**Vortioxetine**

**For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only**

Abbreviated Prescribing information for Vortioxetine (Vortioxetine tablet)

[Please refer the complete prescribing information for details].

## PHARMACOLOGICAL PROPERTIES:

**Mechanism of Action:** The mechanism of action of vortioxetine is thought to be related to its direct modulation of serotonergic receptor activity and inhibition of the serotonin (5-HT) transporter. Nonclinical data indicate that vortioxetine is a 5-HT3, 5-HT7, and 5-HT1D receptor antagonist, 5-HT1B receptor partial agonist, 5-HT1A receptor agonist and inhibitor of the 5-HT transporter, leading to modulation of neurotransmission in several systems, including predominantly the serotonin but probably also the norepinephrine, dopamine, histamine, acetylcholine, GABA and glutamate systems. This multimodal activity is considered responsible for the antidepressant and anxiolytic-like effects and the improvement of cognitive function, learning and memory observed with vortioxetine in animal studies. However, the precise contribution of the individual targets to the observed pharmacodynamic profile remains unclear and caution should be applied when extrapolating animal data directly to man.

**INDICATIONS:** It is indicated for the treatment of major depressive disorder in adults.

**DOSAGE AND ADMINISTRATION:** The Daily recommended dose is as directed by the physician. Vortioxetine tablet should be administered orally. The film-coated tablets can be taken with or without food.

**CONTRAINDICATION:** Hypersensitivity to the active substance or to any of the excipients. Concomitant use with nonselective monoamine oxidase inhibitors (MAOIs) or selective MAO-A inhibitors.

**WARNINGS & PRECAUTIONS:** Talk to your doctor or pharmacist before taking Vortioxetine are taking medicines with a so-called serotonergic effect, such as: tramadol (a strong painkiller), sumatriptan and similar medicines with active substance names ending in “triptans” (used to treat migraine), Taking these medicines together with Vortioxetine may increase the risk of serotonin syndrome. This syndrome may be associated with hallucinations, involuntary twitching, accelerated heartbeat, high blood pressure, fever, nausea and diarrhoea, have had fits (seizures).Your doctor will treat you cautiously if you have a history of fits or have unstable fit disorders/epilepsy. Fits are a potential risk with medicines used to treat depression. Treatment should be discontinued in any patient who develops fits or where there is an increase in the frequency of fits like have had mania, have a tendency to bleed or bruise easily, have low sodium level in the blood., are 65 years of age or older, have a severe kidney disease and have a severe liver disease or a liver disease called cirrhosis.

Thoughts of suicide and worsening of your depression.If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.You may be more likely to think like this if you: have previously had thoughts about killing or harming yourself, are a young adult.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away. You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

**DRUG INTERACTIONS**: Phenelzine, iproniazid, isocarboxazid, nialamide, tranylcypromine (medicines to treat depression called non-selective monoamine oxidase inhibitors); you must not take any of these medicines together with vortioxetine. If you have taken any of these medicines, you will need to Wait 14 days before you start taking vortioxetine. After stopping vortioxetine you must allow 14 days before taking any of these medicines: moclobemide (a medicine to treat depression), selegiline, rasagiline (medicines to treat Parkinson's disease), Linezolid (a medicine to treat bacterial infections), Lithium (a medicine to treat depression and mental disorders) or tryptophan., Medicines know to cause low sodium level, Rifampicin (a medicine to treat tuberculosis and other infections), Carbamazepine, phenytoin (medicines to treat epilepsy or other illness), Warfarin, dipyridamole, phenprocoumon, low-dose acetylsalicylic acid (blood thinning medicines), Medicines that increase the risk of fits: Sumatriptan and similar medicines with active substance names ending in "triptans", Tramadol (a strong painkiller), Mefloquine (a medicine to prevent and treat malaria), Bupropion (a medicine to treat depression also used to wean from smoking), Fluoxetine, paroxetine and other medicines to treat depression called SSRI/SNRIs, tricyclics, St John's wort (hypericum perforatum) (a medicine to treat depression), quinidine (a medicine to treat heart rhythm disorders), chlorpromazine, chlorprothixene, haloperidol (medicines to treat mental disorders belonging to the groups called phenothiazines, thioxanthenes, butyrophenones). Please tell your doctor if you are taking any of the medicines above, since your doctor needs to know if you already are at risk for seizures.

**ADVERSE REACTIONS**: Side effects listed below have been reported in the following frequencies. *Very common:* Nausea. *Common: may affect up to 1 in 10 people:* Diarrhoea, constipation, vomiting, Dizziness, itching of the whole body, Abnormal dreams. *Uncommon: may affect up to 1 in 100 people:* flushing, Night sweats. *Not known: frequency cannot be estimated from available data:* low levels of sodium in the blood (the symptoms may include feeling dizzy, weak, confused, sleepy or very tired, or feeling or being sick; more serious symptoms are fainting, fits or falls), ,Serotonin syndrome, swelling of the face, lips, tongue or throat, hives. An increased risk of bone fractures has been observed in patients taking this type of medicines.

**MARKETED BY:**

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**IN/ VORTIOXETINE 5, 10, 20 mg /NOV-21/01/ABPI**

(Additional information is available on request)