Gemcitabine HCl

[IGEMM] Gemmis ® 200mg/Vial ATC Code : L01BC05

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適應症: 1.非小細胞肺癌、2.胰臟癌、3.膀胱癌。4.與 paclitaxel 併用,可使用於曾經使

用過 anthracycline 之局部復發且無法手術切除或轉移性之乳癌患者。5.用於曾經使用含鉑類藥物(PLATINUM-BASED)治療後復發且間隔至少 6 個月之卵巢

癌,作為第二線治療。6.膽道癌。

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

用法用量: *Note:* Prolongation of the infusion duration > 60 minutes and administration more

frequently than once weekly have been shown to increase toxicity.

Administration: IV infusion over 30 minutes.

Indications and dosage regimens:

Breast cancer, metastatic: IV:

1250 mg/m² over 30 minutes days 1 and 8; repeat cycle every 21 days (in combination with paclitaxel) or (off-label dosing; as a single agent) 800 mg/m² over 30 minutes days 1, 8, and 15 of a 28-day treatment cycle (Carmichael, 1995)

Non-small cell lung cancer, locally advanced or metastatic: IV:

- 1000 mg/m² over 30 minutes days 1, 8, and 15; repeat cycle every 28 days (in combination with cisplatin) or 1250 mg/m² over 30 minutes days 1 and 8; repeat cycle every 21 days (in combination with cisplatin) or
- (off-label dosing/combination) 1000 mg/m² over 30 minutes days 1 and 8; repeat cycle every 21 days (in combination with carboplatin) for up to 4 cycles, or
- (off-label combination) 1000 mg/m² over 30 minutes days 1, 8, and 15; repeat cycle every 28 days (in combination with carboplatin) for up to 4 cycles (Danson, 2003), or
- (off-label combination) 1000 mg/m² over 30 minutes days 1 and 8; repeat cycle every 21 days (in combination with docetaxel) for 8 cycles, or
- (off-label combination) 1000 mg/m² days 1, 8, and 15; repeat cycle every 28 days (in combination with vinorelbine) for 6 cycles.)

Ovarian cancer, advanced: IV:

- 1000 mg/m² over 30 minutes days 1 and 8; repeat cycle every 21 days (in combination with carboplatin) or
- (off-label dosing; as a single agent) 1000 mg/m² over 30-60 minutes days 1 and 8; repeat cycle every 21 days, or
- (off-label combination) 1000 mg/m² over 30 minutes days 1, 8, and 15; repeat cycle every 28 days (in combination with paclitaxel) for up to 6 cycles.

Pancreatic cancer, locally advanced or metastatic: IV:

- Initial: 1000 mg/m² over 30 minutes once weekly for 7 weeks followed by one week rest; then once weekly for 3 weeks out of every 4 weeks or
- (off-label combinations) 1000 mg/m² over 30 minutes weekly for up to 7 weeks followed by one week rest; then weekly for 3 weeks out of every 4 weeks (in combination with erlotinib) or
- 1000 mg/m² over 30 minutes days 1, 8, and 15 every 28 days (in combination with capecitabine) or
- 1000 mg/m² over 30 minutes days 1 and 15 every 28 days (in combination with

- cisplatin) or
- 1000 mg/m² infused at 10 mg/m²/minute every 14 days (in combination with oxaliplatin) or
- 1000 mg/m² days 1, 8, and 15 every 28 days (in combination with paclitaxel [protein bound]).

Bladder cancer (off-label use):

Advanced or metastatic: IV:

- 1000 mg/m² over 30-60 minutes days 1, 8, and 15; repeat cycle every 28 days (in combination with cisplatin) or
- 1000 mg/m² over 30 minutes days 1 and 8; repeat cycle every 21 days (in combination with carboplatin) until disease progression or unacceptable toxicity.

Transitional cell carcinoma: Intravesicular instillation:

2000 mg (in 100 mL NS; retain for 1 hour) twice weekly for 3 weeks; repeat cycle every 4 weeks for at least 2 cycles.

Cervical cancer, recurrent or persistent (off-label use): IV:

- 1000 mg/m² days 1 and 8; repeat cycle every 21 days (in combination with cisplatin) or
- 1250 mg/m² over 30 minutes days 1 and 8; repeat cycle every 21 days (in combination with cisplatin) or
- 800 mg/m² over 30 minutes days 1, 8, and 15; repeat cycle every 28 days (as a single agent) or
- 800 mg/m² days 1 and 8; repeat cycle every 28 days (in combination with cisplatin).

Head and neck cancer, nasopharyngeal (off-label use): IV:

- 1000 mg/m² over 30 minutes days 1, 8, and 15 every 28 days or
- 1000 mg/m² over 30 minutes days 1 and 8 every 21 days (in combination with vinorelbine)

Hepatobiliary cancer, advanced (off-label use): IV:

- 1000 mg/m² over 30 minutes days 1 and 8; repeat cycle every 21 days (in combination with cisplatin) or
- 1000 mg/m² over 30 minutes days 1 and 8; repeat cycle every 21 days (in combination with capecitabine) or
- 1000 mg/m² infused at 10 mg/m²/minute every 2 weeks (in combination with oxaliplatin)

Hodgkin lymphoma, relapsed (off-label use): IV:

- 1000 mg/m² (800 mg/m² for post-transplant patients) over 30 minutes days 1 and 8; repeat cycle every 21 days (in combination with vinorelbine and doxorubicin liposomal) or
- 800 mg/m² days 1 and 4; repeat cycle every 21 days (in combination with ifosfamide, mesna, vinorelbine, and prednisolone)

Malignant pleural mesothelioma (off-label use; in combination with cisplatin):

- 1000 mg/m² over 30 minutes days 1, 8 and 15 every 28 days for up to 6 cycles or
- 1250 mg/m² over 30 minutes days 1 and 8 every 21 days for up to 6 cycles

Non-Hodgkin lymphoma, refractory (off-label use): IV:

• 1000 mg/m² over 30 minutes days 1 and 8; repeat cycle every 21 days (in combination with cisplatin and dexamethasone)) or

• 1000 mg/m² every 15-21 days (in combination with oxaliplatin and rituximab) **Sarcoma (off-label uses):** IV:

Ewing's sarcoma, refractory:

675 mg/m² over 90 minutes days 1 and 8; repeat cycle every 21 days (in combination with docetaxel)

Osteosarcoma, refractory:

- 675 mg/m² over 90 minutes days 1 and 8; repeat cycle every 21 days (in combination with docetaxel) or
- 1000 mg/m² weekly for 7 weeks followed by 1 week rest; then weekly for 3 weeks out of every 4 weeks.

Soft tissue sarcoma, advanced:

- 800 mg/m² over 90 minutes days 1 and 8; repeat cycle every 21 days (in combination with vinorelbine) or
- 675 mg/m² over 90 minutes days 1 and 8; repeat cycle every 21 days (in combination with docetaxel) or
- 900 mg/m² over 90 minutes days 1 and 8; repeat cycle every 21 days (in combination with docetaxel)

Small cell lung cancer, refractory or relapsed (off-label use): IV:

1000-1250 mg/m² over 30 minutes days 1, 8, and 15 every 28 days (as a single agent)

Testicular cancer, refractory germ cell (off-label use): IV:

- 1000-1250 mg/m² over 30 minutes days 1 and 8 every 21 days (in combination with oxaliplatin) or
- 1000 mg/m² over 30 minutes days 1, 8, and 15 every 28 days for up to 6 cycles (in combination with paclitaxel) or
- 800 mg/m² over 30 minutes days 1 and 8 every 21 days (in combination with oxaliplatin and paclitaxel)

Unknown-primary, adenocarcinoma (off-label use): IV:

- 1250 mg/m² days 1 and 8 every 21 days (in combination with cisplatin) or
- 1000 mg/m² over 30 minutes days 1 and 8 every 21 days for up to 6 cycles (in combination with docetaxel)

Uterine cancer (off-label use): IV:

- 900 mg/m² over 90 minutes days 1 and 8 every 21 days (in combination with docetaxel) or
- 1000 mg/m² over 30 minutes days 1, 8, and 15 every 28 days.

不良反應: 週邊水腫、皮膚不良反應、噁心、嘔吐、發燒、疲倦、骨髓抑制。

注意事項: 輸注時間超過60分鐘,或一週給藥多於一次,會增加副作用發生。

懷 孕 期: 1.孕婦施打 Gemcitabine 會對胎兒造成傷害。依據藥品的作用機轉, Gemcitabine 會造成不良的生殖反應。

2.懷孕期間使用本品,或用藥期間懷孕,應告知病患對胎兒可能造成之危險。

授 乳 期: 尚未得知 Gemcitabine 及其代謝物是否會分泌於乳汁中,但基於許多藥物皆會分泌於乳汁,且 Gemcitabine 可能會對授乳嬰兒造成嚴重不良反應,母親應被告知,並根據藥物對母親的重要性與對嬰兒的可能危險性,決定應停止授乳或停止用藥。

配 製: 將注射液用 NS 注射液稀釋,最低濃度可低至 0.1 mg/mL。

安定性: 配製完成之 Gemcitabine 溶液在30℃以下可維持穩定24小時。配置後之

Gemcitabine 溶液不可冷藏,因為可能會形成結晶。

相容輸注液: NS

儲 存: 儲存於攝氏 2℃~8℃,不可冷凍。