

Dapoxetine 30 mg film-coated tablets and Dapoxetine 60 mg film-coated tablets. Abbreviated Prescribing Information - for full prescribing information, including side effects, precautions and contra-indications, see Summary of Product Characteristics (SmPC).

Name of the Medicine: Dapoxetine 30 mg and 60 mg film-coated tablets. **Qualitative and Quantitative**

Composition: Each film-coated tablet contains Dapoxetine hydrochloride equivalent to 30 mg

Dapoxetine. Contains lactose monohydrate. **Therapeutic Indications:** Treatment of premature ejaculation (PE) in adult men aged 18 to 64 years who meet specific criteria.

Dosage and Method of Use: Starting Dose: 30 mg, 1 to 3 hours before sexual activity. Not for continuous daily use. Maximum once every 24 hours. Dose Adjustment: May increase to 60 mg based on individual response and tolerability. **Administration:** Oral use. Tablets should be swallowed whole with at least one full glass of water. Can be taken with or without food. **Contraindications:**

Hypersensitivity to Dapoxetine or excipients, significant pathological cardiac conditions, history of syncope, mania or severe depression, concomitant treatment with MAOIs, thioridazine, SSRIs, SNRIs, TCAs, potent CYP3A4 inhibitors, and other specified medications.

Special Warnings and Precautions: Orthostatic Hypotension and Syncope: Careful medical examination, including history of orthostatic events, is recommended before treatment initiation. Patients should be advised to avoid situations where injury could result, including driving or operating hazardous machinery, should syncope or its prodromal symptoms such as dizziness or light-headedness occur. Patients experiencing these symptoms should immediately lie down or sit down with their head between their knees. Psychiatric Disorders: Patients with signs and symptoms of depression should be evaluated before initiating treatment to rule out undiagnosed depressive disorders. Use with caution in patients with psychiatric disorders. Seizures: Discontinue in any patient who develops seizures and avoid in patients with unstable epilepsy. Sexual Dysfunction: Before treatment, subjects with other forms of sexual dysfunction, including erectile dysfunction, should be carefully investigated. Suicidal Behavior: Antidepressants increased the risk of suicidal thinking and suicidality in short-term studies in children and adolescents with

Major Depressive Disorder and other psychiatric disorders. Use with Recreational Drugs: Advised against using Dapoxetine in combination with recreational drugs that have serotonergic activity or sedative properties. Alcohol: Patients should be advised not to use Dapoxetine in combination with alcohol. Renal Impairment: Caution in patients with mild or moderate renal impairment and contraindicated in severe renal impairment. Hepatic Impairment: Contraindicated in patients with moderate and severe hepatic impairment. CYP2D6 Polymorphism and Drug Interactions: Use caution in patients known to be CYP2D6 poor metabolizers or those taking potent CYP2D6 inhibitors. Adjustments or additional caution may be necessary when co-administered with drugs affecting the enzyme's activity. **Common Adverse Reactions:** Nausea, dizziness, headache, diarrhoea, insomnia, and fatigue. Serious adverse reactions include orthostatic hypotension and syncope. **Legal Classification:** POM **NHS Price:** Dapoxetine 30mg film-coated tablets pack of 3 - £14.71, Dapoxetine 30mg film-coated tablets pack of 6 - £26.48, Dapoxetine 60mg film-coated tablets pack of 3 - £19.12, Dapoxetine 60mg film-coated tablets pack of 6 - £34.42 **MA Number:** 30mg 3 and 6 PL 24837/0156 60mg 3 and 6 PL 24837/0157. **MAH:** Consilient Health Ltd, Miesian Plaza, Dublin 2, Ireland. **Distributor:** Consilient Health (UK) Ltd., No. 1 Church Road, Richmond upon Thames, Surrey, TW9 2QE, UK. Further information is available on request from: Consilient Health (UK) Ltd, No.1 Church Road, Richmond upon Thames, Surrey TW9 2QE or drugsafety@consilienthealth.com. **Date of Revision of the Text:** 02/02/2024. **Job bag number:** UK-GEN-133. **Date of preparation:** February 2024

Adverse events should be reported.

Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/>.

Adverse events should also be reported to Consilient Health (UK) Ltd, No. 1 Church Road, Richmond upon Thames, Surrey TW9 2QE UK or drugsafety@consilienthealth.com