Erlotinib

【OTARC】Tarceva® 150mg/Tab *ATC Code：L01XE03*

中 文 名： 得舒緩膜衣錠 «Roche»

適 應 症：
- 適用於具有 EGFR-TK 突變之局部侵犯性或轉移性之**非小細胞肺癌(NSCLC)**病患之第一線治療。
- 適用於先前已接受過化學治療後，但仍局部惡化或轉移之肺腺癌病患之第二線用藥。
- 適用於已接受 4 個週期含 platinum-based 第一線化學療法且尚未惡化的局部晚期或轉移性肺腺癌的維持療法。

藥理分類： Antineoplastic Agent, Epidermal Growth Factor Receptor (EGFR) Inhibitor; Tyrosine Kinase Inhibitor.

用法用量： **Administration:** orally, taken on an **empty stomach** (at least one hour before or two hours after the ingestion of food), with a cup of water, swallow the whole tablet.

Indications and dosage regimens:

Non-small cell lung cancer (NSCLC), metastatic, first-line therapy in patients with EGFR exon 19 deletions or exon 21 (L858R) substitution mutations:
150 mg QD until disease progression or unacceptable toxicity.

NSCLC, refractory:
150 mg QD until disease progression or unacceptable toxicity.

NSCLC, maintenance therapy:
150 mg QD until disease progression or unacceptable toxicity.

不良反應： 紅疹、腹瀉、食慾不振、疲勞、噁心。

注意事項： 1.應於進食前至少 1 小時或進食後 2 小時服用。

交互作用： 1.**CYP3A4 inhibitors**(eg, **azole antifungals, clarithromycin, erythromycin, nefazodone, protease inhibitors, telithromycin, grapefruit, or grapefruit juice**):
- Avoid concurrent use if possible; consider dose reductions for severe adverse reactions if erlotinib is administered concomitantly with strong CYP3A4 inhibitors.
- Dose reduction (if required) should be done in decrements of 50 mg (after toxicity has resolved to baseline or ≤ grade 1).

2.Concomitant CYP3A4 and CYP1A2 inhibitor (eg, **ciprofloxacin**):
- Avoid concurrent use if possible; consider dose reductions in decrements of 50 mg if severe adverse reactions occur (after toxicity has resolved to baseline or ≤ grade 1).

3.**CYP3A4 inducers** (eg, **carbamazepine, phenobarbital, phenytoin, rifamycins, and St. John's wort)**:
- Alternatives to the enzyme-inducing agent should be utilized first.
- Concomitant administration with CYP3A4 inducers may require increased erlotinib doses (increase as tolerated at 2-week intervals in 50 mg increments to a maximum of 450 mg); doses > 150 mg daily should be considered with rifampin (the maximum erlotinib dose studied in combination with rifampin was 450 mg).
- Immediately reduce erlotinib dose to recommended starting dose when CYP3A4 inducer is discontinued.

懷 孕 期： 只有在母親的潛在效益超越胎兒所面臨之風險的情況下，才可讓孕婦繼續接受治療。在治療期間，以及治療完成後的至少 2 週內，都應採取適當的避孕方

法。

授 乳 期： 目前未知 erlotinib 是否會分泌進入人類的乳汁。由於許多藥物都會分泌進入人類乳汁，且 Tarceva®對哺乳嬰兒可能造成的嚴重不良反應，因此應在考慮這個藥品對母親的重要性下決定應停止授乳或者停用此藥。