Docetaxel

【ITYN2】Tynen® 20mg/1mL/Vial *ATC Code：L01CD02*

【ITYN8】Tynen® 80mg/4mL/Vial *ATC Code：L01CD02*

中文名： 鈦能注射劑 《東洋》

適應症： 1.乳癌 2.非小細胞肺癌 3.前列腺癌 4.胃腺癌 5.頭頸癌。

【INOL2】 Nolbaxol® 20mg/1mL/Vial *ATC Code：L01CD02*

【INOL8】 Nolbaxol® 80mg/4mL/Vial *ATC Code：L01CD02*

中文名： 活克癌注射液 《永信》

適應症： 乳癌、非小細胞肺癌、前列腺癌、胃腺癌、頭頸癌。

藥理分類：Antineoplastic Agent, Antimicrotubular; Taxane Derivative.

用法用量：***Note:*** Premedicate with corticosteroids for 3 days, beginning one day prior to docetaxel administration, to reduce the severity of hypersensitivity reactions and fluid retention.

Administration: IV: Infuse over 1 hour through nonsorbing polyethylene lined (non-DEHP) tubing.

Indications and dosage regimens:

Breast cancer: IV infusion:

-Locally advanced or metastatic:
60 to 100 mg/m^2 every 3 weeks (as a single agent)

-Operable, node-positive (adjuvant treatment): TAC regimen:
75 mg/m^2 every 3 weeks for 6 courses (in combination with doxorubicin and cyclophosphamide)

-Adjuvant treatment (off-label dosing):
75 mg/m^2 every 21 days (in combination with cyclophosphamide) for 4 cycles (Jones, 2006) or 75 mg/m^2 every 21 days (in combination with carboplatin and trastuzumab) for 6 cycles

-Neoadjuvant treatment (off-label dosing):
75 mg/m^2 (cycle 1; if tolerated, may increase to 100 mg/m^2 in subsequent cycles) every 21 days for a total of 4 cycles (in combination with trastuzumab and pertuzumab)

-Metastatic treatment (off-label dosing):

Every-3-week administration:

- 75 mg/m^2 (cycle 1; may increase to 100 mg/m^2 in subsequent cycles) every 21 days for at least 6 cycles (in combination with trastuzumab and pertuzumab) or
- 100 mg/m^2 every 21 days (in combination with trastuzumab) for at least 6 cycles or
- 75 mg/m^2 every 21 days (in combination with capecitabine) until disease progression or unacceptable toxicity or
- 60 mg/m^2, 75 mg/m^2, or 100 mg/m^2 every 21 days for at least 6 cycles until disease progression, unacceptable toxicity, or discontinuation

Weekly administration:

- 40 mg/m^2/dose once a week (as a single agent) for 6 weeks followed by a 2-week rest, repeat until disease progression or unacceptable toxicity (Burstein, 2000) or
- 35 mg/m^2/dose once weekly for 3 weeks, followed by a 1-week rest, may

increase to 40 mg/m^2 once weekly for 3 weeks followed by a 1-week rest with cycle 2 (Rivera, 2008) or

- 35 mg/m^2/dose once weekly (in combination with trastuzumab) for 3 weeks followed by a 1-week rest; repeat until disease progression or unacceptable toxicity

Non-small cell lung cancer: IV infusion:
75 mg/m^2 every 3 weeks (as a single agent or in combination with cisplatin)
Prostate cancer: IV infusion:
75 mg/m^2 every 3 weeks (in combination with prednisone)
Gastric adenocarcinoma: IV infusion:
75 mg/m^2 every 3 weeks (in combination with cisplatin and fluorouracil)
Sequential chemotherapy and chemoradiation (off-label dosing):
Induction: 75 mg/m^2 on days 1 and 22 (in combination with cisplatin) for 2 cycles, followed by chemoradiation: 20 mg/m^2 weekly for 5 weeks (in combination with cisplatin and radiation) (Ruhstaller, 2009)
Locally advanced or metastatic disease (off-label dosing):
50 mg/m^2 on day 1 every 2 weeks (in combination with fluorouracil, leucovorin, and oxaliplatin) until disease progression or unacceptable toxicity up to a maximum of 8 cycles (Al-Batran, 2008)
Head and neck cancer: IV infusion:
75 mg/m^2 every 3 weeks (in combination with cisplatin and fluorouracil) for 3 or 4 cycles, followed by radiation therapy.

禁　　忌：Docetaxel 禁用於嗜中性白血球(neutrophil)數目小於 1,500 cells/mm^3 之患者。

不良反應：水腫、腹瀉、骨髓抑制、掉髮、虛弱、皮疹、感覺異常、噁心嘔吐、口腔炎、指甲病變。

注意事項：1.輸注液須在配製好 6 小時內(含輸注時間 1 小時)使用。
2.乳癌，非小細胞肺癌、胃腺癌及頭頸癌的治療前給藥應包含口服腎上腺皮質類固醇，但若有使用禁忌則除外。例如，於每個 docetaxel 治療週期開始前一天起，連續 3 天，每日服用 dexamethasone 16mg(例如一天兩次，每次 8mg)。
3.併用 prednisone 或 prednisolone 治療前列腺癌時，治療前給藥，建議於輸注 docetaxel 前 12 小時、3 小時及 1 小時投予 dexamethasone 8mg。
4.可預防性投予 G-CSF 以減少發生血液毒性的危險。

懷 孕 期：1.不宜使用於孕婦。Docetaxel 可能造成胎兒傷害。
2. Females of reproductive potential should use effective contraceptive measures before beginning treatment, during therapy, and for 6 months after the last docetaxel dose.

授 乳 期：1.Docetaxel 禁用於授乳之女性。
2.It is not known if docetaxel is present in breast milk.
3.Due to the potential for serious adverse reactions in breastfed infants, breastfeeding is not recommended during treatment and for 1 week after the last docetaxel dose.

輸注液稀釋：輸注用濃縮液的所需藥量必須注入 250 mL D5W 或 NS 的輸注袋或瓶內才能進行注射。
將所需之混合前溶液注入 **250 mL D5W 或 NS** 之輸注袋或輸注瓶中。
若病人所需之劑量超過 200 毫克 docetaxel，應使用較大容量之輸注容器，**避免 docetaxel 之濃度超過 0.74 毫克/毫升**。 輸注袋或輸注瓶須以手搖動以確保均勻混合。

安 定 性： 輸注液須在配製好 6 小時內以靜脈輸注方式使用(包含輸注時間 1 小時)，在低於 25℃之環境下給予病患。

儲　　存： 1. Tynen® 濃縮液應儲存於 2-8℃。 請儲存於原有包裝以避免光照。

2. Nolbaxol®濃縮液應儲存於 25℃。 請儲存於原有包裝以避免光照。