

## Amikacin Sulfate

【IAMIK】 Acemycin® 500mg/2mL/Vial

ATC Code : J01GB06

中文名：時欣黴素注射液 《永信》

適應症：對 gentamicin 具耐藥性之綠膿菌、變形菌、鋸桿菌、大腸菌、克雷白氏桿菌、腸內桿菌、檸檬桿菌屬 Citrobacter 等對於 amikacin 具敏感性之細菌所引起之下列感染症：敗血症、支氣管擴張症之感染症、肺炎、肺化膿症、腹膜炎、腎盂腎炎、膀胱炎、尿道炎、創傷、熱傷及手術後之繼發性感染症。

藥理分類：Antibiotic, Aminoglycoside.

用法用量：**Administration:** Administer by IV infusion or IM injection.

- In adults and older children, administer by IV infusion over 30- 60 minutes.
- In infants, administer by IV infusion over 1-2 hours.

### Indications and dosage regimens:

#### Usual adults and adolescent dose:

— 5 mg/kg Q8H; or 7.5 mg/kg Q12H for 7-10 days. Up to 15 mg/kg/day, but not to exceed 1.5 g/day for more than 10 days.

#### Urinary tract infections, bacterial (uncomplicated):

250 mg Q12H.

Following hemodialysis, a supplemental dose of 3-5 mg/kg may be administered.

#### Conventional/traditional dosing:

#### Amikacin Dose Adjustments for Altered Kidney Function in Adults

CrCl (mL/minute)	If the usual indication-specific dose is 7.5 mg/kg every 12 hours or 5 mg/kg every 8 hours
≥60	No dosage adjustment necessary.
40 to <60	5 to 7.5 mg/kg every 12 hours.
20 to <40	5 to 7.5 mg/kg every 24 hours.
<20	5 to 7.5 mg/kg once; subsequent doses should be based on amikacin serum concentrations.

※ There are no dosage adjustments provided in the manufacturer's labeling.

#### Usual pediatric dose:

— Premature neonates:

Initially, 10 mg/kg, then 7.5 mg/kg every 18 to 24 hours for 7-10 days.

— Neonates:

Initially, 10 mg/kg, then 7.5 mg/kg Q12H for 7-10 days.

— Older infants and children:

See usual adults and adolescents dose

#### 一級互斥：

- Aminoglycosides 與 loop diuretics (如 furosemide)這兩類藥品分別都具有耳毒性，當兩者並用時可能因此發生聽覺毒性加重的協同(synergistic)作用，而造成程度不一的聽覺傷害，甚至永久性的聽力喪失。
- 如臨床確認有併用之必要時，應嚴格控制劑量並於治療前對聽力進行基準測驗，治療過程中定期監測聽力變化情形及 aminoglycoside 的血中濃度。
- 腎功能不全病人，應適度調降劑量，以避免增加聽覺毒性發生的機率。

## 注意事項：

- 1、應避免與 beta-lactam (如 cephalosporins、penicillins)混合於注射劑中使用，因會使 aminoglycosides 失去活性。建議於 Amikacin 投與前 1 小時或投與後 1 小時，給與 beta-lactams。
- 2、為避免其副作用與之產生，應監測其血中濃度。其有效治療範圍為：最大 peak 濃度 35 mcg/mL，最大 trough 濃度 5 mcg/mL。
- 3、具腎毒性及耳毒性；耳毒性包括前庭與聽神經的損傷，特別是使用超過 2 星期的病人應特別小心。
- 4、對於疑似或已知腎機能障礙患者之建議給藥時間間隔（以小時為單位）如下：以病患的 serum creatinine 值乘以「9」（例如，病患的 serum creatinine 值為 2 mg/dL，則其投藥間隔時間為  $2 \times 9 = 18$  小時）。

## 懷孕期：

1. Amikacin crosses the placenta.

Aminoglycosides may cause fetal harm if administered to a pregnant woman.

There are several reports of total irreversible bilateral congenital deafness in children whose mothers received a different aminoglycoside (streptomycin) during pregnancy.

2. Amikacin may be one of the preferred antibiotics when an aminoglycoside is needed for multidrug resistant TB in pregnancy (*HHS /OI/ 2018*).

## 授乳期：

1. Amikacin 會分泌至母乳中，應小心使用。

2. Aminoglycosides have **poor oral bioavailability** and therefore use may be considered in breastfeeding women following maternal injection (*Panchaud 2016*)

## 配製：

可用 NS、D5W、lactated Ringer's 或 lactated Ringer's with 5% dextrose 調配成濃度為 2.5-5 mg/mL 之溶液。

## 安定性：

配製後溶液於室溫下可維持 24 小時安定。

## 相容輸注液：

D5W、NS、1/2NS、Ringer's inj.、Lactated Ringer's、Dextrose 5% -saline combinations、Dextrose 5% in Ringer's inj.、Dextrose 5% in Lactated Ringer's。

## 備註：

The following dosing chart by Sarubbi and Hull (*Ann Intern Med 1978; 89: 612-8*) may be used to provide the clinician with an initial loading dose and maintenance dosage regimen in adult patients.

1. Select loading dose in mg/kg (IBW) to provide peak serum levels in the range listed below for the desired aminoglycoside.

Table 1.

Aminoglycoside	Usual loading dose (mg/kg)	Expected peak serum level (mg/L)
Amikacin / Kanamycin	5-7.5	15-30
Centamicin / Tobramycin	1.5-2	4-10
Netilmicin	1.3-3.25	4-12

2. Select maintenance dose (as % of chosen loading dose) to maintain peak serum concentrations indicated above according to desired dosing interval and the patient's corrected creatinine clearance. This chart is not applicable to neonates and children.

Clcr (mL/min)	Half-life (hr)	Percentage of Loading Dose Required for Dosage interval Selected		
		8 hours	12 hours	24 hours
90	3.1	84 %	-	-
80	3.4	80	91 %	-
70	3.9	76	88	-
60	4.5	71	84	-

50	5.3	75	79	-
40	6.5	57	72	92 %
30	8.4	48	63	86
25	9.9	43	57	81
20	11.9	37	50	75
17	13.6	33	46	70
15	15.1	31	42	67
12	17.9	27	37	61
10*	20.4	24	34	56
7	25.9	19	28	47
5	31.5	16	23	41
2	46.8	11	16	30
0	69.3	8	11	21

\*Dosing for patients with Clcr < 10 mL/min should be assisted by measured serum levels.