Prescribing Information Sheet February 2019

**Vortioxetine (Brintellix ®) – third line for major depression**

**Formulary Status**

For the treatment of major depressive episodes in patients for whom other anti-depressants have not been efficacious or when potential or actual side effects of other anti-depressants prohibit use

GP may initiate or continue prescribing if initiated in secondary care

Recommended by NICE as an option for treating major depressive episodes in adults whose condition has responded inadequately to 2 antidepressants within the current episode.

## Full prescribing guidance – Summary of Product Characteristics [www.emc.medicines.org.uk](http://www.emc.medicines.org.uk/)

**Indication and Dosage**

**Indication:** Vortioxetine is licensed for the treatment of major depressive episodes in adults

**Presentation:** Film-coated tablets: 5, 10, 15 and 20mg

**Dosage and Administration:** The recommended starting dose is 10 mg vortioxetine once daily in adults less than 65 years of age.

Depending on individual patient response, the dose may be increased to a maximum of 20 mg vortioxetine once daily or decreased to a minimum of 5 mg vortioxetine once daily.

*Renal impairment:* No dose adjustment is required, however caution should be exercised when prescribing vortioxetine to patients with severe renal impairment.

*Hepatic impairment:* No dose adjustment is required, however caution should be exercised when prescribing vortioxetine to patients with severe renal impairment.

*Elderly:* The lowest effective dose of 5 mg vortioxetine once daily should always be used as the starting dose in patients ≥ 65 years of age. Caution is advised when treating patients ≥ 65 years of age with doses higher than 10 mg vortioxetine once daily for which data are limited

**CYP2D6 inhibitors**

Vortioxetine is metabolised primarily by CYP2D6.

Depending on individual patient response, a lower dose of vortioxetine may be considered if strong CYP2D6 inhibitor (e.g., bupropion, quinidine, fluoxetine, paroxetine) is added to vortioxetine treatment

**CYP2D6 inducers**

Depending on individual patient response, a dose adjustment of vortioxetine may be considered if a broad cytochrome P450 inducer (e.g., rifampicin, carbamazepine, phenytoin) is added to vortioxetine treatment

**Adverse effects, special warnings and precautions for use (consult SPC for full list)**

**Pregnancy**

There is limited data from the use of vortioxetine in pregnant women. should only be administered to pregnant women if the expected benefits outweigh the potential risk to the foetus

**Breast-feeding**

Available data in animals have shown excretion of vortioxetine/ vortioxetine metabolites in milk. It is expected that vortioxetine will be excreted into human milk.

A risk to the breastfeeding child cannot be excluded.

A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Brintellix treatment taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

**Bipolar disorder/ mania / hypomania**

Vortioxetine should be used with caution in patients with a history of bipolar disorder, mania or hypomania and should be discontinued if a patient develops manic symptoms

**Suicide/suicidal thoughts**

Depression is associated with an increased risk of suicidal thoughts, self-harm and suicide (suicide-related events). This risk persists until significant remission occurs. As improvement may not occur during the first few weeks or more of treatment, patients should be closely monitored until such improvement occurs. It is general clinical experience that the risk of suicide may increase in the early stages of recovery.

Patients with a history of suicide-related events or those exhibiting a significant degree of suicidal ideation prior to commencement of treatment are known to be at greater risk of suicidal thoughts or suicide attempts, and should receive careful monitoring during treatment. A meta-analysis of placebo-controlled clinical trials of antidepressants in adult patients with psychiatric disorders showed an increased risk of suicidal behaviour with antidepressants compared to placebo, in patients less than 25 years old.

Close supervision of patients and in particular those at high risk should accompany treatment especially in early treatment and following dose changes. Patients (and caregivers of patients) should be alerted to the need to monitor for any clinical worsening, suicidal behaviour or thoughts and unusual changes in behaviour and to seek medical advice immediately if these symptoms present.

**Cautions related to all SSRIs**

Caution should be exercised in the same way as for all SSRIs when treating patients at risk of hyponatraemia, seizures, haemorrhage or serotonin syndrome

The most common **adverse reaction** with vortioxetine was nausea.

The incidence of adverse reactions increases at doses of 20mg.

Common side effects include abnormal dreams, dizziness, diarrhoea, constipation, vomiting and pruritus, including generalised pruritus

## Drug Interactions (consult SPC for full list)

Vortioxetine is metabolised mainly by cytochrome P450 2D6. Medicinal products that interact with these isoenzymes may decrease or increase the bioavailability of vortioxetine.

The combination of vortioxetine with MAO-A inhibitors is contraindicated.

Co-administration of medicinal products with serotonergic effect (e.g., tramadol, sumatriptan and other triptans) may lead to serotonin syndrome

Concomitant use of antidepressants with serotonergic effect and herbal remedies containing St. John's wort (Hypericum perforatum) may result in a higher incidence of adverse reactions including Serotonin Syndrome

Antidepressants with serotonergic effect can lower the seizure threshold. Caution is advised when concomitantly using other medicinal products capable of lowering the seizure threshold [e.g., antidepressants (tricyclics, SSRIs, SNRIs), neuroleptics (phenothiazines, thioxanthenes and butyrophenones), mefloquine, bupropion, tramadol

Caution should be exercised when vortioxetine is combined with oral anticoagulants or antiplatelet medicinal products due to a potential increased risk of bleeding attributable to a pharmacodynamic interaction

No effect on the pharmacokinetics of vortioxetine or ethanol and no significant impairment, relative to placebo, in cognitive function were observed when vortioxetine in a single dose of 20 mg or 40 mg was co-administered with a single dose of ethanol (0.6 g/kg) in healthy subjects. However, alcohol intake is not advisable during antidepressant treatment.

**Contact details of Specialist team**

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