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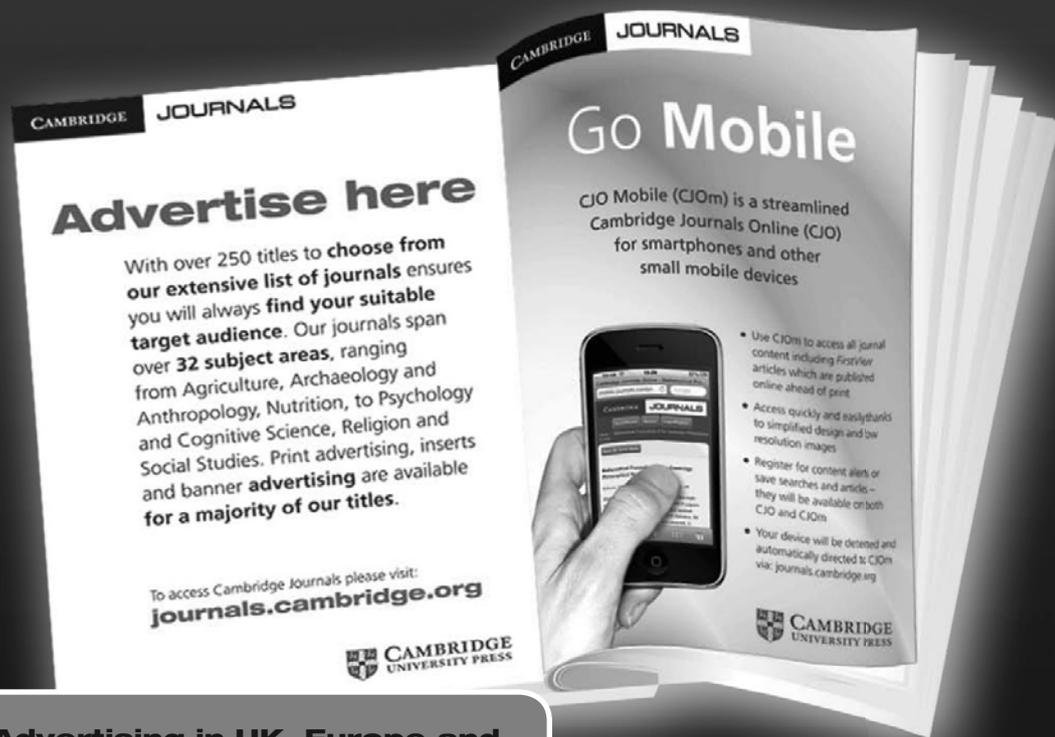


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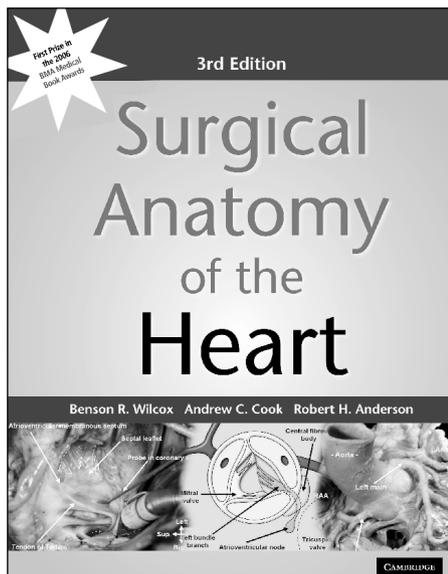
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ABBREVIATED PRESCRIBING INFORMATION

Please refer to the SmPC before prescribing Revatio 20mg Tablets.

Presentation: White, round, biconvex film-coated tablets marked "PFIZER" on one side and "RVT 20" on the other containing 20mg of sildenafil as the citrate. **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 primary pulmonary hypertension and pulmonary hypertension associated with connective tissue disease. Treatment of paediatric patients aged 1 to 17 years old with PAH. Efficacy in improvement in exercise capacity or pulmonary haemodynamics has been shown in primary pulmonary hypertension and pulmonary hypertension associated with congenital heart disease. **Dosage:** For oral use. Treatment should only be initiated and monitored by a physician experienced in the treatment of PAH. In case of clinical deterioration in spite of Revatio treatment, alternative therapies should be considered. **Adults:** 20mg taken three times a day with or without food. **Elderly:** Dosage adjustments not required. **Paediatric Population:** For patients aged 1 to 17 years old ≤ 20 kg the recommended dose is 10 mg (1 ml of compounded solution) three times a day, and for patients ≥ 20 kg is 20mg (2ml of compounded solution or 1 tablet) three times a day. For instructions on compounding of the medicinal product please refer to the SmPC. **Renal impairment:** Initial dosage adjustments not required. If therapy is not well tolerated consider adjusting dose to 20mg twice daily. **Hepatic impairment (Child-Pugh class A and B):** Initial dose adjustments not required, if therapy is not well tolerated consider adjusting dose to 20 mg twice daily. **Severely impaired hepatic function (Child-Pugh class C):** Revatio is contraindicated in patients with severe hepatic impairment, see Contraindications. **Children and adolescents:** The safety and efficacy of Revatio in children below 1 year of age has not been established. **Discontinuation of treatment:** Limited data suggest abrupt discontinuation of Revatio is not associated with rebound worsening of PAH. To avoid the possibility of clinical deterioration a gradual dose reduction should be considered. Intensified monitoring is recommended during this period. **Use in patients using other medicines:** Any dose

adjustment should be administered only after a careful benefit-risk assessment. For use with CYP3A4 inhibitors like erythromycin or saquinavir consider adjusting dose to 20mg twice daily. For use with more potent CYP3A4 inhibitors like clarithromycin, telithromycin and nefazodone, consider adjusting dose to 20mg once daily. Dose adjustments of Revatio may be required with CYP3A4 inducers (see Drug Interactions). **Contraindications:** Hypersensitivity to Revatio or to any of the excipients. Co-administration with nitric oxide donors (such as amyl nitrite) or nitrates in any form due to hypotensive effects (see pharmacodynamic properties). Combination with the most potent of the CYP3A4 inhibitors e.g. ketoconazole, itraconazole, ritonavir (see Drug Interactions). Patients who have loss of vision in one eye because of non-arteritic anterior ischaemic optic neuropathy (NAION) (see special warnings). Severe hepatic impairment; recent stroke or myocardial infarction; severe hypotension at initiation. **Warnings and Precautions:** Efficacy not established in patients with functional class IV PAH. Risk-benefit balance of Revatio not established in functional class I PAH. Studies have been performed in forms of PAH related to primary (idiopathic), connective tissue disease or congenital heart disease. Use not recommended in other forms of PAH. Use not recommended in patients with known hereditary degenerative retinal disorders e.g. retinitis pigmentosa. Susceptible patients could be adversely affected by mild to moderate vasodilatory effects of Revatio. Sildenafil potentiates the hypotensive effect of nitrates (see Contraindications). Caution advised in patients with anatomical deformation of the penis or predisposed to priapism. Visual defects and cases of non-arteritic anterior ischaemic optic neuropathy have been reported in connection with the intake of sildenafil and other PDE5 inhibitors. Caution is advised when sildenafil is administered with an alpha-blocker, symptomatic hypotension may develop in susceptible patients (see Drug Interactions). Patients should be hemodynamically stable on alpha-blocker therapy prior to initiating sildenafil. Administration to patients with bleeding disorders or active peptic ulceration only after careful benefit-risk assessment. Increased risk for bleeding when sildenafil is initiated in PAH patients already using a Vitamin K antagonist, particularly in patients with PAH secondary to connective tissue disease. No data are available with sildenafil in patients with pulmonary hypertension associated with veno-occlusive disease. In these patients life-

threatening pulmonary oedema has been reported with use of other vasodilators. Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take Revatio. **Drug Interactions:** Revatio tablets is principally metabolised by the CYP P450 isoforms 3A4 and 2C9. Co-administration of Revatio is not advised with potent P450 inhibitors (see Contraindications). A lower starting dose of Revatio should be considered in patients taking CYP3A4 inhibitors (see Warnings and Precautions). Co-administration of bosentan (a moderate inducer of CYP3A4, CYP2C9 and possibly of CYP2C19) 125mg twice daily with Revatio tablets 80 mg three times a day (at steady state) resulted in a 63% decrease of Revatio AUC and a 50% increase in bosentan AUC. Caution is recommended. Revatio potentiates the hypotensive effect of nitrates (see Contraindications). Nicorandil, amlodipine and alpha-blockers in combination with Revatio have the potential to drop blood pressure in susceptible patients (see Warnings and Precautions). No significant interactions have been observed between Revatio and warfarin or acenocoumarol. For other Drug Interactions please refer to the SmPC. **Paediatric population:** Interaction studies have only been performed in adults. **Pregnancy and lactation:** Due to lack of data Revatio should not be used in pregnant women unless also using appropriate contraceptive measures. Revatio should not be administered to breast-feeding mothers. **Driving and operating machinery:** Caution if affected by dizziness or altered vision. **Side-Effects:** Clinical study experience: The most commonly reported side-effects were headache, flushing, dyspepsia, back pain, diarrhoea and limb pain. Other side-effects reported were as follows: Myalgia, cough, epistaxis, insomnia, pyrexia, influenza, visual disturbance not otherwise specified (NOS), anaemia, vertigo, abnormal sensation in eye, chromatopsia, cyanopsia, diplopia, eye irritation, blood shot eyes/red eyes, photophobia, retinal haemorrhage, visual acuity reduced, abdominal distension, gastritis, gastroenteritis, gastroesophageal reflux disease, haemorrhoids, sinusitis, nasal congestion, dry mouth, cellulitis, weight increased, fluid retention, paraesthesia, tremor, burning sensation, migraine, hypoaesthesia, anxiety, bronchitis, rhinitis, gynaecomastia, alopecia, erythema, night sweats. In postmarketing surveillance, the adverse event/reactions that have been reported with an unknown frequency are skin rash, hypotension, priapism and sudden death.

In the treatment of male erectile dysfunction adverse events/reactions reported include: Eye disorders: Non-arteritic anterior ischemic optic neuropathy (NAION), retinal vascular occlusion and visual field defect. Paediatric Population: In a paediatric study over 16 weeks, side effects were generally consistent with that in adults, the most common reported were: vomiting, cough, pyrexia, nausea, abdominal pain, photobia, and spontaneous penile erections in male patients. In a long term extension study at 2.2 years the most commonly reported adverse events were headache, erection increased, vomiting, abdominal pain, cough and dyspepsia. Over the first two years of the study, 4 of 229 subjects had a serious event: these were convulsion, hypersensitivity, hypoxia and ventricular arrhythmia. **Overdose:** Standard supportive measures to be adopted as required. **Legal category:** POM. **Basic NHS cost:** Packs of 90, 20mg tablets (EU/1/05/318/001) £373.50. Marketing Authorisation Holder: Pfizer Limited, Sandwich, Kent, CT13 9NJ, United Kingdom. Further information on request: Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey KT20 7NS Last revised: 05/2011. Ref: RV11_0

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk Adverse events should also be reported to Pfizer Medical Information on +44 (0)1304 616161

Date of preparation: June 2011 EUPV0453a

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