

Ezetimibe, Atorvastatin

【OATO】Atozet® 10/20 Tablet

ATC Code : C10BA05

中文名：優泰脂膜衣錠 10/20 毫克 «MSD»

適應症：高膽固醇血症。

主成分：Each Tablet contains: Ezetimibe 10mg, Atorvastatin 20mg

藥理分類：**Antilipemic Agent, 2-Azetidinone; HMG-CoA Reductase Inhibitor.**

用法用量：**Note:** High-intensity statin therapy (atorvastatin 40 to 80 mg/day) generally reduces LDL-C by $\geq 50\%$. Moderate-intensity statin therapy (atorvastatin 10 to 20 mg/day) generally reduces LDL-C by $\sim 30\%$ to 49% . Assess response 1 to 3 months after initiation of therapy or dose adjustment and every 3 to 12 months thereafter.

Administrations:

- 1) Take at least 2 hours before or 4 hours after the administration of **bile acid sequestrants**.
- 2) The tablet should be taken once daily **with or without food** at any time of day.
- 3) Administer the tablet whole and do not crush, dissolve, or chew.

Indications and dosage regimens:

Homozygous familial hypercholesterolemia:

Usual dosage: Ezetimibe 10 mg/atorvastatin 40 mg or ezetimibe 10 mg/atorvastatin 80 mg orally once daily.

Primary hyperlipidemia; Mixed hyperlipidemia:

- a) Initial dosage: Ezetimibe 10 mg/atorvastatin 10 mg or Ezetimibe 10 mg/atorvastatin 20 mg orally once daily.
 - b) Initial dosage: Greater than 55% reduction in LDL desired, start with ezetimibe 10 mg/atorvastatin 40 mg orally once daily.
 - c) Dosage titration: Adjust dose based on lipid levels after 2 or more weeks of therapy, up to ezetimibe 10 mg/atorvastatin 80 mg orally once daily.
- Dosing range: Ezetimibe 10 mg and atorvastatin 10 to 80 mg once daily.

Dosage adjustment with concomitant medications:

- 1) Cyclosporine, Tipranavir plus Ritonavir, or Telaprevir:
 - a) Avoid concomitant administration of ezetimibe/atorvastatin with cyclosporine, tipranavir plus ritonavir, or telaprevir.
- 2) Clarithromycin, Itraconazole, Saquinavir or Darunavir plus Ritonavir, Fosamprenavir, Fosamprenavir plus Ritonavir, Elbasvir, or Grazoprevir:
 - a) The lowest dose possible of ezetimibe/atorvastatin is recommended, not to exceed ezetimibe 10 mg/atorvastatin 20 mg orally once daily.
- 3) Nelfinavir or Boceprevir:
 - a) The lowest dose possible of ezetimibe/atorvastatin is recommended, not to exceed ezetimibe 10 mg/atorvastatin 40 mg orally once daily.
- 4) Lopinavir plus Ritonavir:
 - a) Use caution and use of the lowest dose possible of ezetimibe/atorvastatin is recommended.

不良反應：腹瀉、肌肉無力、肌肉疼痛、頭暈。頭暈。腹痛、噁心。肌肉疼痛或虛弱、關節痛。ALT 升高、AST 升高

注意事項：1. Atozet®可於一天當中的任何時間隨食物或不隨食物投予。避免吃葡萄柚或喝葡萄柚汁。
2. 應將 Atozet®錠劑整粒吞服。不可將錠劑研碎、溶解或咀嚼使用。

- 3.在開始使用 Atozet®之後及/或調整劑量時，應於2週(含)以上的時間內進行血脂檢測，並據以調整劑量。
4. 活動性肝病或血清轉氨酶(serum transaminase)不明原因持續上升者禁用。

交互作用：

- 1.因含有 atorvastatin，與下列藥物併用會**增加肌病變/橫紋肌溶解症的危險性**：
 - 1) CYP 3A4 強效抑制劑如，itraconazole、ketoconazole、voriconazole、erythromycin、clarithromycin、HIV 蛋白質分解酶抑制劑、boceprevir、telaprevir、nefazodone 或含有 cobicistat 的藥品：禁止併用。若須短期使用強效 CYP3A4 抑制劑治療，治療期間應暫停使用本藥。
 - 2)Gemfibrozil、cyclosporine 或 Niacin：這些藥物禁止與本藥併用。
2. Rifampin 或其他的細胞色素 P450 3A4 誘導劑：**會導致 atorvastatin 血中濃度降低**。避免使用或改用其他藥物。

懷 孕 期： 禁用。對孕婦投予 Atozet®可能會導致胎兒損害。

授 乳 期： 禁用。由於 HMG-CoA 還原酶抑制劑可能造成哺乳中嬰兒的不良反應，因此如同其他的 HMG-CoA 還原酶抑制劑，禁止用於孕婦及授乳中的母親。