Prescribing Information: Spedra (avanafil) 50 mg, 100 mg and 200 mg tablets.
Please consult the Summary of Product Characteristics (SmPC) for full prescribing information.
Presentation: Tablets containing 50 mg, 100 mg or 200 mg of avanafil.
Use: Treatment of erectile dysfunction in adult men. In order for Spedra to be effective, sexual stimulation is required.
Dosage and administration: Oral administration. Adult men: Recommended dose 100 mg, taken as needed, approximately 15 to 30 minutes before sexual activity. Dose may be increased to a maximum dose of 200 mg or decreased to 50 mg. Maximum recommended dosing frequency is once per day. Special populations: No dose adjustment needed for older men or men with diabetes. Renal impairment: Dose adjustments are not required with mild to moderate renal impairment, contraindicated with severe renal impairment. Hepatic impairment: Patients with mild to moderate hepatic impairment should initiate treatment at minimum efficacious dose and adjust posology based on tolerance, contraindicated in severe hepatic impairment. Do not exceed 100 mg with concomitant treatment with moderate CYP3A4 inhibitors and leave at least 48 hours between doses. Concomitant food intake may delay activity.
Contraindications: Hypersensitivity to active substance or excipients. Patients using any form of organic nitrate or nitric oxide donors. Consider potential cardiac risk of sexual activity in patients with pre-existing cardiovascular disease before prescribing. Contraindicated in cases of myocardial infarction, stroke, or life-threatening arrhythmia within the last 6 months, resting hypotension (BP < 90/50 mmHg) or hypertension (BP > 170/100 mmHg), unstable angina, angina with sexual intercourse, or congestive heart failure. Severe hepatic or renal impairment (CrCl < 30 mL/min). Patients with loss of vision in one eye because of non-arteritic anterior ischemic optic neuropathy. Known hereditary degenerative retinal disorders. Concomitant use of potent CYP3A4 inhibitors. Co-administration of type 5 phosphodiesterase (PDE5) inhibitors, including avanafil, with guanylate cyclase stimulators, such as riociguat.
Warnings and Precautions: Consider the cardiovascular status of patients before initiating treatment. Patients experiencing priapism should seek immediate medical assistance. Use with caution in patients with anatomical deformation of the penis or conditions which may predispose them to priapism. Patients experiencing sudden visual effects or loss of hearing should stop taking Spedra and consult a physician immediately. Careful use in patients with bleeding disorders or active peptic ulceration only after careful benefit-risk assessment. Concomitant use with alpha-blockers may lead to symptomatic hypotension in some patients. Co-administration with potent inhibitors of CYP3A4 is contraindicated. Concomitant use of avanafil with other treatments for erectile dysfunction is not recommended. Concurrent use of avanafil and alcohol may increase the likelihood of hypotension, dizziness or syncope. Populations not studied: Patients with erectile dysfunction due to spinal cord injury or other neurological disorders and in subjects with severe renal or hepatic impairment.
Interactions: Co-administration with organic nitrate or nitric oxide donor is contraindicated. Co-administration of avanafil with medicinal products reducing systemic blood pressure, alpha-blockers, antihypertensives other than alpha-blockers or with alcohol may cause symptomatic hypotension. Co-administration with moderate CYP3A4 inhibitors: Maximum recommended dose of avanafil is 100 mg not to exceed once every 48 hours. Avoid grapefruit juice for 24 hours prior to taking avanafil. Concomitant use with CYP inducers not recommended. Concomitant use of riociguat is contraindicated.
Side-effects: Common (≥ 1/100 to < 1/10): Headache, flushing, nasal congestion. Uncommon (≥ 1/1000 to < 1/100): dizziness, somnolence, blurred vision, palpitations, hot flush, dyspepsia, nausea, vomiting, stomach discomfort, back pain, fatigue, hepatic enzyme increased, heart rate increased. Rare (≥ 1/10000 < 1/1000): Angina pectoris, tachycardia, hypertension.
Pack sizes and price: 50 mg: 4 tablets £10.94; 8 tablets £19.70. 100mg: 4 tablets £14.08; 8 tablets £26.26. 200 mg: 4 tablets £21.90; 8 tablets £39.40.
Legal category: POM.
Marketing Authorisation Number: EU/1/13/841/001-022.
Marketing Authorisation holder: Menarini International Operations Luxembourg S.A.
Marketed by: A. Menarini Farmaceutica Internazionale SRL, Menarini House, Mercury Park, Wycombe Lane, Wooburn Green, Buckinghamshire, HP10 0HH, UK.
Further information is available on request to A. Menarini Farmaceutica Internazionale SRL or may be found in the SmPC.

Last updated: July 2021

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to A. Menarini Farmaceutica Internazionale SRL. Phone no. 0800 085 8678 or email: menarini@medinformation.co.uk