

## Prescribing tips for Simvastatin

Simvastatin is available in tablet form in doses ranging from 10 mg to 40 mg. An up-to-date listing of all available preparations is freely accessible on the Irish Medicines Board website [www.imb.ie](http://www.imb.ie).

### Therapeutic Indications

- Hypercholesterolaemia, including homozygous familial hypercholesterolaemia
- Prevention of cardiovascular events

### Dosing & Administration

The dose range is 10 mg to 80 mg\* given as a single oral dose in the evening. Simvastatin may be taken with or without food.

Indication	Starting Dose	Comment
Hypercholesterolaemia	10 - 20 mg daily	Those requiring a large reduction in low density lipoprotein (LDL) cholesterol (>45%) may commence on 20-40 mg daily.
Homozygous familial hypercholesterolaemia	40 mg daily	Used as an adjunct to other lipid-lowering treatments
Prevention of cardiovascular events	20 - 40 mg daily	

\* Simvastatin 80 mg is recommended only in patients with severe hypercholesterolaemia at high risk of cardiovascular events and should preferably be initiated and managed under specialist supervision.

### Dose Adjustments

Dose adjustments may be made at intervals of at least 4 weeks. Liver function tests are recommended following dose increases.

## Important prescribing Information

**Muscle Effects** Cases of myopathy, myositis & rhabdomyolysis associated with statin use are rare. Muscle toxicity can occur with all statins, however, the likelihood increases with higher doses and in certain patients, e.g. the elderly (>65 years), women, patients with renal impairment or uncontrolled hypothyroidism, patients with heavy alcohol consumption, and those with a personal or family history of muscle problems during statin therapy. Concomitant drug therapy may also increase the risk of statin-related muscle toxicity.

**Drug Interactions** Simvastatin is metabolised via the cytochrome P450 3A4 (CYP3A4) enzyme system. Consequently, concomitant use with **CYP3A4 inhibitors** may increase the risk of statin-related toxicity including myopathy and/or rhabdomyolysis.

- **Contraindicated combinations:** Potent CYP3A4 inhibitors, e.g. itraconazole, ketoconazole, posaconazole, HIV protease inhibitors (e.g. ritonavir), boceprevir, telaprevir, erythromycin, clarithromycin, telithromycin & nefazodone. Concomitant administration of gemfibrozil, ciclosporin, danazol or grapefruit juice is also contraindicated.
- **Maximum recommended dose** for simvastatin in conjunction with amlodipine, diltiazem, verapamil and amiodarone is 20 mg daily.
- **Fusidic acid:** temporary suspension of simvastatin treatment may be considered.

For additional information please consult the relevant Summary of Product characteristics (SmPC).