

## 認識TERIFLUNOMIDE (特立氟胺)

每日一粒，適用於復發-緩解型多發性硬化症<sup>1</sup>

### 參考資料：

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本小冊子僅供參考，並不能取代醫生的專業意見，亦不能成為自我診斷或選擇治療的依據，  
只有醫生方能鑑別病位，並提供適當的治療。



# 甚麼是多發性硬化症？

## 認識多發性硬化症<sup>2,3</sup>

- 多發性硬化症(multiple sclerosis, MS)是一種慢性而且難以預測的疾病
- 它影響大腦及脊髓，這些區域統稱為中樞神經系統(central nervous system, CNS)
- 它被認為是一種自體免疫性疾病，即人體的免疫系統錯誤地攻擊自己身體的細胞、組織及器官
- 多發性硬化症會導致髓鞘質發炎及退化，髓鞘質是脂肪外罩，包圍及保護中樞神經系統的神經纖維
- 當髓鞘質受損或被破壞，神經的電脈衝傳導會被中斷，相當於接線錯誤
- 在多發性硬化症中，發炎可導致多個地方的髓鞘質脫失，留下的疤痕組織稱為硬化

## 多發性硬化症的常見症狀<sup>2,3</sup>

- 走路困難或肌肉協調不佳
- 視力受損
- 膀胱及腸道功能問題
- 虛弱或疲勞
- 麻痺及刺痛

最常見的多發性硬化症為「復發-緩解型多發性硬化症」(relapsing-remitting multiple sclerosis, RRMS)，約85%的初次診斷患者均為此類型。患有此疾病的人會週期性發作或「惡化」，也就是在症狀部份或全部消失之後又再度出現(即「復發」)。<sup>4</sup>



## TERIFLUNOMIDE簡介

### 關於teriflunomide<sup>1,5</sup>

- teriflunomide是用於治療復發-緩解型多發性硬化症的口服藥物
- teriflunomide是一粒細小的口服藥片，每片劑量為14毫克
- 患者可於每天任何時間服用，空腹或飽肚均可
- 毋須冷藏或調配
- 毋須校藥



## TERIFLUNOMIDE如何發揮作用？

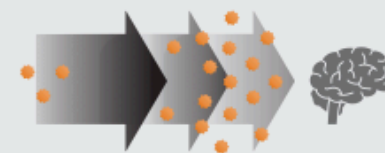
### teriflunomide幫助對抗過度活躍的免疫細胞，保護神經系統

- 在多發性硬化症患者體內，過度活躍的免疫細胞迅速複製，然後經血液抵達腦部，攻擊神經系統<sup>6</sup>
- teriflunomide主要用於抑制過度活躍免疫細胞複製時所需要的酵素<sup>6</sup>，從而減少過度活躍細胞的數量<sup>1</sup>
- teriflunomide不會影響正常免疫細胞，保持自體免疫力<sup>6</sup>

### teriflunomide在身體的運作機理

#### 沒有接受治療

- 過度活躍的免疫細胞  
攻擊中樞神經系統



#### 接受teriflunomide治療

- 產生較少免疫細胞攻擊  
中樞神經系統





## TERIFLUNOMIDE可帶來甚麼幫助？

teriflunomide證實可減慢多發性硬化症惡化的速度

teriflunomide能幫助患者維持現有身體機能



持續服用2年teriflunomide(14毫克)

**80%**

患者身體機能

**持續三個月沒有惡化**

服用安慰劑的有73%<sup>1</sup>

teriflunomide可減少復發率及復發的嚴重程度<sup>1,7</sup>



持續服用2年teriflunomide(14毫克)

患者平均每3年才復發一次<sup>1</sup>

**56%**

患者

**沒有出現復發**

服用安慰劑的有46%<sup>1</sup>

透過磁力共振(MRI)診斷teriflunomide能減少新形成的腦部損傷<sup>1,8</sup>



持續服用2年teriflunomide(14毫克)

**64%**

患者在顯影劑(gadolinium)下

**沒有發現腦部損傷**

服用安慰劑的有39%<sup>8</sup>

## TERIFLUNOMIDE的安全性如何？

teriflunomide(14毫克)的安全性共獲得4個臨床研究支持，  
超過2,200名患者參與<sup>1</sup>

- 常見副作用包括<sup>1</sup>：
  - 腹瀉及噁心
  - 肝酵素(ALT)上升
  - 頭髮變薄或頭髮密度減少，或可能影響頭髮髮質
- 頭髮變薄或變少、腹瀉及噁心乃是短暫性的，程度介乎輕微至中等，患者甚少需因此中斷治療<sup>1</sup>
- 服用teriflunomide(14毫克)的患者出現肝酵素急劇上升的發生率，與服用安慰劑的患者相近<sup>1</sup>

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➔ teriflunomide的藥物說明書列載  
最新藥物副作用的概覽<sup>1</sup>

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## 在接受TERIFLUNOMIDE治療前需要留意甚麼？

### 接受teriflunomide治療前需進行基本檢查<sup>1</sup>

- 任何具生育能力的女性需確定沒有懷孕及沒有計劃懷孕
- 量度血壓
- 量度肝酵素水平(ALT)
- 血球數量檢查(complete blood cell count)，包括白血球分類數值及血小板數量

## 服用TERIFLUNOMIDE需接受哪些監察？

### 服用teriflunomide需接受一般的常規監察

#### 當展開teriflunomide治療後，患者需要接受以下監察<sup>1</sup>

- 在首6個月的teriflunomide治療期間，需每2星期檢查肝酵素水平
  - 此後則每8星期檢查一次，或視乎病徵而定
- 治療期間需定期量度血壓
- 視乎病徵及實際情況而決定是否需要進行血球數量檢查



## 常見問題

### 問：如何服食及貯存teriflunomide？

答：建議每天服用一粒teriflunomide(14毫克)，服用時間不限，空腹或飽肚服用均可。teriflunomide毋須冷藏，可放置於室溫中，方便隨身攜帶，甚至無礙出國旅行。<sup>1,5</sup>

### 問：哪些人不適宜服用teriflunomide呢？

答：以下人士不適宜服用teriflunomide<sup>1</sup>

- 對特立氟胺(teriflunomide)或AUBAGIO®內其他物質過敏的人士
- 嚴重肝病患者
- 孕婦、授乳婦女或正值生育年齡卻沒有進行安全避孕措施的女士
- 嚴重免疫力不足、骨髓功能不足、血球數量不足或正處於發炎期間的患者
- 正接受透析治療或患有低蛋白血症的腎病患者

### 問：正值生育年齡的女性能否接受teriflunomide治療呢？

答：可以，只需採取安全可靠的避孕措施，避免在teriflunomide治療期間懷孕便可。倘若在治療期間懷疑懷有身孕，請立即通知醫生。醫生可連續11天處方膽酸解松脂(cholestyramine)或活性碳，為已懷孕或打算懷孕的女性，迅速把teriflunomide排出體外。<sup>1</sup>

## TERIFLUNOMIDE藥物說明簡要

**Presentation:** teriflunomide film-coated tablet.

**Indication:** Treatment of adult patients with relapsing remitting multiple sclerosis.

**Dosage:** 14mg once daily.

**Contraindications:** Hypersensitivity to the active substance or excipients. Severe hepatic impairment (Child-Pugh class C). Pregnancy and lactation. Patients with severe immunodeficiency states, e.g. AIDS. Patients with significantly impaired bone marrow function or significant anaemia, leucopenia, neutropenia or thrombocytopenia. Patients with severe active infection. Patients with severe renal impairment undergoing dialysis. Patients with severe hypoproteinaemia, e.g. nephrotic syndrome.

**Precautions:** Blood pressure, ALG/SGPT and complete blood cell counts should be monitored before and during treatment. Liver enzymes should be assessed before initiation of therapy - every two weeks during the first 6 months of treatment, and every 8 weeks thereafter or as indicated by clinical signs and symptoms such as unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, or jaundice and/or dark urine. Patients who consume substantial quantity of alcohol. Patients who develop serious infection during treatment. Patients who had a history of interstitial lung disease. Patients with pre-existing anaemia, leucopenia, and/or thrombocytopenia as well as in patients with impaired bone marrow function or those at risk of bone marrow suppression. Use of live attenuated vaccines. Co-administration of teriflunomide with leflunomide. Co-administration with antineoplastic or immunosuppressive therapies. Patients with galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. **Drug Interactions:** Rifampicin and other known potent CYP and transporter inducers such as carbamazepine, phenobarbital, phenytoin and St John's Wort. Cholestyramine or activated charcoal. Medicinal products metabolised by CYP2C8, such as repaglinide, paclitaxel, pioglitazone or rosiglitazone. Oral contraceptives. Medicinal products metabolised by CYP1A2 (such as duloxetine, alosetron, theophylline and tizanidine). Warfarin. Organic anion transporter 3 (OAT3) substrates such as cefaclor, benzylpenicillin, ciprofloxacin, indometacin, ketoprofen, furosemide, cimetidine, methotrexate, zidovudine. BCRP and/or organic anion transporting polypeptide B1 and B3 (OATP1B1/B3) substrates such as methotrexate, topotecan, sulfasalazine, daunorubicin, doxorubicin, statins, nateglinide, repaglinide, rifampicin. **Undesirable Effects:** Influenza, upper respiratory tract infection, urinary tract infection, bronchitis, sinusitis, pharyngitis, cystitis, gastroenteritis viral, oral herpes, tooth infection, laryngitis, tinea pedis. Neutropenia, anaemia, mild allergic reactions, anxiety, paraesthesia, sciatica, carpal tunnel syndrome, hypertension, diarrhoea, nausea, abdominal pain upper, vomiting, toothache, alopecia, rash, acne, musculoskeletal pain, myalgia, pollakiuria, menorrhagia, pain, elevation of hepatic enzymes, weight decrease, neutrophil count decrease, white blood cell count decrease. For uncommon, rare and very rare undesirable effects, please refer to the full prescribing information.

**Preparations:** 14mg x 28's.

**Full prescribing information is available upon request.**

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