Amber with Guidance (Amber-G) = To be recommended or initiated by a specialist with follow up prescribing and monitoring by primary care clinicians.*
**Specialist is defined by the APC as a clinician who has undertaken an appropriate formal qualification or recognised training programme, or who has the appropriate knowledge and competencies within the described area of practice.*

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Vortioxetine (Brintellix®)

The details of side-effects, cautions, contraindications and interactions are not a complete list and the current BNF (https://www.medicinescomplete.com/#/) and the SPC (https://www.medicines.org.uk/emc/) remain authoritative.

Background Information	Vortioxetine is recommended by NICE (TA367) as a possible treatment for adults having a first or recurrent major depressive episode, if the current episode has not responded to 2 antidepressants. Target population: Adults over 18 years of age
BNF therapeutic class	Other Antidepressant drugs
Indication	Vortioxetine is indicated for the treatment of major depressive episodes in adults.
Dosage and administration	The starting and recommended 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. After the depressive symptoms resolve, treatment for at least 6 months is recommended for consolidation of the antidepressive response. Treatment discontinuation Patients treated with vortioxetine can abruptly stop taking the medicinal product without the need for a gradual reduction in dose. Elderly Patients 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
Cautions and Contraindications	**Contraindications** Hypersensitivity to the active substance or to any of the excipients Concomitant use with nonselective monoamine oxidase inhibitors (MAOIs) or selective MAO-A inhibitors **Cautions:** Not recommended in patients under 18 years of age due to lack of data. Avoid in pregnancy due to lack of data. Suicidal thoughts and ideation. Seizures. Serotonin syndrome or Neuroleptic malignant syndrome. Mania or hypomania. Decrease in renal or hepatic function. Hyponatremia. Hemorrhage. Glaucoma. Aggression/Agitation. CYP2D6 inhibitors (consider lower dose if co-prescribed with potent inhibitor). CYP3A4 & CYP2D6 (consider lower dose if co-prescribed with potent inhibitor).
Pregnancy and breast feeding	**Pregnancy:** Limited data from the use in pregnant women. Studies in animals have shown reproductive toxicity.

	The following symptoms may occur in the newborn after maternal use of a serotonergic medicinal product in the later stages of pregnancy: respiratory distress, cyanosis, apnoea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycaemia, hypertonia, hypotonia, hyperreflexia, tremor, jitteriness, irritability, lethargy, constant crying, somnolence and difficulty sleeping. These symptoms could be due to either discontinuation effects or excess serotonergic activity. In the majority of instances, such complications began immediately or soon (<24 hours) after delivery. Epidemiological data suggest that the use of SSRIs in pregnancy, particularly in late pregnancy, may increase the risk of persistent pulmonary hypertension in the newborn (PPHN). Although no studies have investigated the association of PPHN with vortioxetine treatment, this potential risk cannot be ruled out taking into account the related mechanism of action (increase in serotonin concentrations). Brintellix should only be administered to pregnant women if the expected benefits outweigh the potential risk to the foetus. Observational data have provided evidence of an increased risk (less than 2-fold) of postpartum haemorrhage following exposure to an SSRI or SNRI within the month prior to birth. Although no studies have investigated an association between vortioxetine treatment and postpartum haemorrhage, there is a potential risk, taking into account the related mechanism of action **Breastfeeding:** 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.
Adverse Drug Reactions	• Abnormal dreams • Dizziness • GI effects including nausea • Pruritus • Flushing • Bleeding
Monitoring	No ongoing monitoring required
Interactions	• MAOI • Linelozid • Selegiline/rasagiline • Tramadol/sumatriptan • St Johns Wort
Additional information	N/A
Ordering information	N/A

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Equality and diversity

- N/A

References

- **Vortioxetine (Brintellix)** Summary of Product Characteristics. September 2015. Available at: Brintellix 20 mg film-coated tablets - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) Accessed: 21/11/23
- NICE TA 367 Available at https://www.nice.org.uk/guidance/ta367 Accessed: 21/11/2023

Development Process

This guidance has been produced by Patrick Cleary, Lead Clinical Pharmacist at Kendray Hospital following an AMBER-G classification status of Vortioxetine by the Barnsley Area Prescribing Committee. This guideline was ratified by the Area Prescribing Committee on 14th February 2024.