Capecitabine

【OXELO】Xeloda® 500mg/Tab *ATC Code：L01BC06*

中文名： 截瘤達錠 «Roche»

適應症： 1.治療轉移性大腸（結腸直腸）癌病患。2.作為第三期結腸癌患者手術後輔助性療法。3. 與 docetaxel 併用於治療對 anthracycline 化學治療無效之局部晚期或轉移性乳癌病患。4.亦可單獨用於對紫杉醇（Taxane）及 anthracycline 化學治療無效，或無法使用 anthracycline 治療之局部晚期或轉移性乳癌病患。5.合併 platinum 可使用於晚期胃癌之第一線治療。

藥理分類： **Antineoplastic Agent, Antimetabolite (Pyrimidine Analog).**

用法用量： **Administration:**

Oral: Usually administered in 2 divided doses (in the morning and evening). Doses should be **taken with water within 30 minutes after a meal.** Swallow tablets hole. Avoid cutting or crushing tablets.

Indications and Dosage regimens:

Breast cancer, metastatic:

1,250 mg/m^2 twice daily for 2 weeks, every 21 days (as either monotherapy or in combination with docetaxel)

Breast cancer, metastatic (off-label dosing):

1,000 mg/m^2 twice daily (in combination with ixabepilone) on days 1 to 14 of a 3-week cycle until disease progression or unacceptable toxicity (Thomas, 2007)

Breast cancer, metastatic, HER2+ (off-label dosing):

1,000 mg/m^2 twice daily (in combination with lapatinib) on days 1 to 14 of a 3-week cycle until disease progression or unacceptable toxicity (Geyer, 2006) or 1,250 mg/m^2 twice daily (in combination with trastuzumab) on days 1 to 14 of a 3-week cycle (Bartsch, 2007)

Breast cancer, metastatic, HER2+ with brain metastases, first-line therapy (off-label dosing):

1,000 mg/m^2 twice daily (in combination with lapatinib) on days 1 to 14 of a 3-week cycle until disease progression or unacceptable toxicity (Bachelot, 2012)

Colorectal cancer, metastatic:

1,250 mg/m^2 twice daily for 2 weeks, every 21 days. Note: Capecitabine toxicities, particularly hand-foot syndrome, may be higher in North American populations; therapy initiation at doses of 1,000 mg/m2 twice daily (for 2 weeks every 21 days) may be considered (Haller, 2008).

Colorectal cancer (off-label dosing):

1,000 mg/m^2 twice daily (in combination with oxaliplatin) on days 1 to 14 of a 3-week cycle for 8 or 16 cycles (Cassidy, 2008; Haller, 2011; Schmoll, 2007)

Dukes' C colon cancer, adjuvant therapy:

1,250 mg/m^2 twice daily for 2 weeks, every 21 days, for a recommended total duration of 24 weeks (8 cycles of 2 weeks of drug administration and 1 week rest period).

Esophageal and gastric cancers (off-label uses): Oral:

Preoperative or definitive chemoradiation:

800 mg/m^2 twice daily (in combination with cisplatin and radiation) on days 1 to 5 weekly for 5 weeks (Lee, 2007) or 625 mg/m^2 twice daily (in combination with oxaliplatin and radiation) on days 1 to 5 weekly for 5 weeks (Javle, 2009).

Postoperative chemoradiation:

625 to 825 mg/m^2 twice daily during radiation therapy (Lee, 2006)

Locally advanced or metastatic (chemoradiation not indicated):

1,000 to 1,250 mg/m^2 twice daily (monotherapy or in combination with cisplatin

with or without trastuzumab) on days 1 to 14 of a 3-week cycle (Bang, 2010; Hong, 2004; Kang, 2009) or 625 mg/m^2 twice daily (in combination with epirubicin and cisplatin or oxaliplatin) on days 1 to 21 of a 3-week cycle for up to 8 cycles (Cunningham, 2008; Sumpter, 2005)

Hepatobiliary cancers, advanced (off-label):

650 mg/m^2 twice daily (in combination with gemcitabine) on days 1 to 14 of a 3-week cycle (Knox, 2005) or 1,000 mg/m^2 twice daily (in combination with oxaliplatin) on days 1 to 14 of a 3-week cycle (Nehls, 2008) or 1,250 mg/m^2 twice daily (in combination with cisplatin) on days 1 to 14 of a 3-week cycle (Kim, 2003); all regimens continued until disease progression or unacceptable toxicity

Neuroendocrine (pancreatic/islet cell) tumors, metastatic or unresectable (off label):

750 mg/m^2 twice daily (in combination with temozolomide) on days 1 to 14 of a 4-week cycle (Strosberg, 2011)

Ovarian, fallopian tube, or peritoneal cancer, platinum-refractory(off label):

1,000 mg/m^2 twice daily on days 1 to 14 of a 3-week cycle until disease progression or unacceptable toxicity (Wolf, 2006)

Pancreatic cancer, metastatic (off-label use):

1,250 mg/m^2 twice daily on days 1 to 14 of a 3-week cycle (Cartwright , 2002) or 830 mg/m^2 twice daily (in combination with gemcitabine) on days 1 to 21 of a 4-week cycle until disease progression or unacceptable toxicity.

Unknown primary cancer (off-label use):

1,000 mg/m^2 twice daily (in combination with oxaliplatin) on days 1 to 14 of a 3-week cycle for up to 6 cycles or until disease progression (Hainsworth, 2010) or 800 mg/m^2 twice daily (in combination with carboplatin and gemcitabine) on days 1 to 14 of a 3-week cycle for up to 8 cycles or until disease progression or unacceptable toxicity.

計算方式：Table 1 Standard and reduced dose calculations according to body surface area for a starting dose of Xeloda of 1250 mg/m^2

Dose level 1250 mg/m^2 (twice daily)					
	Full dose 1250 mg/m^2	Number of 150 mg tablets and/or 500 mg tablets per administration (each administration to be given morning and evening)		Reduced dose (75%) 950 mg/m^2	Reduced dose (50%) 625 mg/m^2
Body Surface Area (m^2)	Dose per administration (mg)	150 mg	500 mg	Dose per administration (mg)	Dose per administration (mg)
≦ 1.26	1500	-	3	1150	800
1.27 – 1.38	1650	1	3	1300	800
1.39 – 1.52	1800	2	3	1450	950
1.53 – 1.66	2000	-	4	1500	1000
1.67 – 1.78	2150	1	4	1650	1000
1.79 – 1.92	2300	2	4	1800	1150
1.93 – 2.06	2500	-	5	1950	1300
2.07 – 2.18	2650	1	5	2000	1300
≧ 2.19	2800	2	5	2150	1450

Table 2 Standard and reduced dose calculations according to body surface area for a starting dose of Xeloda of 1000 mg/m^2

Dose level 1000 mg/m^2 (twice daily)					
	Full dose 1000 mg/m^2	Number of 150 mg tablets and/or 500 mg tablets per administration (each administration to be given morning and evening		Reduced dose (75%) 750 mg/m^2	Reduced dose (50%) 500 mg/m^2
Body Surface Area (m^2)	Dose per administration (mg)	150 mg	500 mg	Dose per administration (mg)	Dose per administration (mg)
≦ 1.26	1150	1	2	800	600
1.27 – 1.38	1300	2	2	1000	600
1.39 – 1.52	1450	3	2	1100	750
1.53 – 1.66	1600	4	2	1200	800
1.67 – 1.78	1750	5	2	1300	800
1.79 – 1.92	1800	2	3	1400	900
1.93 – 2.06	2000	-	4	1500	1000
2.07 – 2.18	2150	1	4	1600	1050
≧ 2.19	2300	2	4	1750	1100

不良反應： 便秘、口腔炎、噁心、腹瀉、手足皮膚反應、疲倦。

交互作用：

- RUBELLA VIRUS VACCINE, LIVE ; MUMPS VIRUS VACCINE, LIVE ; MEASLES VIRUS VACCINE, LIVE; VARICELLA VIRUS VACCINE, LIVE ; ZOSTER VACCINE, LIVE : ↑ risk of infection by the live vaccine.
- COUMARIN- DERIVATIVE ANTICOAGULANTS : ↑ risk of bleeding.
- PROTON PUMP INHIBITORS: ↓ in capecitabine bioavailability.
- TAMOXIFEN: ↑ risk of thromboembolism.
- CELECOXIB : ↑ celecoxib exposure that persists for at least 7 days after capecitabine discontinuation.
- ALLOPURINOL : ↓ efficacy of capecitabine.
- METHOTREXATE : ↑ 5-fluorouracil toxicity.

注意事項： 1.飯後 30 分鐘內與水一起吞服。整顆吞服。
2.若發生嚴重腹瀉或皮膚反應，請告知醫師。
3.有生育能力的女性 / 男性與女性，治療期間應採行有效的避孕方法。

懷 孕 期： 懷孕期間應禁止使用 Xeloda®。

授 乳 期： 使用 Xeloda®治療期間應停止餵哺母乳。

使用規定： 全民健保給付規範：
1.Capecitabine 與 docetaxel 併用於治療對 anthracycline 化學治療無效之局部晚期或轉移性乳癌病患。
2.單獨用於對 taxanes 及 anthracycline 化學治療無效，或無法使用 anthracycline 治療之局部晚期或轉移性乳癌病患。
3.治療轉移性結腸直腸癌的第一線用藥。
4.第三期結腸癌患者手術後的輔助性療法，以八個療程為限。
5.Capecitabine 合併 platinum 可使用於晚期胃癌之第一線治療。