Epirubicin

【IEPIR】 Epicin® 20mg/10mL/Vial *ATC Code：L01DB03*

中文名： 益彼欣注射液 «東洋»

適應症： 乳腺癌、惡性淋巴瘤、軟組織肉瘤、胃癌、肺癌、卵巢瘤。

藥理分類： **Topoisomerase II Inhibitor; Antineoplastic Agent, Anthracycline.**

用法用量： ***Note:***

- Patients receiving 120 mg/m^2/cycle as part of combination therapy (CEF-120 regimen) should receive prophylactic antibiotic therapy.
- Lower starting doses may be necessary for heavily pretreated patients, patients with preexisting myelosuppression, or with bone marrow involvement.
- If clinically reasonable, delay epirubicin therapy until other cardiotoxic agents with long half-lives (eg, trastuzumab) have been cleared.
- A lifetime maximum cumulative dose >900 mg/m^2 should be avoided.
- Epirubicin is associated with a moderate to high emetic potential (depending on regimen); antiemetics are recommended to prevent nausea and vomiting.

Administration:

- Infuse over 15 to 20 minutes or slow IV push; if lower doses due to dose reduction are administered, may reduce infusion time proportionally.
- Do not infuse over <3 minutes. Infuse into a free-flowing IV solution (NS or D5W).

Indications and dosage regimens:

Breast cancer, adjuvant treatment:

IV: Usual dose: 100-120 mg/m2 per 3- or 4-week treatment cycle as follows:

60 mg/m^2 on days 1 and 8 every 28 days for 6 cycles in combination with cyclophosphamide and fluorouracil (CEF-120 regimen; Levine 2005) or

100 mg/m^2 on day 1 every 21 days for 6 cycles in combination with cyclophosphamide and fluorouracil (FEC-100 regimen; Bonneterre 2005) or

Breast cancer (off-label regimens):

IV:

EC regimen:

100 mg/m^2 on day 1 every 21 days for 8 cycles in combination with cyclophosphamide (Piccart 2001)

EP or EC regimen:

75 mg/m^2 on day 1 every 21 days for up to 6 cycles in combination with either paclitaxel or cyclophosphamide (Langley 2005)

FEC regimen ± paclitaxel:

90 mg/m^2 on day 1 every 21 days for 6 cycles in combination with fluorouracil and cyclophosphamide or for 4 cycles in combination with fluorouracil and cyclophosphamide followed by paclitaxel (Martin 2008)

FEC regimen followed by pertuzumab + trastuzumab + docetaxel:

100 mg/m^2 on day 1 every 21 days for 3 cycles in combination with fluorouracil and cyclophosphamide, followed by 3 cycles of pertuzumab, trastuzumab, and docetaxel (Schneeweiss 2013)

CEF regimen:

50 mg/m^2 on days 1 and 8 every 21 or 28 days for 6 to 9 cycles in combination with cyclophosphamide and fluorouracil (Ackland 2001)

Esophageal cancer (off-label use): IV:

ECF, ECX, EOF, and EOX regimens:

50 mg/m^2 on day 1 every 21 days for up to 8 cycles in combination with cisplatin

(C), oxaliplatin (O), fluorouracil (F), and/or capecitabine (X) (Cunningham 2008)

ECF regimen:

50 mg/m^2 on day 1 every 21 days for 3 preoperative and 3 postoperative cycles in combination with cisplatin and fluorouracil (Cunningham 2006)

Gastric cancer (off-label use): IV:

ECF, ECX, EOF, and EOX regimens:

50 mg/m^2 on day 1 every 21 days for up to 8 cycles in combination with cisplatin (C), oxaliplatin (O), fluorouracil (F), and/or capecitabine (X) (Cunningham 2008; Waters 1999)

ECF regimen:

50 mg/m^2 on day 1 every 21 days for 3 preoperative and 3 postoperative cycles in combination with cisplatin and fluorouracil (Cunningham 2006)

Osteosarcoma (off-label use): IV:

90 mg/m^2 on day 1 every 21 days for 3 cycles before surgery and 90 mg/m^2 on day 1 every 28 days for 3 cycles after surgery (in combination with cisplatin, ifosfamide and mesna) (Basaran 2007)

Soft tissue sarcoma (off-label use): IV:

25 mg/m^2 on days 1, 2, and 3 every 28 days for 4 cycles (in combination with ifosfamide and mesna) (Petrioli 2002) or 60 mg/m^2 on days 1 and 2 every 21 days for 5 cycles (in combination with ifosfamide, mesna, and filgrastim)

注意事項：

1. Epirubicin 注射液必須小心處理。若接觸到皮膚或黏膜，應立刻以肥皂及清水或重碳酸鈉（Sodium bicarbonate）溶液清洗可能碰觸之區域。
2. 投藥時間不得少於 3 至 4 分鐘。若有靜脈沿線局部紅斑及面部潮紅現象，即顯示投藥速度太快，灼燒感或刺痛感代表藥物已滲出至靜脈四周，應立即終止注射，並另選一條靜脈重新開始注射。
3. Epirubicin 不得以肌肉或皮下投與途徑治療給藥。
4. 外滲之物理性處置方式: 冷敷。

不良反應：

骨髓抑制及心臟毒性、噁心、嘔吐、腹瀉、黏膜炎、脫髮。

懷 孕 期：

1. 應建議育齡婦女於治療期間避免懷孕，並使用有效避孕方式。 動物實驗顯示 epirubicin 用於懷孕婦女可能造成胎兒傷害。若懷孕期間使用 Epirubicin，或者患者於用藥期間懷孕，需將胎兒潛在危險告知患者。目前仍無懷孕婦女之試驗，唯有其可能效益大於胎兒潛在風險時，才可於懷孕期間使用。
2. Epirubicin may cause irreversible amenorrhea in premenopausal women.
3. If chemotherapy is indicated, it should not be administered in the first trimester, but may begin in the second trimester. There should be a 3-week time period between the last chemotherapy dose and anticipated delivery, and chemotherapy should not be administered beyond week 33 of gestation.

授 乳 期：

1. 母親應於使用此藥前停止哺乳。目前不確定 Epirubicin 是否會分泌至人類乳汁中。由於許多藥物，包含其他 anthracycline 類，皆可分泌至人類乳汁中， Epirubicin 對哺乳中嬰兒可能有嚴重不良反應。
2. Due to the potential for serious adverse reactions in the breastfed infant, breastfeeding is not recommended by the manufacturer during treatment and for ≥7 days after the last epirubicin dose.

安 定 性：

室溫 24 小時；冷藏 48 小時。