Statins (HMG-CoA Reductase Inhibitors)

NICE CG181 (2014, updated 2023) | BNF | MHRA Drug Safety Update

HEADLINE: Critical Safety Warning

- ☐ Myopathy and rhabdomyolysis (muscle breakdown) can cause acute kidney injury and be life-threatening.
- ☐ Common dispensing error: interacting medicine added without adjusting statin dose (clarithromycin, ciclosporin, high-dose amlodipine with simvastatin).
- ☐ Statins should not be used during pregnancy.

FIRST DISPENSE: Mandatory Items & Checks

- ☐ Baseline liver function tests. Avoid in active liver disease.
- ☐ Creatine kinase if high risk: older age, hypothyroidism, renal impairment, or family history of muscle problems.
- ☐ Check thyroid function. Untreated hypothyroidism significantly increases myopathy risk.
- ☐ Confirm patient is not pregnant and is aware to seek advice if pregnancy occurs.

Counsel: "Tell us before starting any new medicine. Report unexplained muscle pain, weakness, or dark urine urgently. Contact your prescriber if pregnancy occurs."

Key Interactions

Interacting Drug	Statin	Risk/Action
Clarithromycin, erythromycin	Simvastatin, atorvastatin	Increased muscle toxicity risk; check if statin pause advised
Amlodipine, diltiazem, verapamil, amiodarone	Simvastatin	Maximum dose 20 mg; check current dose
Gemfibrozil	Simvastatin	Contraindicated; severe myopathy risk
Ciclosporin (and to a lesser extent tacrolimus)	All statins	Increased statin exposure; specialist oversight required
Grapefruit juice (large amounts)	Simvastatin, atorvastatin	Raises levels; rosuvastatin and pravastatin unaffected
Warfarin	Any statin	Check International Normalised Ratio monitoring after initiation or dose change

REPEAT DISPENSE: Screen & Monitor

- ☐ Liver function tests: baseline, within 3 months, and at 12 months. Further testing only if clinically indicated.
- ☐ Lipid profile: after starting and periodically to assess response.
- ☐ Creatine kinase only if muscle symptoms are reported; not required routinely.
- ☐ Ask: "Any unexplained muscle pain, weakness, or tenderness since your last prescription?"
- ☐ Ask: "New medicines, including antibiotics, antifungals, hospital medicines, or herbal remedies?"

RED FLAGS: Stop Statin and Seek Care

- ☐ Muscle pain or weakness with dark or brown urine: stop statin; seek urgent same-day assessment. Possible rhabdomyolysis.
- ☐ Severe unexplained muscle pain or weakness (no dark urine): stop statin; contact general practitioner same day for urgent creatine kinase testing.
- ☐ Jaundice, severe nausea, or upper abdominal pain: possible liver injury. Stop statin and seek urgent medical assessment.
- ☐ Dark urine without obvious cause, particularly after starting an interacting medicine: seek urgent medical assessment.
- ☐ Suspected or confirmed pregnancy: stop statin and contact prescriber promptly.

Key reminders: New or intensive exercise may increase muscle injury risk; advise gradual build-up. Heavy alcohol intake increases liver toxicity risk. Rosuvastatin and pravastatin are not affected by grapefruit.