COMPOSITION*: Valdoxan 25 mg: film-coated tablet containing 25 mg of agomelatine. Contains lactose as an excipient. **INDICATION*:** Treatment in adults of major depressive disorder (MDD) and generalized anxiety disorder (GAD). **DOSAGE AND ADMINISTRATION*:** The recommended dose is one 25 mg tablet taken orally at bedtime for both MDD and GAD. If there is no improvement of symptoms, the dose may be increased to 50 mg once daily, taken as a single dose of two tablets at bedtim, 2 weeks after treatment initiation in patients with MDD and 4 weeks after treatment initiation in patients with GAD. Liver function tests (LFT) should be performed in all patients before initiation of treatment and before a dose increase to 50mg. Treatment should not be initiated if serum transaminases levels are exceed 3x upper limit of normal (see "Contraindications" and "Warnings" sections). During treatment transaminases should be monitored periodically after around 3 weeks, 6 weeks (end of acute phase), 12 weeks and 24 weeks (end of maintenance phase) and thereafter when clinically indicated (see "Warnings" section). Treatment should be discontinued if serum transaminases exceed 3x upper limit of normal (see "Contraindications" and "Warnings" sections). When increasing the dosage, LFTs should again be performed at the same frequency as when initiating treatment. Decision of dose increase has to be balanced with a higher risk of transaminases elevation. Any dose increase to 50 mg should be made on an individual patient benefit/risk basis and with strict respect of LFT monitoring. Patients should be treated for at least 6 months. **CONTRAINDICATIONS*:** Hypersensitivity to the active substance or to any of the excipients. Hepatic impairment (i.e. cirrhosis or active liver disease) or transaminases exceeding 3x upper limit of normal (see "Dosage and administration" and "Warnings" sections). Concomitant use of potent CYP1A2 inhibitors (e.g. fluvoxamine, ciprofloxacin) (see "Interactions" section). **WARNINGS*:** Cases of liver injury, including hepatic failure (few cases were exceptionally reported with fatal outcome or liver transplantation in patients with hepatic risk factors), elevations of liver enzymes exceeding 10 times upper limit of normal, hepatitis and jaundice have been reported in patients treated with Valdoxan. Monitoring of liver function: Before starting treatment: Treatment with Valdoxan should only be prescribed after careful consideration of benefit and risk in patients with hepatic injury risk factors e.g. obesity/overweight/non-alcoholic fatty liver disease, diabetes, alcohol use disorder and/or substantial alcohol intake and in patients receiving concomitant medicinal products associated with risk of hepatic injury. Baseline liver function tests should be undertaken in all patients and treatment should not be initiated in patients with baseline values of ALT and/or AST >3x upper limit of normal. Caution should be exercised when Valdoxan is administered to patients with pretreatment elevated transaminases (> the upper limit of the normal ranges and 3 times the upper limit of the normal range). Frequency of liver function tests: Liver function tests should be performed in all patients (see "Posology" section). Any patient who develops increased serum transaminases should have his/her liver function tests repeated within 48 hours. During treatment period: Valdoxan treatment should be discontinued immediately if patient develops symptoms or signs of potential liver injury, if the increase in serum transaminases exceeds 3x upper limit of normal. Following discontinuation of Valdoxan therapy liver function tests should be repeated until serum transaminases return to normal. Patients under 18 years of age: not recommended. Elderly patients (75 years for MDE and 65 years for GAD): should not be used. Elderly patients with dementia: should not be used. Bipolar disorder/mania/hypomania: used with caution and discontinued if maniac symptoms appear. Suicide/suicidal thoughts: patients should be closely monitored. Combination with potent CYP1A2 inhibitors: contraindicated. Excipients: contains lactose, sodium-free. **INTERACTION(S)*:** Contraindicated: potent CYP1A2 inhibitors. Not recommended: alcohol; moderate CYP1A2 inhibitors. **FERTILITY*. PREGNANCY*:** not recommended. **BREASTFEEDING*:** With precautions. **DRIVE AND USE MACHINES*:** Possible occurrence of dizziness and somnolence should be taken into account. **UNDESIRABLE EFFECTS*:** Very common: headache. Common: Anxiety, abnormal dreams, dizziness, somnolence, insomnia, nausea, diarrhoea, constipation, abdominal pain, vomiting, increased ALT and/or AST, back pain, fatigue, weight increased. Uncommon: Suicidal thoughts or behavior, agitation, irritability, restlessness, aggression, nightmares, mania/hypomania, confusional state, migraine, paraesthesia, restless leg syndrome, blurred vision, tinnitus, increased gamma-glutamyltransferase, hyperhidrosis, eczema, pruritus, urticaria, myalgia, weight decreased. Rare: Hallucinations, akathisia, hepatitis, increased alkaline phosphatase, hepatic failure, jaundice, erythematous rash, face oedema and angioedema, urinary retention. **OVERDOSE*. PROPERTIES*:** Agomelatine is a melatonergic agonist (MT1 and MT2 receptors) and 5-HT2C antagonist. Agomelatine resynchronises circadian rhythms in animal models of circadian rhythm disruption. Agomelatine increases noradrenaline and dopamine release specifically in the frontal cortex and has no influence on the extracellular levels of serotonin. **PRESENTATION*:** Pack of 28 film-coated tablets of Valdoxan 25 mg. **SERVIER HONG KONG LIMITED**, Flat 08-09, 43/F, Times Square Tower One, 1 Matheson Street, Causeway Bay, Hong Kong. www.servier.hk ***For complete information, please refer to the Summary of Product Characteristics.**