

Sulfasalazine

【OSALZ】 Salazine® 500mg/Tab

ATC Code : A07EC01

中文名：撒樂腸溶錠 «信東»

適應症：潰瘍性結腸炎(ulcerative colitis)、Crohn's disease、類風濕性關節炎(rheumatoid arthritis)。

藥理分類：**5-Aminosalicylic Acid Derivative.**

用法用量：**Administration:** orally, preferably after meals. The enteric coated tablets **should not** be crushed or broken.

Maintain adequate fluid intake to prevent crystalluria and stone formation.

Indications and dosage regimens:

Inflammatory Bowel Diseases:

— Adults:

Initial dosage is 3-4 g/day given in equally divided doses; interval between doses should not exceed 8 hours. Usual maintenance dosage is 2 g/day in 4 divided doses.

— Children \geq 6 yrs:

Initially, 40-60 mg/kg/day in 3-6 divided doses; maintenance, 30 mg/kg/day in 4 divided doses. Interval between doses should not exceed 8 hours.

Rheumatoid arthritis in adults:

Dosage titration: **Week 1**, 500 mg evening dose; **week 2**, 500 mg twice daily; **week 3**, 500 mg in the morning then 1 g in the evening; **week 4**, 1 g twice daily.

Maintenance dosage: 2 g/day in 2 evenly divided doses; may increase up to 3 g/day if inadequate clinical response after 12 weeks of therapy.

不良反應：噁心、食慾不振、體溫上升、紅斑、癢、頭痛。尿液呈現黃橘色。

交互作用

- NSAIDs, salicylates: ↑ risk of bleeding.
- Amoxicillin: ↑ risk of drug reaction with eosinophilia and systemic symptoms.
- Leflunomide: ↑ exposure of sulfasalazine substrate.
- Azathioprine and metabolites : ↑ risk of bone marrow suppression.

注意事項：1.腸溶錠須整粒吞服，不可嚼碎。可與食物併服。
2.每日投與劑量超過 2 g 者，應小心監控其療效與毒性。
3.肝、腎功能不良者應小心使用，且應定期檢查肝功能及尿液。
4.目前尚無足夠之資料可建議幼年型慢性關節炎(juvenile chronic arthritis)之劑量。(仿單)
5.本品會降低 digoxin 吸收、抑制 folate 之吸收。
6.G-6-PD 缺乏者須監測是否發生溶血性貧血。

懷 孕 期：1.長期之臨床研究及使用顯示無任何致畸胎性與 Sulfasalazine 有關聯。
2.Although sulfapyridine has poor bilirubin-displacing ability, a potential for kernicterus in the newborn exists.

授 乳 期：1.進入乳汁之量極少，而其代謝物 sulfapyridine 分泌至乳汁之濃度約為血中濃度的 40%，治療劑量下哺乳幼兒見產生核質性黃疸(kernicterus)之危險性很低。

2. Some guidelines consider sulfasalazine compatible if breastfeeding **full-term** healthy infants (*Flint 2016; Huang 2014; Mahadevan 2015*), while others recommend caution (*Habal 2012*) or avoiding use (*WHO 2002*).

3. Breastfeeding during therapy should be avoided if the infant is **premature**, ill, has hyperbilirubinemia, or G-6-PD deficiency. Infants should be monitored for diarrhea.