Statin monotherapy for the treatment of hypercholesterolaemia & prevention of cardiovascular events in adults

Preferred Drugs
THE RIGHT CHOICE, RIGHT NOW.

The MMP recommends ATORVASTATIN as the preferred statin for the treatment of hypercholesterolaemia & prevention of cardiovascular events

- This recommendation is based on a number of factors including cost, prescribing frequency, patient factors, contraindications and cautions
- A full evaluation report is available at www.hse.ie/yourmedicines

Prior to initiation of statin therapy[1]

1. **Check baseline lipid levels** (TC, LDL-C, HDL-C, TG)
2. **Address lifestyle issues** including advice on healthy eating, smoking cessation, alcohol consumption, weight reduction (where appropriate) and physical activity
3. **Consider:**
   - **Thyroid function**- treat uncontrolled hypothyroidism prior to starting statin therapy
   - **Liver function- check prior to commencing treatment;** if transaminases are >3x ULN, do NOT start statin therapy
   - **Renal function-** check individual SmPCs. Dose adjustment may be necessary in renal impairment*
   - History of **unexplained muscle pain-** check CK levels. If elevated, re-measure after 5-7 days. If still >5x ULN, do NOT start statin therapy.

Prescribing statin therapy

1. **Consider** prescribing the MMP-preferred statin, **atorvastatin**
2. **Consider** drug interactions with concomitant medications & adjust dose accordingly*
3. **Advise** patients to report any unexplained muscle pain, tenderness or weakness
4. **Arrange** a follow-up appointment for 1-3 months

Review and follow up[2-6]

1. **Measure** liver transaminase enzymes after three months and 12 months of treatment, but not again unless clinically indicated
2. **Review patients** after three months of treatment and at least annually thereafter, to discuss medication adherence, dose response, lifestyle modifications, drug interactions and tolerability
3. **Monitor** for clinically significant adverse events including severe myalgia, myositis or unexplained, persistent elevations of serum transaminases (>3x ULN)
4. **Monitor** for undesirable effects including elevated blood glucose levels, interstitial lung disease and renal effects e.g. proteinuria and haematuria*
5. **Adjust** the dose or medication as required

Atorvastatin dosing information[2]

Indication	Starting Dose	Note
Hypercholesterolaemia	10 mg daily	Adjustment of dose should be made at intervals of 4 weeks or more. The maximum dose is 80 mg once a day.
Homozygous familial hypercholesterolaemia	10-80 mg daily	Used as an adjunct to other lipid-lowering treatments
Prevention of cardiovascular events	10 mg daily	Higher doses may be necessary in order to attain LDL-C levels according to current guidelines

Managing statin intolerance[2-7]

1. **Patients intolerant** to high-intensity statins (atorvastatin ≥ 40 mg, rosuvastatin ≥ 20 mg) should use the maximum tolerated dose
2. **Address adverse effects of statins which relate to muscle pain or weakness by*:**
   - Checking CK levels AND
   - **If CK ≤ ULN:** Stop the statin and restart treatment when symptoms have resolved, to determine if symptoms were statin-related. Reassess CK and symptoms in 6-12 weeks OR
   - **If CK ≤ 5 x ULN and muscle symptoms are severe:** Stop the statin, eliminate any predisposing factors. Consider reintroducing treatment (same statin at lower dose or different statin at low dose) once CK ≤ ULN and patient is asymptomatic. Monitor regularly OR
   - **If CK ≥ 5 x ULN:** Stop the statin, eliminate any predisposing factors and consider specialist advice
3. **Reduce the dose or change to a different statin** if intolerance is non-muscle related and CK is normal
4. **Seek specialist advice** for patients at high risk of CVD who are intolerant to at least two statins

CK: creatine kinase; CVD: cardiovascular disease; HDL-C: high density lipoprotein cholesterol; LDL-C: low density lipoprotein cholesterol; SmPC: summary of product characteristics; TC: total cholesterol; TG: triglycerides; ULN: Upper limit of normal

References: 1. National Institute for Health and Care Excellence (NICE) Guidance CG181: Cardiovascular disease: risk assessment and reduction, including lipid modification (2016) 2. SmPCs atorvastatin (Lipitor®) 10 mg, 20 mg & 40 mg 3. SmPCs fluvastatin (Lescol®) XL 80 mg. 4. SmPCs pravastatin (Lipostat®) 10 mg, 20 mg & 40 mg 5. SmPCs rosuvastatin (Crestor®) 5 mg, 10 mg, 20 mg & 40 mg 6. SmPCs simvastatin (Zocor®) 10 mg, 20 mg & 40 mg 7. Guidance on prescribing statins. NHS South East London Area Prescribing Committee, 2016 *** See individual SmPCs for further information**

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