**新藥上線相關資料規格範例**

**2019.08 修訂**

**一、藥品手冊內容**

1. 請以英文撰寫以下藥品手冊資料內容，因資料庫欄位容量有限，請不要超過4頁，並將完成電子檔案直接寄至 tcvghtc.pt@vghtc.gov.tw ，撰寫上如有疑問，請致電04-23592525轉4639廖婕羽藥師。
2. 有特殊使用方法之藥品如：吸入劑、筆針等，請檢附**中文衛教單張說明**或**操作影片**。

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| **藥品手冊欄位** | **資料內容** |
| **英文商品名** | Sevatrim Inj 5ml |
| **中文商品名** | 雪白淨注射液 |
| **成分規格** | Inj. Trimethoprim 80 mg+,Sulfamethoxazole 400 mg/amp |

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| **藥品手冊欄位** | **資料內容** (支援表格、字形色彩、粗體、超連結) |
| **Indication**適應症 | Treatment of UTI due to Escherichia coli, Klebsiella and Enterobacter sp, Morganella morganii, Proteus mirabilis and Proteus vulgaris; acute otitis media; acute exacerbations of COPD due to susceptible strains of Haemophilus influenzae or Streptococcus pneumoniae; treatment and prophylaxis of Pneumocystis pneumonia (PCP); traveler's diarrhea due to enterotoxigenic E. coli; treatment of Shigellosis caused by Shigella flexneri or Shigella sonnei.由革蘭氏陽性菌及陰性菌所引起之呼吸道、胃腸道及尿道感染。(補上TFDA中文適應症) |
| **Pharmacology**藥理 | Sulfamethoxazole(SMX ) interferes with bacterial folic acid synthesis and growth via inhibition of dihydrofolic acid formation from para-aminobenzoic acid; trimethoprim(TMP ) inhibits dihydrofolic acid reduction to tetrahydrofolate resulting in sequential inhibition of enzymes of the folic acid pathway. |
| **Pharmacokinetics**藥動 | Absorption: Rapid; almost completely (90% to 100%); Excretion: Both are excreted in urine as metabolites and unchanged drug; Elimination half-life: SMX: 9 to 12 hrs, prolonged in renal failure; TMP: Adults: 6 to 11 hrs, Prolonged in renal failure. |
| **Contraindication**禁忌症 | Hypersensitivity to any sulfa drug, trimethoprim, or any component of the formulation; history of drug induced-immune thrombocytopenia with use of sulfonamides or trimethoprim; megaloblastic anemia due to folate deficiency; infants <2 months (manufacturer's labeling), infants <4 weeks (CDC 2009); marked hepatic damage or severe renal disease (if patient not monitored); concomitant administration with dofetilide. Pregnancy, lactation. |
| **Pregnancy risk category**懷孕分類 | C |
| **Breast milk feeding**哺乳分類 | Sulfamethoxazole and trimethoprim are excreted in breast milk. |
| **Adverse effect**副作用 | Agranulocytosis, aplastic and megaloblastic anemia, nausea, erythema multiforme, headache, and mental depression. |
| **Dosage and Administration**劑量和給藥方法 | **IV for *P. jiroveci* pneumonia (PCP)**: 15-20 mg/kg/day of TMP and 75 mg-100 mg/kg/day of SMZ in 2-4 equally divided doses for 21 days. |
| **Pediatric Dosage** 小兒調整劑量 | Infants ≥2 months of age, Children, and Adolescents: Oral, IV: 6 to 12 mg TMP/kg/day in divided doses every 12 hours; maximum single dose: 160 mg TMP/dose . |
| **Dosing in renal impairment**腎功能調整劑量 | The following dosage adjustments are based on a usual maintenance dose of 4 to 5 mg TMP/kg every 6 hours.

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| GFR 10 to 50 mL/min | 4 to 5 mg TMP/kg every 12 hours |
| GFR <10 mL/min: | Avoid use; if necessary, 2.5 to 5 mg TMP/kg every 24 hours |
| Hemodialysis: | 2.5 to 5 mg TMP/kg every 24 hours (dose after hemodialysis on dialysis days) |

***Pneumocystis* pneumonia (PCP), treatment**: **Note:** Renal function may be estimated using the Cockcroft-Gault formula for dosage adjustment purposes. The following dosage adjustments are based on a usual maintenance dose of 5 mg TMP/kg every 8 hours.

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| CrCl 10 to 30 mL/min | 5 mg TMP/kg every 12 hours |
| CrCl <10 mL/min | 5 mg TMP/kg every 24 hours |
| Hemodialysis: | 5 mg TMP/kg once daily (dose after hemodialysis on dialysis days); consider therapeutic drug monitoring to optimize therapy |

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| **Dosing in hepatic impairment**肝功能調整劑量 | Use with caution; use is contraindicated in cases of marked hepatic damage. |
| 注意事項 | 1. 在G-6-PD 缺乏的病人可能會發生溶血症。
2. 應避免投與已知或疑似為紫質症危險群之病人，trimethoprim 和sulphonamides 可能使紫質惡化。
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| 藥物安定性 | (儲存方式、冷藏藥品室溫安定性、泡製後安定性…等) |
| 磨粉建議 | (不建議磨粉藥品須填寫，可註明詳細原因，管灌說明也可以放在此) |
| 其他 | (其他藥品相關資訊) |
| **Supply**規格 | Inj. Trimethoprim 80 mg+,Sulfamethoxazole 400 mg/amp |

**注射給藥指引 (注射劑型須填寫)**

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| **藥品手冊欄位** | **資料內容** (只有注意事項支援表格、字形色彩、粗體、超連結) |
| 給藥途徑 | IV |
| 靜脈輸注液 | D5W, D10W, N/S(仿單) |
| 每瓶稀釋液體積 | (需泡製的劑型如凍晶乾粉) |
| 給藥濃度 | 1 amp in 125 ml；1 amp in 75ml (限水者) |
| 給藥速率 | 60-90 mins |
| 安定性 |

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| 配製後(室溫) | 配製後(冷藏) | 進一步稀釋後(室溫) | 進一步稀釋後(冷藏) |
|  |  | 6 hrs |  |

(配製後：需泡製的劑型，於原瓶內之安定性；進一步稀釋後：稀釋至點滴安定性) |
| 注意事項 | 1.最好以D5W稀釋，稀釋後須於 6 hrs內用完。(Micromedex)2.不可以和其他藥物混合給藥 |

**民眾用藥指導單張 (請以淺顯易懂字眼填寫)**

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| **藥品手冊欄位** | **資料內容** (支援表格、字形色彩、粗體、超連結) |
| 臨床用途 | 退燒、止痛（頭痛、牙痛、咽喉痛、關節痛、神經痛、肌肉酸痛、月經痛） |
| 主要副作用 | 1. 可能產生噁心、嘔吐、食慾不振等副作用。
2. 當您發生下列少見症狀時，請停藥並馬上和醫師聯絡：皮膚發疹、蕁痲疹或搔癢、不明原因喉嚨痛發燒或異常之流血或瘀血、異常疲倦或虛弱、皮膚或眼睛變黃、腹瀉、上腹部脹痛、濁尿，尿液突然變少等。
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| 用藥須知 | 1. 服藥前告知您的醫師或藥師，您正在服用的藥品，尤其是抗癲癇藥物（如Carbamazepine、Phenobarbital、Phenytoin）、抗肺結核藥物（如Isoniazide、Rifampin）、高尿酸血症治療劑（Sulfinpyrazone）、維他命等。
2. 如果您有肝臟疾病、嚴重腎功能不良請先告訴您的醫師或藥師。
3. 如果您每天喝三杯或更多酒精性飲料，詢問您的醫師或藥師您是否適合使用Acetaminophen。
4. 建議您服用acetaminophen，小孩勿超過五天，成人勿超過十天，除非醫師特別交代，因長期服用或大於規定劑量可能造成肝損害。
5. 小孩在24小時內不要使用超過5次藥物，除非醫師有特別交代。
6. 自行購買感冒藥、止痛藥時，請告訴藥師您正在服用acetaminophen。
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| 如何正確用藥  | 1. 請確實依照醫師處方的用法與用量服藥。
2. 如果您必須按時服用acetaminophen，當忘記服藥時應立即補吃。若已經接近下一次服用時間，就不需補吃，並於下一次正確的時間服用一次的藥量。請不要服用雙倍的量，以免過量可能發生危險。
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| 如何保存藥品  | 1. 請維持藥品原來的包裝，避免放在兒童可以拿到的地方。
2. 請在室溫下保存，避免放在潮濕、過熱或陽光直曬的環境下。
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**二、藥品一級交互作用範例**

**(可參考Drug Interaction Facts**, **Lexicomp, Micromedex)**

請撰寫以下交互作用各項目資料，並將完成電子檔案直接寄至 tcvghtc.pt@vghtc.gov.tw ，撰寫上如有疑問，請致電04-23592525轉4639廖婕羽藥師。

**藥名**：PHENYTOIN

**等級:** 1

**onset:** Delay

**嚴重度:** 嚴重

**可信度:** Probable

**會產生一級交互作用藥品:**
CICLOSPORIN  、 CICLOSPORINE

**Effects:**
CYCLOSPORINE concentrations are decreased by PHENYTOIN, resulting in a decrease in the immunosuppressive activity of CYCLOSPORINE, which may predispose patients to transplant rejection. This appears to occur within 48 hours of PHENYTOIN therapy and abates within 1 week of PHENYTOIN discontinuation.

**Management:**
Closely monitor CYCLOSPORINE concentrations during concurrent PHENYTOIN administration; tailor CYCLOSPORINE dosage to maintain concentrations in the therapeutic range.

**Mechanism:**
Possibly decreased CYCLOSPORINE absorption or increased metabolism.

**Discussion:**
In a controlled study of six subjects, the mean cyclosporine area under the plasma concentration-time curve (AUC) was reduced ？ 50% after 9 days of phenytoin dosing.2 These reductions were observed regardless of the assay (RIA polyclonal or HPLC) or sample matrix (serum or whole blood)utilized. Similar reductions were also observed in the concentrations of two of the cyclosporine metabolites. Little change was observed in the cyclosporine/metabolite ratios or in the terminal slope following phenytoin therapy compared with cyclosporine alone, suggesting that the observed decrease in cyclosporine concentrations with phenytoin is most likely the result of a decrease in absorption.4 However, in a separate report, a similar decrease in cyclosporine concentrations was observed in one patient receiving IV cyclosporine.3 A 50% reduction in cyclosporine AUC occurred in five patients following phenytoin therapy; the interaction was not present within 72 hours of phenytoin discontinuation.1 There was no evidence of graft rejection. It does not appear that separation of the administration times of cyclosporine and phenytoin will circumvent this interaction.

**Ref items:** 請註明參考

**三、藥品照片規格**

1. 藥品裸錠及外觀不能有陰影，存檔格式：**\*.jpg**，**請勿將照片轉貼在WORD檔**。
2. 請將完成電子檔案直接寄至tcvghtc.pt@vghtc.gov.tw ，照片製作如有疑問，請電04-23592525轉4640二醫藥局林逸銘藥師。

**底色：** R60

# G160

B190

**裸錠：** 檔案大小約200K

 寬：8 cm高：6 cm

 解析度：300 dpi/inch

裸錠大小與標尺刻度一樣

**針劑、瓶裝：**

檔案大小約：200~500K 解析度：300 dpi/inch

寬：8 cm高：12 cm 藥品盡量滿版 外包裝上字體清楚

 

**片裝、外盒包裝**

檔案大小約：200~500K 解析度：300 dpi/inch

寬：8 cm高：8 cm 藥品盡量滿版 外包裝上字體清楚

 