Valdoxan®

Agomelatine

The MT_1/MT_2 agonist and 5-HT_{2C} antagonist[1]

- **Treatment of major depressive episodes in adults.[2]**
- **25 mg once daily at bedtime. After 2 weeks of treatment, if there is no improvement of symptoms, the dose may be increased to 50 mg once daily.[2]**
- **Improve mood symptoms and social and occupational functioning,[3] together with a good tolerability profile.[4]**

Valdoxan **Composition :** Valdoxan 25 mg: film-coated tablet containing 25 mg of agomelatine. Contains lactose as an excipient**. Indications*:** Treatment of major depressive episodes in adults. **Dosage and administration*:** The recommended dose is 25 mg once daily taken orally at bedtime. After two weeks of treatment, if there is no improvement of symptoms, the dose may be increased to 50 mg once daily. Liver function tests should be performed in all patients before starting treatment. Treatment should not be initiated if transaminases exceed 3 upper limit of normal (see "Contraindications" and "Warnings" sections).During treatment transaminases should be monitored periodically afteraround three weeks, six weeks (end of acute phase), twelve weeks and twenty four weeks (end of maintenance phase) and thereafter when clinically indicated (see "warnings"section). Treatment should be discontinued if transaminases exceed 3 upper limit of normal (see "Contraindications" and "Warnings" sections). When increasing the dosage, liverfunction tests 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 3 upper limit of normal (see "Posology" and "Warnings" sections). Concomitant use of potent CYP1A2 inhibitors (e.g. fluvoxamine, ciprofloxacin) (see "Interaction" 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, 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 L3 X upper limit of normal. Caution should be exercised when Valdoxan is administered to patients with pretreatment elevated transaminases (L the upper limit of the normal ranges and o3 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 3 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 (O75 years):* 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. **Interaction(s) :** *Contra-indicated:* potent CYP1A2 inhibitors. *Not recommended:* alcohol; moderate CYP1A2 inhibitors. **Fertility , Pregnancy :** Not recommended. **Breastfeeding :** With precautions. **Drive & use machines :** Possible occurrence of dizziness and somnolence should be taken into account. **Undesirable effects :** *Common:* Anxiety, headache, dizziness, somnolence, insomnia, migraine, nausea diarrhoea, constipation, abdominal pain, vomiting, increased ALAT and/or ASAT, hyperhidrosis, back pain, fatigue. *Uncommon:* Agitation, irritability, restlessness, aggression, nightmares, abnormal dreams, confusional state, paraesthesia, restless leg syndrome, blurred vision, tinnitus, eczema, pruritus, urticaria. *Rare:* Mania/hypomania, hallucinations, hepatitis, increased gamma-glutamyltransferase, increased alkaline phospha- tase, hepatic failure, jaundice, erythematous rash, face oedema and angioedema, weight increased, weight decreased. *Frequency not known:* Suicidal thoughts or behavior. **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 (THAILAND)LTD., 2 Ploenchit Center Building, 15th Floor, Sukhumvit Road, Klongtoey, Bangkok.

โปรดอ่านรายละเอียดเพิ่มเติมในเอกสารอ้างอิงฉบับสมบูรณ์และเอกสารกำกับยา

ใบอนุญาตโฆษณา เลขที่ ฆศ. 38/2564

Reference:

1. Racagni G et al. *World J Biol Psychiatry.* 2011;12:574-587.
2. Product information.
3 Kennedy SH et al. *Eur Neuropsychopharmacol*. 2016; 26 : 378-389.
4.Kasper S et al. *J Clin Psychiatry*. 2010 ; 71(2) : 109-120.