Teicoplanin

【ITEIC】 Teicod for injection® 200mg/Vial *ATC Code：J01XA02*

中文名： 得那林凍晶注射劑 《中國化學》

適應症： 葡萄球菌感染所導致之心內膜炎、骨髓炎、肺炎、敗血病、軟組織感染、腸炎、梭狀桿菌感染所致之假膜性結腸炎。

藥理分類： **Antibiotic, Miscellaneous**

用法用量： **Administration:**

- Adults and adolescents older than 12 years: **IV bolus, IV infusion, or IM** (at lower doses).
- Pediatric patients 2 months to 12 years of age: **IV bolus or IV infusion**.
- Neonates: **only IV infusion** should be used.
- Reconstitute the vial:
  (1) Reconstitute **each vial with 3.14 mL** of sterile water for injection;
  (2) rotate until all powder is dissolved to avoid foaming; if foaming occurs, let stand for about 15 minutes until all foam has disappeared and solution is clear or yellowish.
- **IM**: Administer reconstituted solution as an IM injection
- **IV**:
  May administer reconstituted solution
  (1) directly as an **IV bolus over 3 to 5 minutes** or
  (2) further dilute and given as an **IV infusion over 30 minutes**.
  (3) (**IV infusion**) Further dilute reconstituted solution in a compatible infusion solution (NS, Ringer solution, Ringer-lactate solution, D5W, D10W, sodium chloride 0.18%/glucose 4%, sodium chloride 0.45%/glucose 5%) and administer over 30 minutes.
- **Instillation, continuous ambulatory peritoneal dialysis port:**
  (1) Reconstitute each 200-mg vial with 3.14 mL of sterile water for injection; rotate until all powder is dissolved to avoid foaming; if foaming occurs, let stand for about 15 minutes until all foam has disappeared and solution is clear or yellowish.
  (2) Dilute reconstituted solution in peritoneal dialysis solution containing 1.36% or 3.86% glucose solution.
- **Oral**: The reconstituted solution may also be administered orally when appropriate for *Clostridium difficile* infection.

Indications and dosage regimens:

***C. difficile*-associated infections: Oral:**

Adults: 100 to 200 mg BID for 7~14days.

Gram-positive infections: IV/IM:

Neonates and Infants <2 months: IV:
Initial: 16 mg/kg loading dose on day 1,
followed by 8 mg/kg once daily starting on day 2.

Infants ≥2 months and Children ≤12 years: IV:

Initial: 10 mg/kg every 12 hours for 3 doses,
followed by 6 to 10 mg/kg once daily.

Adolescents and Adults: IV:
6 to 12 mg/kg every 12 hours for 3 to 5 doses.
Maintenance: IV or IM: 6 to 12 mg/kg once daily to achieve targeted trough concentration.

Surgical (orthopedic) prophylaxis: IV:
400 mg (or 6 mg/kg) given once at induction of anesthesia.

Dose adjustment: in Renal impairment

- **CrCl 30 to 80 mL/min:**
  (1) After 4 days of treatment decrease the maintenance dose by 50% either by increasing the dosing interval to **every 2 days** or administering **50%** of the regular dose once daily;
  (2) adjust to maintain appropriate trough levels of at least 10 mg/L when measured by HPLC
- Receiving **hemodialysis or CrCl less than 30 mL/min**:
  (1) After 4 days of treatment decrease maintenance dose to one-third of the regular dose either by increasing the dosing interval to **every 3 days** or administering **one-third** of the regular dose once daily;
  (2) adjust to maintain appropriate trough levels of at least 10 mg/L when measured by HPLC.

兒童：

- 本品可用於 2 個月以上兒童的革蘭氏陽性菌感染。
- 對於嚴重感染及嗜中性白血球減少症，建議劑量為每 12 小時投予 10mg/Kg 連續三劑後，改以每日一次靜脈或肌肉注射 10mg/Kg。
- 中度感染的建議劑量為每 12 小時投予 10mg/Kg 連續三劑後，改以每日一次靜脈或肌肉注射 6mg/Kg。
- 新生兒建議負荷劑量為 16mg/Kg，再改以 8mg/Kg 每日投予一次。

不良反應： 紅斑、局部疼痛、血栓性靜脈炎、皮疹、搔癢、水腫、眩暈。

交互作用：

- 與其他可能具有腎毒性或耳毒性藥品併用或接著使用時應特別注意，特別是 streptomycin，neomycin，kanamycin，gentamicin，amikacin，tobramycin，cephaloridine，colistin。
- Cholera vaccine, live: ↓ immune response to the cholera vaccine.

注意事項：

1. 對 vancomycin 過敏者應小心使用，以免發生交叉過敏，但 vancomycin 所引起的紅人症(Red Man Syndrome)並非本品的禁忌症。
2. 本品製備後可靜脈注射或肌肉注射。靜脈注射可以直接靜脈注射 3~5 分鐘或靜脈輸注 30 分鐘。
2. 腎功能不全患者應調整劑量。
3. Teicoplanin 不會經由血液透析移除。
4. 本品和 aminoglycosides 不相容，注射前不可相混合。
5. **口服投與**—
   - 口服 Teicoplanin 是用來治療伴隨抗生素而由難治梭狀桿菌(*C. difficile*)所致假膜性結腸炎。
   - 製備後的溶液可直接口服。

懷 孕 期：

1. 動物生殖研究，並未發現本品對生殖機能的影響或致畸形作用。老鼠在大劑量下則曾出現死胎和新生兒死亡增加的現象，因此孕婦或欲懷孕的婦女，未經醫師衡量其利弊得失時，應避免使用。
2. There is a potential risk for inner ear and renal damage to the developing fetus. Use during pregnancy only if clearly needed.
3. Reproductive toxicity, including an increased incidence of stillbirths and neonatal mortality, has been reported in animals following high doses of teicoplanin.

授 乳 期：

1. 目前仍無本品經乳汁分泌或通過胎盤的研究結果。未經醫師衡量其利弊得失時，應避免使用。
2. It is unknown if teicoplanin is excreted into human breast milk. Discontinue treatment or discontinue nursing, taking into account the importance of the drug to the mother and the value of breastfeeding for the infant.

配　　製：

1. 製備：將整安瓿**注射用水(3mL)**緩慢加入小瓶中，**輕輕轉動**小瓶直至粉末完全溶解為止，並小心避免泡沫的產生。若產生泡沫時，可靜置約 15 分鐘待泡沫消除。濃度為 200mg/3ml。
2. 製備後的溶液可直接注射，或以下列製劑稀釋使用：

・0.9% Sodium Chloride 注射液
・Compound Sodium Lactate 注射液(Ringer-Lactate Solution，Hartmanns Sol'n)
・5% Dextrose 注射液
・0.18% Sodium Chloride 和 4% Dextrose 注射液
・含 1.36%或 3.86% Dextrose 的腹膜透析液

安 定 性：

- 製備後應立即使用，未用完者應丟棄，但某些情況無法立即使用時，應於 2-8℃保存，24 小時後則應丟棄。
- 不可將藥抽出置於注射針筒內保存。

備　　註：　每 1 小瓶本藥(200 mg)，附加 1 支 3 mL 安瓿裝注射用水。