

Amiodarone HCl

【ICOR】 Cordarone® 150mg/3mL/Amp

ATC Code : C01BD01

中文名： 臙得樂注射液 «Sanofi»

適應症： 短期使用治療心室纖維顫動、Wolff-Parkinson-White 氏症候群、上室性及心室性心搏過速、心房撲動心房纖維顫動。用於對電擊具抗性的室室纖維顫動相關之心跳停止時所進行的心肺復甦術。

【OAMIO】 Amiorone (Amiorone®) 200mg/Tab

ATC Code : C01BD01

中文名： 艾歐隆錠 «信東»

適應症： Wolff-Parkinson-White 氏症候群、上室性及心室性心搏過速、心房撲動、心房纖維顫動、心室纖維顫動。

藥理分類： Antiarrhythmic Agent, Class III. (with alpha- and beta-blocking properties, affects Na⁺, K⁺, and Ca²⁺, prolongs the action potential and refractory period in myocardial tissue; decreases AV conduction and sinus node function.)

用法用量： **Administration:**

Oral tablet:

- Administer consistently with regard to meals. Take in divided doses with meals if GI upset occurs or if taking large daily dose (≥1,000 mg).
- If GI intolerance occurs with single-dose therapy, use twice daily dosing.

IV:

UpToDate, 2023--

- For infusions >1 hour, use concentrations ≤2 mg/mL unless a central venous catheter is used.
- Use only volumetric infusion pump; use of drop counting may lead to underdosage.
- Administer through an IV line located as centrally as possible. For peripheral infusions, an in-line filter has been recommended during administration to reduce the incidence of phlebitis.
- During pulseless VT/VF, administering undiluted is preferred.

中文仿單--

- 儘可能從中央靜脈導管點滴給藥，可能的話，請使用電動注射器。對於用於對電擊具抗性的室室纖維顫動相關之心跳停止時的心肺復甦術，無法由中央靜脈給藥時，可由周邊靜脈輸注。

Indications and dosage regimens:

Ventricular arrhythmias:

-Secondary prevention of sudden cardiac death due to ventricular arrhythmias (eg, ventricular fibrillation or hemodynamically unstable ventricular tachycardia):

Oral:

- 400 mg every 8 to 24 hours for 1 to 2 weeks (loading dose of ~6 to 10 g [total of IV plus oral doses]),
- Maintenance dose: 200 to 400 mg QD.

-Sudden cardiac arrest due to ventricular fibrillation or pulseless ventricular tachycardia (unresponsive to CPR, defibrillation, and epinephrine):

- IV push , Intraosseous (IO):
- **Initial:** 300 mg (undiluted) rapid bolus; if ventricular fibrillation or pulseless ventricular tachycardia continues after subsequent

defibrillation attempt or reoccurs after initially achieving return of spontaneous circulation, administer supplemental dose of 150 mg.

仿單—

- 起始劑量為 300 mg (或 5 mg/kg)，以 20 mL D5W 稀釋後，靜脈注射 3 分鐘，若心室性纖維顫動持續時，可再次給予 150 mg (或 2.5 mg/kg)。

—Switching to Oral Therapy Following IV Therapy

Duration of IV Therapy	Initial Oral Daily Dosage*
<1 week	400 - 1,200 mg
1-2 week	400 - 800 mg
>2 weeks	100 - 400 mg

※Initial Oral daily dosage in divided doses until loading dose of ~6 to 10 g (total of IV plus oral doses) has been administered.

Maintenance Dosage:

100-400 mg daily QD

Supraventricular arrhythmias:

-Atrial fibrillation:

IV: 150 mg over 10 minutes, then 1 mg/minute for 6 hours, then 0.5 mg/minute for 18 hours. Continue for a total loading dose of up to 10 g; may finish load with oral dosing. Change to oral maintenance dose when clinically indicated.

Oral:

- 400 mg every 8 to 24 hours for a total loading dose of ~6 to 10 g (total of IV plus oral doses),
- then change to a maintenance dose.

Maintenance of sinus rhythm (off-label use):

Oral: 100 to 200 mg once daily.

Dosing: Kidney Impairment: Adult

- **Mild to severe** impairment: No dosage adjustment necessary.
- **Hemodialysis**, intermittent (thrice weekly): No supplemental dose or dosage adjustment necessary.
- **Peritoneal dialysis**: No dosage adjustment necessary.

Dosing: Hepatic Impairment: Adult

- Dosage adjustment is probably necessary in substantial hepatic impairment.
- If hepatic enzymes exceed 3 times normal or double in a patient with an elevated baseline, consider decreasing the dose or discontinuing amiodarone.

中文仿單--

- 嚴重的節律失調且無法口服治療時，除上述之對電擊具抗性的心室纖維顫動相關之心跳停止時所進行的心肺復甦術外：應儘可能中央靜脈點滴輸注。
 - 起始劑量：5mg/kg 溶解於等張葡萄糖溶液中。輸注時間：20 min~2 hr，2~3 次/24hr。若可能的話，請使用電動注射器。
 - 維持劑量：10~20 mg / kg/ day(通常 600~800 mg/24hr，至多 1.2g/24hr)，配以 250ml 葡萄糖溶液，輸注數天。應由輸注之第一日開始以口服給藥取代治療，一天三錠，劑量可增至每天四錠或甚至五錠。

不良反應： 低血壓、心跳徐緩、光敏感、皮膚色素沉著、便秘、食慾減低、噁心、嘔吐、關節痛等。

交互作用：

- **Fentanyl**: may result in cardiac toxicity (low cardiac output) and ↑ risk of fentanyl toxicity (CNS depression, respiratory depression).
- **Colchicine**: ↑ colchicine plasma concentrations and risk of colchicine toxicity.
- **Fluconazole**, ketoconazole, isoniazid, ritonavir: ↑ amiodarone exposure and risk of cardiotoxicity (QT prolongation, torsades de pointes, cardiac arrest).
- **STATINs**: ↑ exposure to statins and risk of myopathy or rhabdomyolysis.
- **Digoxin**: digoxin toxicity (nausea, vomiting, cardiac arrhythmias) and potentiated effects of amiodarone.
- **Rifampin**: ↓ amiodarone exposure and reduced efficacy.
- **Cisapride**; fluoroquinolones: ↑ risk of QT-interval prolongation.
- **Azithromycin**, clarithromycin, erythromycin: ↑ risk of cardiotoxicity (QT prolongation, torsades de pointes, cardiac arrest).
- **Grapefruit juice**: ↑ amiodarone exposure.

注意事項：

- 投與 amiodarone 前最好先測甲狀腺功能及甲狀腺抗體；用藥 3 個月後再測一次甲狀腺功能。若甲狀腺功能正常，則每 3 至 6 個月測一次 TSH 和 free T4 即可。Amiodarone 化學結構類似 thyroxine，含有高量的碘，但並非每個服用者都會出現甲狀腺功能異常。
- 葡萄柚汁與本藥可能發生交互作用，應避免以葡萄柚汁送服。
- 含 DEHP (di(2-ethylhexyl)phthalate) 的 PVC 容器或醫療器材，amiodarone 注射液的存在**可能會導致 DEHP 成分釋出**(因 amiodarone 注射液含有界面活性劑 polysorbate 80 100 mg/mL，會使塑化劑 DEHP 由 PVC 容器及 IV set 滲漏，滲漏程度與界面活性劑濃度、軟袋大小、接觸時間及濃度成正比)。
- 為降低病人暴露在 DEHP 下之危險，**建議在製備 amiodarone 注射液時應以 D5W 稀釋**，並使用不含 DEHP 的裝置，如玻璃瓶或 polyolefin 材質容器。
- 請勿將任何其他產品加入注射針筒中或輸注液。

懷 孕 期：禁用於孕婦。超過懷孕第一期後，本藥所造成碘過量可能會導致生物學上或臨床上(甲狀腺腫)的胎兒甲狀腺官能不足。本品禁用於懷孕之第二期及第三期。

授 乳 期：禁用於授乳婦。Amiodarone、其代謝產物和碘均會分泌於乳汁中，且其乳汁中的藥品濃度高於母親的血漿濃度。由於對新生兒有引起甲狀腺官能不足的危險，故本藥禁用於授乳婦。

配 製：1. **只能使用 D5W 稀釋**，若濃度低於 600 mg/L (即 2 安瓿溶於 500 mL 稀釋液)，則不可使用。
2. 勿將任何其他產品加入於已配製完成之輸注溶液。

相容輸注液：D5W。