

Tadalafil

Cardiology shared care guideline

Specialist details

Name: _____
Location: _____
Tel: _____

Patient identifier

Date: _____

Introduction

Licensed indications:

Treatment of adult patients with pulmonary arterial hypertension (PAH) classified as WHO functional class II and III, to improve exercise capacity.

Efficacy has been shown in idiopathic PAH (IPAH) and in PAH related to collagen vascular disease.

Treatment should only be initiated by a physician experienced in the treatment of pulmonary arterial hypertension and should be in conjunction with clinical colleagues from one of the recognised national PAH centres.

Adult dosage and administration

The recommended adult dose is 40mg once daily with or without food. Dosage regime differs in mild to moderate hepatic or renal impairment.

Available as:

Tadalafil 20mg tablets (Adcirca®).

Hospital specialist responsibilities

- Assess patient's suitability for treatment with tadalafil.
- Arrange shared care with the patient's GP.
- Provide patient/carer with relevant (preferably written) information on use, side-effects and need for monitoring of medication.
- Baseline tests:
 - Blood pressure
 - LFT
 - U&E.
- Review results of safety monitoring and request additional tests as required.
- Monitor disease response to treatment and need to continue therapy.
- Continue to review the patient at agreed specified intervals, sending a written summary to the GP whenever the patient is reviewed.
- Provide any other advice or information for the GP including dose adjustments.

GP responsibilities

- Prescribe tadalafil as Adcirca® according to dose advised by specialist.
- Report adverse drug reactions to initiating specialist and usual bodies (eg. MHRA).
- Ensure no drug interactions with other medicines.

Adverse effects, precautions and contraindications

- **Contraindications include:** Severe hepatic impairment, severe renal impairment, recent MI, hypotension (BP < 90/50 mmHg), history of non-arteritic anterior ischaemic optic neuropathy.
- Use with **nitrates, nicorandil** and **riociguat** is contraindicated.
- **Caution advised with:** hypotension (avoid if systolic blood pressure below 90 mmHg); aortic and mitral valve disease; pericardial constriction; congestive cardiomyopathy; left ventricular dysfunction; life-threatening arrhythmias; coronary artery disease; uncontrolled hypertension; pulmonary veno-occlusive disease; predisposition to priapism (eg. in sickle-cell disease, multiple myeloma, or leukaemia) ; anatomical deformation of the penis; hereditary degenerative retinal disorders.
- Abrupt discontinuation does not seem to be associated with rebound worsening of PAH, but gradual discontinuation with increased monitoring is recommended.
- **Most commonly reported side effects:** dyspepsia, nausea, vomiting, headache, flushing, back pain, pain in extremity, myalgia, and nasopharyngitis.
- **Ischaemic optic neuropathy, and raised intra-ocular pressure** have been reported. Patients should be advised in the case of a sudden visual defect to stop taking tadalafil and contact their specialist or GP immediately.
- **Decreased or sudden hearing loss** has been reported and patients should be advised to seek prompt medical attention in the event of sudden decrease or loss of hearing.
- Hypersensitivity reactions (including rash), priapism, and painful red eyes have been reported.
- **Pregnancy.** Due to lack of data, tadalafil should not be used in pregnant women unless strictly necessary.
- **Breast feeding.** Tadalafil should not be administered to breast-feeding mothers.

Common drug interactions

Tadalafil is contraindicated in combination with:

- nitrates and nicorandil as can potentiate hypotensive effects
- riociguat as it may potentially lead to symptomatic hypotension.

Tadalafil is not recommended in combination with:

- doxazosin
- potent CYP3A4 inhibitors (e.g. ketoconazole, ritonavir)
- rifampicin.

Use tadalafil with caution in association with:

- alpha blockers due to possibility of postural hypotension
- intermediate potency CYP3A4 inhibitors (e.g. erythromycin, clarithromycin, nefazodone), a decrease in dose of tadalafil may be required
- potent CYP3A4 inducers (e.g. carbamazepine, phenytoin, phenobarbital, and St John's Wort) or when tadalafil is administered with bosentan, a moderate inducer of CYP3A4. Dose adjustment of tadalafil may be required.

Communication

For any queries relating to this patient's treatment with tadalafil, please contact the specialist named at the top of this document.

This information is not inclusive of all prescribing information and potential adverse effects.
Please refer to full prescribing data in the SPC or the BNF

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