Prescribing Information: Priligy (dapoxetine) 30 mg and 60 mg film-coated tablets.
Please consult the Summary of Product Characteristics (SmPC) for full prescribing information.
Presentation: Film-coated tablets containing dapoxetine hydrochloride equivalent to 30 mg or 60 mg dapoxetine. Contains lactose.
Use: Treatment of premature ejaculation (PE) in adult men aged 18 to 64 years. Only for prescription to patients who meet all the following criteria: intravaginal ejaculatory latency time of less than two minutes; persistent or recurrent ejaculation with minimal sexual stimulation before, on, or shortly after penetration and before patient wishes; marked personal distress or interpersonal difficulty as a consequence of PE; poor control over ejaculation; and history of premature ejaculation in the majority of intercourse attempts over the prior 6 months. Priligy should be administered only as on-demand treatment before anticipated sexual activity. Priligy should not be prescribed to delay ejaculation in men who have not been diagnosed with PE.
Dosage and administration: Oral administration. Medical examination including an orthostatic test should be performed before initiating treatment. Adult men (aged 18 to 64 years): Recommended starting dose 30 mg, taken as needed, approximately 1 to 3 hours prior to sexual activity and no more frequently than once every 24 hours. Depending on response, dose may be increased to a maximum recommended dose of 60 mg. If the patient experiences orthostatic reactions on the starting dose, no dose escalation should be performed.
Contraindications: Hypersensitivity to active substance or excipients, significant pathological cardiac conditions such as heart failure (NYHA class II-IV), conduction abnormalities, significant ischaemic heart disease, significant valvular disease, history of syncope. History of mania or severe depression. Concomitant or recent discontinuation of treatment (within 14 days) with MAOIs, thioridazine, SSRIs, SNRIs, tricyclic antidepressants or other medicinal/herbal products with serotonergic effects. Do not administer an MAOI, thioridazine, SSRIs, SNRIs, tricyclic antidepressants or other medicinal/herbal products with serotonergic effects within 7 days after Priligy is discontinued. Concomitant treatment of potent CYP3A4 inhibitors. Moderate or severe hepatic impairment.
Warnings and Precautions: Concomitant use of PDE5 inhibitors, history of documented or suspected orthostatic reaction. Advise patients of possible prodromal symptoms and orthostatic reactions. Avoid situations where injury could result as a result of syncope or prodromal symptoms. Cardiovascular risk factors. Concomitant use of recreational drugs. Discontinue in patients who develop seizures and avoid in unstable epilepsy. Carefully monitor patients with controlled epilepsy. Evaluate depression signs/symptoms before treatment. Concomitant treatment with anti-depressants is contraindicated. Discontinuation of ongoing depression/anxiety treatment before starting Priligy is not recommended. Not to be used in psychiatric disorders. Discontinue Priligy if signs/symptoms of depression develop during treatment. Caution in patients taking medicinal products known to affect platelet function or anti-coagulants, history of bleeding or coagulation disorders. Do not use in severe renal impairment, caution in mild or moderate renal impairment. Withdrawal effects. Caution in patients with raised intraocular pressure or risk of angle closure glaucoma. Not suitable to patients with galactose intolerance, total lactase deficiency or glucose-galactose malabsorption. Not indicated for women.
Interactions: Potential for interaction with monoamine oxidase inhibitors, thioridazine, medicinal/herbal products with serotonergic effects. Caution with CNS active medicinal products and medicinal products with vasodilatation properties. Do not use with potent CYP3A4 inhibitors, maximum dose of 30 mg with moderate CYP3A4 inhibitors, potent CYP2D6 inhibitors, PDE5 inhibitors, tamsulosin, medicinal products metabolized by CYP2D6, CYP3A4, CYP2C19, CYP2C9, warfarin and medicinal products known to affect coagulation and/or platelet function, alcohol.
Side-effects: Very common (> 1/10): dizziness, headache, nausea. Common (≥ 1/100 to < 1/10): anxiety, agitation, restlessness, insomnia, abnormal dreams, libido decreased, somnolence, disturbance in attention, tremor, paraesthesia, vision blurred, tinnitus, flushing, sinus congestion, yawning, diarrhoea, vomiting, constipation, abdominal pain, abdominal pain upper, dyspepsia, flatulence, stomach discomfort, abdominal distension, dry mouth, hyperhidrosis, erectile dysfunction, fatigue, irritability, blood pressure increased. Uncommon (≥ 1/1000 to < 1/100): depression, sleep disorders, syncope, dizziness postural, vertigo, sinus arrest, sinus bradycardia, tachycardia, hypotension, systolic hypertension, ejaculation failure, male orgasmic disorder, blood pressure diastolic increased, blood pressure orthostatic increased. Rare (≥ 1/10000 to < 1/1000): Sudden onset of sleep.
Package quantities and price: 30 mg: 3 tablets £14.71, 6 tablets £26.48. 60 mg: 3 tablets £19.12, 6

tablets £34.42.
Legal category: POM.
Marketing Authorisation Holder: A. Menarini Farmaceutica Internazionale SRL, Menarini House, Mercury Park, Wycombe Lane, Wooburn Green, Buckinghamshire, HP10 0HH
Marketing authorisation numbers: PL 41549/0001-0002
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