Acyclovir

【OACY】Acylete® 200mg/Tab *ATC Code：J05AB01*

中文名： 敵疱治錠 «中化»

適應症： 帶狀疱疹病毒引起之感染、單純疱疹病毒引起之皮膚及粘膜感染、預防骨髓移植及白血病所引起之免疫不全病人之單純疱疹感染、復發性單純疱疹感染之抑制。

藥理分類： **Antiviral Agent.**

用法用量： **Administration:** Administer without regard to meals.

Indications and Dosage regimens:

Treatment of initial and recurrent herpes simplex infections of the skin and mucous membranes:

- 200 mg Q4H, 5 doses/day (omitting the night-time dose).
- Treatment should continue for **5 days**, but in a case of severe initial infection, may have to be extended.

In severely immunocompromised patients (e.g. after marrow transplant) or in patients with impaired absorption from the gut:

- **400** mg Q4H, 5 doses/day (omitting the night-time dose). or, alternatively, **intravenous dosing** could be considered.

For suppression of recurrent genital herpes simplex infections in immunocompetent adults:

- 200 mg Q6H or 400 mg Q12H.
- Dosage titration: may down to 200 mg Q8H, or 200mg Q12H.
- Therapy should be interrupted periodically at intervals of six to twelve months, in order to observe possible changes in the natural history of the disease.

For prophylaxis of herpes simplex infections in immunocompromised adults:

- 200 mg Q6H.
- In severely immunocompromised patients (e.g. after marrow transplant) or in patients with impaired absorption from the gut, the dose can be **doubled** to 400 mg, or alternatively **intravenous** dosing could be considered.
- The duration of prophylactic administration is determined by the duration of the period at risk.

For treatment of varicella-zoster infections in adolescents (12 to 18 years):

A dose of **800** mg should be taken **four** times daily for five days.

For treatment of varicella-zoster and herpes zoster infections in adults:

- **800 mg Q4H**, **5** doses/day (omitting the night-time dose) x7 **seven days**.
- In severely immunocompromised patients (e.g. after marrow transplant) or in patients with impaired absorption from the gut: **intravenous** dosing.
- Dosing should begin as early as possible after the start of an infection: treatment yields better results if initiated as soon as possible after rash onset.

Dosage for management of severely immunocompromised patients:

- **800** mg Q6H.
- In the management of **bone marrow recipients** this would be preceded by up to one month's therapy with **intravenous** acyclovir 500 mg/m^2 three

times daily.

- The duration of treatment studied in **bone marrow transplant** patients was **6 months** (from 1 to 7 months post-transplant). In patients with advanced HIV disease, study treatment was 12 months.

Varicella (chickenpox), treatment:

- Ideally initiate therapy within 24 hours of symptom onset, but may start later if the patient still has active lesions:
- **Immunocompetent patients** with uncomplicated infection:
  800 mg 5 times daily for ≥5 to 7 days and until all lesions have crusted.
- **Immunocompromised patients** (including patients with HIV):
  Uncomplicated infection:
  800 mg 5 times daily for 5 to 7 days; some experts recommend a minimum duration of 7 days, extending the course until all lesions have crusted.

Dosage in renal impairment:
Caution is advised when administering acyclovir to patients with impaired renal function. Adequate hydration should be maintained.

Table. Oral Dosage in Renal Impairment

Usual Dosage Regimen	Clcr (mL/min)	Adjusted Dosage Regimen
200 mg Q4h 5 times daily	> 10	No adjustment necessary
	0-10	200 mg every 12 hours
400 mg Q12h	> 10	No adjustment necessary
	0-10	200 mg every 12 hours
800 mg Q4h 5 times daily	> 25	No adjustment necessary
	10-25	800 mg every 8 hours
	0-10	800mg every 12 hours

－Hemodialysis:
An additional dose is recommended after each dialysis (a 6-hour dialysis session removes 60% of drug).
－Peritoneal dialysis:
No supplemental dose is recommended.

不良反應： 口服治療－噁心、嘔吐、腹瀉；IV 治療－注射部位局部反應。

交互作用：

1. **BUPROPION**: ↑ risk of seizures.
2. **LEFLUNOMIDE**: ↑ exposure of acyclovir.
3. **TENOFOVIR** ALAFENAMIDE: ↑ tenofovir alafenamide exposure and and ↑ risk of tenofovir alafenamide-related adverse effects.

注意事項： 使用於腎功能不全之患者時須降低劑量。

1.**治療成人單純性疱疹的劑量**：

- 治療單純性疱疹感染時，應以 4 小時的間隔，每日服用 5 次每次 200mg，夜晚時的一次可略去。治療應持續 5 天，但嚴重的初次感染，可能需治療較久。
- 嚴重免疫不全患者(如骨髓移植後)或是胃腸吸收不良的患者，可將劑量加倍為 400mg 或考慮間歇性的使用靜脈投藥。應在感染發生後，儘速開

始投藥；復發的患者，最好在前驅期或是傷口一出現時，即開始投藥。

2.**抑制成人單純性疱疹復發的劑量：**

- 用於抑制免疫機能健全患者之單純性疱疹復發時，應以 6 小時的間隔，每日使用 4 次每次 200mg。
- 有許多患者，以 12 小時的間隔，每日使用二次每次 400mg，就可以很方便的控制病情。有些患者可以每 8 小時服用一次每次 200mg，一天服用三次，或甚至每 12 小 時一次，一天服用二次就足夠了。有些患者，在每日使用 800mg，還會有復發的情形。
- 每次治療約 6~12 個月應中斷，以觀察疾病有無任何的變化。

3.**預防成人單純性疱疹的劑量：**

- 用於預防免疫不全患者發生單純性疱疹感染時，應以 6 小時的間隔，每天使用 4 次每次 200mg。
- 嚴重的免疫不全患者(如骨髓移植之後)或是患有胃腸吸收不好時，可以將劑量加倍到 400mg 或是考慮輪流的以靜脈給藥。預防性的投藥持續期間應視患者危險期的長短而定。

4.**治療成人帶狀疱疹的劑量：**

- 治療帶狀疱疹感染時，應以 4 小時的間隔，每日投予 5 次每次 800mg，夜晚的一次略去。治療應持續 7 天。
- 嚴重免疫不全患者(如骨髓移植之後)或是患者胃腸吸收不好時，應考慮靜脈注射給藥。應在感染一發生時，即開始給藥；如果在皮疹發生時，即儘早開始給藥，可得到最好的治療效果。

5. **腎功能不全時之劑量：**

- 嚴重腎功能不全的患者(Creatinine 廓清率少於 10ml/min)，建議調整其劑量為每日 2 次，每次 200mg，投藥間隔 12 小時。
- 治療**帶狀疱疹感染**時，若有嚴重腎衰竭的患者(Creatinine 廓清率少於 10ml/min)，建議調整其劑量為每日 2 次，每次 800mg，投藥間隔 12 小時；中度腎功能不全的患者(Creatinine 廓清率約在 10-25ml/min) ，建議每 6-8 小時，投予 800mg，每日 3-4 次。

懷 孕 期： 1. Acyclovir has been shown to cross the human placenta.
2. Acyclovir is recommended for the treatment of genital herpes in pregnant patients.
3. The manufacturer recommends **using during pregnancy with caution and only when clearly needed.**

授 乳 期： 1. Acyclovir is present in breast milk.
2. Acyclovir is considered compatible with breastfeeding (WHO 2002). Acyclovir may be used for the treatment of genital herpes in breastfeeding women.
3.The manufacturer recommends that **caution be exercised when administering acyclovir to breastfeeding women**.。

安 定 性： 於 25℃以下室溫儲存。