than at weekly intervals based on response and tolerability.
  Maintenance dose: has not been established;
  Highest dose used in clinical trials was 12 mg QD.

Dosing: Kidney Impairment: Adult

- **CrCl ≥50** mL/minute: No dosage adjustment necessary.
- **CrCl 30 to 49** mL/minute: No dosage adjustment necessary; monitor closely and consider slower titration based on response and tolerability.
- **CrCl <30** mL/minute: Use not recommended (has not been studied).
- **Hemodialysis:** Use not recommended (has not been studied).

Dosing: Hepatic Impairment: Adult

- **Mild impairment** (Child-Pugh class A): Initial 2 mg QD; may increase daily dose by 2 mg QD no more frequently than every 2 weeks based on response and tolerability. Maximum: 6 mg QD

- **Moderate impairment** (Child-Pugh class B): Initial 2 mg QD; may increase daily dose by 2 mg QD no more frequently than every 2 weeks based on response and tolerability. Maximum: 4 mg QD
- **Severe impairment** (Child-Pugh class C): Use not recommended (has not been studied)

Children ≥4 years and Adolescents:

Partial seizures; adjunct or monotherapy:

- **Patients not receiving moderate or strong CYP3A4 inducers:**
  Initial: 2 mg QD at bedtime; may increase daily dose by 2 mg increments no more frequently than at weekly intervals;
  Maintenance dose range: 8 to 12 mg QD at bedtime; some patients may respond to doses of 4 mg/day.
  Maximum daily dose: 12 mg/day.

- **Patients receiving moderate or strong CYP3A4 inducers (eg, phenytoin, carbamazepine, oxcarbazepine):**
  Initial: 4 mg QD at bedtime; may increase daily dose by 2 mg increments no more frequently than at weekly intervals;
  Maintenance dose range: not established;
  Maximum reported dose is 12 mg/day.

Primary generalized tonic-clonic seizures (adjunct):

- **Patients not receiving moderate or strong CYP3A4 inducers**:
  Initial: 2 mg once daily at bedtime; may increase dose by 2 mg once daily no more frequently than at weekly intervals based on response and tolerability.
  Maintenance dose: 8 mg once daily at bedtime.
  Maximum daily dose: 12 mg/day

- **Patients receiving moderate or strong CYP3A4 inducers (eg, phenytoin, carbamazepine, oxcarbazepine):**
  Initial: 4 mg QD at bedtime; may increase daily dose by 2 mg QD no more frequently than at weekly intervals; individualize dose based on response and tolerability;
  Maximum reported dose was 12 mg/day.

不良反應： 頭暈、嗜睡、食慾減退或增加、易發怒、焦慮、平衡障礙、視覺模糊、噁心、背痛、體重增加、泌尿道感染。

交互作用：

- Perampanel may enhance the CNS depressant effect of Alcohol (Ethyl). Alcohol may also worsen the negative behavioral and psychiatric effects of Perampanel.
- Azelastine (Nasal), HydrOXYzine : ↑ the CNS depressant effect.
- Buprenorphine: ↑ the CNS depressant effect of Buprenorphine.
- CYP3A4 Inducers (CarBAMazepine, PHENobarbital, Phenytoin, Primidone, RifAMPin, Efavirenz, Rifabutin, Rifapentine, St John's Wort) : ↓ the serum concentration of Perampanel.

注意事項：

1. 睡前服用。可與食物或不與食物一起服用。本品搭配水吞服。不可咀嚼、壓碎或剝半服用。本品無剝半線，無法準確剝半。
2. Perampanel 可能引起頭暈和嗜睡，因此可能影響駕駛或操作機器之能力，

應　告知病人在了解 perampanel 是否會影響其從事下列事務之能力前，不要駕駛、操作複雜機器或從事其它危險性活動。

3. 在服用 Fycompa®的病人中，曾通報有嚴重或危及生命的精神和行為不良反應，包含攻擊性、敵意、不安、易怒和傷人意念。
4. 在服用 Fycompa®時或停藥後，若觀察到病人情緒、行為或個性上非典型的反應或改變，建議病人及照顧者應立即聯繫醫師。
5. 在調升劑量或使用高劑量的期間，應密切監測病人。

懷 孕 期：1. 懷孕婦女使用 perampanel 之資料有限。於兔子之試驗未顯示致畸性，但於大鼠可觀察到胚胎的腸道憩室增加，於母體毒性劑量時可觀察到胚胎毒性。

2. 不建議懷孕婦女使用 Fycompa®。

授 乳 期：1. 於授乳大鼠之試驗顯示 perampanel 及/或其代謝物會分泌至乳汁中。尚未知 Perampanel 是否會分泌於人類乳汁中。無法排除對新生兒/嬰兒之風險。

2. 須評估授乳對小孩之益處和治療對婦女之益處後，決定停止授乳或停止/放棄 Fycompa®治療。

儲　　存：30℃以下儲存。