

Shared Care Guideline. Sildenafil for secondary severe Raynaud's phenomenon associated with scleroderma in adults (GP Summary)

It is essential that a transfer of care only takes place with agreement of the GP and when sufficient information has been received. If the GP does not agree to share care they will inform the Consultant responsible for the patient's care

Basingstoke,
Southampton
& Winchester
District
Prescribing
Committee

Specialist Contact Details Name: _____ Location: _____ Date: _____ Tel: _____	Patient ID Label Surname: _____ Forename: _____ NHS Number: _____ Date of Birth: _____
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Indications	<p>"Off-label" use for secondary severe Raynaud's phenomena associated with scleroderma. Treatment must be initiated and monitored by a specialist experienced in the diagnosis and treatment of Raynaud's disease in accordance with National and international best practice, when the following criteria apply:</p> <ul style="list-style-type: none"> • Patient has severe Raynaud's causing digital ischaemia & ulceration • Patient is following lifestyle management (proper body insulation, avoidance of cold exposure, smoking cessation support, avoidance of sympathomimetic drugs); and • Patient has persisting severe symptoms despite standard treatment with calcium channel blockers, ACE inhibitors and fluoxetine (unless contraindicated or not tolerated) <p>Treatment will usually be offered prior to the use of iloprost.</p>
Dose & response	<p>Sildenafil tablets 25 – 50mg three times daily according to response.</p> <ul style="list-style-type: none"> • Treatment is usually initiated at 25mg three times a day as per National guidance. • If the patient has renal or hepatic impairment, low baseline blood pressure or judged to be at risk of hypotension, the specialist may advise the patient to introduce treatment cautiously • The specialist will prescribe the first month of sildenafil treatment and ensure the patient understands their treatment, including which side effects to report promptly and advise the patient to stop treatment if they experience hypotensive side effects. • The specialist will advise the patient to book an appointment for a BP check at their GP practice before starting treatment and to take the first tablet 2 hours before the appointment. • Once stabilised the dose may be further increased (by the specialist) to 50mg three times a day in accordance with response and tolerability. • No dose reduction is required for patients >65yrs. • Clearance may be reduced in renal impairment (creatinine clearance <30 mL/min) or hepatic impairment (such as cirrhosis) -start with 25 mg and titrate cautiously.
GP Responsibilities	<ul style="list-style-type: none"> • The GP will be asked to continue to prescribe generic sildenafil at the dose recommended by the specialist. • The GP practice will provide the initial BP monitoring • Dose may be upwardly titrated by specialist at follow up appointment. Specialist will prescribe a further month of sildenafil after an increase in dose. The GP will be asked to continue to prescribe at the increased dose after the initial month. • Identify & report any adverse events to the specialist & MHRA and take appropriate action. • Report any worsening of the condition to the specialist
Primary care monitoring	<p>Unless otherwise advised by the specialist:</p> <p>GP practice to monitor patient's blood pressure on initiation. If hypotensive seek advice from specialist.</p>
Actions to be taken in response to monitoring	<p>Contact specialist if sildenafil not tolerated after initial dose.</p> <p>If on established treatment, the patient develops: Symptomatic hypotension at dose of 25mg TDS - Stop sildenafil and refer to specialist. Symptomatic hypotension at dose of 50mg TDS - Decrease dose from 50mg TDS to 25mg TDS.</p>

<p>Contra-indications</p>	<ul style="list-style-type: none"> • Co-administration with nitric oxide donors (such as amyl nitrite) or nitrates in any form - potentiates the hypotensive effects of nitrates due to effects on the nitric oxide/cyclic guanosine monophosphate (cGMP) pathway. • Loss of vision in one eye because of non-arteritic anterior ischaemic optic neuropathy (NAION), regardless of whether this episode was in connection or not with previous PDE5 inhibitor exposure. • Severe hepatic impairment • Hypotension (blood pressure <90/50 mmHg) • Recent history of stroke or myocardial infarction • known hereditary degenerative retinal disorders such as retinitis pigmentosa (a minority of these patients have genetic disorders of retinal phosphodiesterases) • Pregnant or breastfeeding women- no adequate and well-controlled studies available • Rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption due to lactose content of tablet. • Pulmonary hypertension secondary to sickle cell anaemia
<p>Cautions</p>	<ul style="list-style-type: none"> • Patients with increased susceptibility to vasodilators, including those with postural hypotension, fluid depletion, left ventricular outflow obstruction (e.g., aortic stenosis, hypertrophic obstructive cardiomyopathy).
<p>Important adverse effects & management</p>	<ul style="list-style-type: none"> • Dizziness. Advise patients to be aware of how they react to sildenafil, before driving or operating machinery • Priapism. Advise patients to seek immediate medical assistance if an erection persists longer than 4 hours. • Visual defects. Advise patients to stop taking Sildenafil and seek medical attention immediately in the event of any sudden visual defect or loss of vision. • Headaches, flushing, night sweats- Very Common. • Diarrhoea, dyspepsia - Very Common.
<p>Important Drug Interactions</p>	<p>Alpha Blockers -Caution. May lead to symptomatic hypotension in a few susceptible individuals. Most likely to occur within 4 hours post sildenafil dosing. Patients should be haemodynamically stable on an alpha blocker prior to initiating sildenafil.</p> <p>Clarithromycin -Caution. Increases serum concentrations of sildenafil. Reduce dose of sildenafil if symptoms of hypotension develop.</p> <p>Disopyramide -Avoid. Risk of ventricular arrhythmias.</p> <p>Erythromycin - Caution. Increases serum concentrations of sildenafil. Reduce dose of sildenafil if symptoms of hypotension develop.</p> <p>Grapefruit juice -Avoid. May increase serum concentrations of sildenafil</p> <p>Itraconazole -Avoid. Increases serum concentrations of sildenafil, consider dose reduction if unavoidable.</p> <p>Ketoconazole -Avoid. Increases serum concentrations of sildenafil, consider dose reduction if unavoidable.</p> <p>Nicorandil -Avoid. Potentiates the hypotensive effect of nicorandil.</p> <p>Nitrates - Avoid. Potentiates the hypotensive effect of nitrates.</p> <p>Pulmonary Arterial Hypertension Drugs - Avoid. Potentiation likely.</p> <p>Ritonavir -Avoid. Substantially increases serum concentrations of sildenafil</p> <p>Saquinavir- Avoid. Increases serum concentrations of sildenafil.</p>

This guidance should be read in conjunction with the NHS England Policy on Treatment of Systemic Sclerosis (Scleroderma) IN DEVELOPMENT