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DRUG PROFILE

DAPOXITINE

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

Indications : for the treatment of premature ejaculation in men 18 to 64 years of age.

Dose and administration: Starting dose: 30mg, taken as needed approximately 1 to 3 hours prior to sexual activity. The maximum recommended dosing frequency: once every 24hrs. If the effect of 30mg is insufficient and the side effects are acceptable, the dose may be increased to the maximum recommended dose of 60mg.

Contraindications: Hypersensitivity to the formulation. Significant ischemic heart disease; significant valvular disease. Concomitant treatment with monoamine oxidase inhibitors (MAOIs), thioridazone or within 14days of discontinuing treatment with MAOIs, thioridazone or within 7days after dapoxetine has been discontinued. Concomitant treatment of potent CYP3A4 inhibitors such as ketoconazole, itraconazole, ritonavir, saquinavir, telithromycin, nefazadone, nelfinavir, atazanavir etc. Moderate and severe hepatic impairment.

Pregnancy and Lactation: Dapoxetine is not indicated for use by women.

Adverse effects: *Very common:* dizziness, headache, nausea *Common:* insomnia, anxiety, agitation, restlessness, libido decreased, abnormal dreams, somnolence, disturbance in attention, tremor, paraesthesia, vision blurred, tinnitus, flushing sinus congestion, yawning, diarrhoea, dry mouth, vomiting, constipation, abdominal pain, abdominal pain upper, dyspepsia, flatulence, stomach discomfort, abdominal distention, hyperhidrosis, erectile dysfunction, fatigue, irritability, increased blood pressure *Uncommon:* depression, depressed mood, nervousness, nightmare, sleep disorder, bruxism, euphoric mood, dizziness postural, ejaculation failure, feeling hot, feeling jittery