

## Gemcitabine HCl

【IGEMM】 Gemmis® 200mg/Vial

ATC Code : L01BC05

中文名：健仕注射液 «東洋»

適應症：1.非小細胞肺癌 2.胰臟癌 3.膀胱癌 4.Gemcitabine 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。

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/m<sup>2</sup> 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/m<sup>2</sup> 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/m<sup>2</sup> over 30 minutes days 1, 8, and 15; repeat cycle every 28 days (in combination with cisplatin) or 1250 mg/m<sup>2</sup> over 30 minutes days 1 and 8; repeat cycle every 21 days (in combination with cisplatin) or
- (off-label dosing/combination) 1000 mg/m<sup>2</sup> 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/m<sup>2</sup> 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/m<sup>2</sup> 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/m<sup>2</sup> days 1, 8, and 15; repeat cycle every 28 days (in combination with vinorelbine) for 6 cycles.)

#### Ovarian cancer, advanced: IV:

- 1000 mg/m<sup>2</sup> 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/m<sup>2</sup> over 30-60 minutes days 1 and 8; repeat cycle every 21 days, or
- (off-label combination) 1000 mg/m<sup>2</sup> 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/m<sup>2</sup> 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/m<sup>2</sup> 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/m<sup>2</sup> over 30 minutes days 1, 8, and 15 every 28 days (in combination with capecitabine) or
- 1000 mg/m<sup>2</sup> over 30 minutes days 1 and 15 every 28 days (in combination with

- cisplatin) or
- 1000 mg/m<sup>2</sup> infused at 10 mg/m<sup>2</sup>/minute every 14 days (in combination with oxaliplatin) or
  - 1000 mg/m<sup>2</sup> 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/m<sup>2</sup> over 30-60 minutes days 1, 8, and 15; repeat cycle every 28 days (in combination with cisplatin) or
- 1000 mg/m<sup>2</sup> 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/m<sup>2</sup> days 1 and 8; repeat cycle every 21 days (in combination with cisplatin) or
- 1250 mg/m<sup>2</sup> over 30 minutes days 1 and 8; repeat cycle every 21 days (in combination with cisplatin) or
- 800 mg/m<sup>2</sup> over 30 minutes days 1, 8, and 15; repeat cycle every 28 days (as a single agent) or
- 800 mg/m<sup>2</sup> days 1 and 8; repeat cycle every 28 days (in combination with cisplatin).

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

- 1000 mg/m<sup>2</sup> over 30 minutes days 1, 8, and 15 every 28 days or
- 1000 mg/m<sup>2</sup> over 30 minutes days 1 and 8 every 21 days (in combination with vinorelbine)

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

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

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

- 1000 mg/m<sup>2</sup> (800 mg/m<sup>2</sup> 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/m<sup>2</sup> 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/m<sup>2</sup> over 30 minutes days 1, 8 and 15 every 28 days for up to 6 cycles or
- 1250 mg/m<sup>2</sup> 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/m<sup>2</sup> over 30 minutes days 1 and 8; repeat cycle every 21 days (in combination with cisplatin and dexamethasone) or

- 1000 mg/m<sup>2</sup> every 15-21 days (in combination with oxaliplatin and rituximab)

**Sarcoma (off-label uses): IV:**

**Ewing's sarcoma**, refractory:

- 675 mg/m<sup>2</sup> over 90 minutes days 1 and 8; repeat cycle every 21 days (in combination with docetaxel)

**Osteosarcoma**, refractory:

- 675 mg/m<sup>2</sup> over 90 minutes days 1 and 8; repeat cycle every 21 days (in combination with docetaxel) or
- 1000 mg/m<sup>2</sup> 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/m<sup>2</sup> over 90 minutes days 1 and 8; repeat cycle every 21 days (in combination with vinorelbine) or
- 675 mg/m<sup>2</sup> over 90 minutes days 1 and 8; repeat cycle every 21 days (in combination with docetaxel) or
- 900 mg/m<sup>2</sup> 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/m<sup>2</sup> 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/m<sup>2</sup> over 30 minutes days 1 and 8 every 21 days (in combination with oxaliplatin) or
- 1000 mg/m<sup>2</sup> over 30 minutes days 1, 8, and 15 every 28 days for up to 6 cycles (in combination with paclitaxel) or
- 800 mg/m<sup>2</sup> 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/m<sup>2</sup> days 1 and 8 every 21 days (in combination with cisplatin) or
- 1000 mg/m<sup>2</sup> 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/m<sup>2</sup> over 90 minutes days 1 and 8 every 21 days (in combination with docetaxel) or
- 1000 mg/m<sup>2</sup> 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 0.1mg/mL。

安 定 性： 配製完成之 Gemcitabine 溶液在 30°C 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°C~8°C，不可冷凍。