Prescribing Information

Brintellix® (vortioxetine) film-coated tablets

Prescribing information: Please refer to the full Summary of Product Characteristics (SPC) before prescribing, particularly in relation to side effects, precautions and contraindications.
Presentation: Tablets containing 5, 10 or 20mg of vortioxetine.
Indication: Treatment of major depressive episodes in adults.
Dosage: 10mg once daily. May be increased to maximum 20mg daily or reduced to 5mg if necessary. After symptoms resolve, treatment recommended for at least 6 months. Can be taken with or without food. *Treatment discontinuation:* Gradual reduction in dosage may be considered to avoid occurrence of discontinuation symptoms.
Elderly (≥65 years): Initial dosage, 5mg once daily. Caution advised if using doses above 10mg daily.
Children (7-11 years): Not recommended.
Adolescents (12-17 years): Not recommended in major depressive disorder; efficacy not established.
Cytochrome P450 inhibitors and inducers: Consider a dose reduction if a strong CYP2D6 inhibitor is added. Consider a dose adjustment if a broad CYP450 inducer is added to treatment.
Renal or hepatic impairment: No dose adjustment; subpopulations are vulnerable and data is limited.
Contraindications: Hypersensitivity to the active substance or excipients. Concomitant use with non-selective, monoamine oxidase inhibitors (MAOIs) or selective MAO-A inhibitors (e.g. moclobemide).
Fertility, pregnancy and lactation: Limited data, should only be administered to pregnant women if the expected benefits outweigh the potential risk to the foetus. Animal studies showed reproductive toxicity. Use of SSRIs in pregnancy, particularly in late pregnancy, may increase the risk of persistent pulmonary hypertension in the newborn (PPHN). Potential risk of postpartum haemorrhage following exposure to an SSRI or SNRI within the month prior to birth. Excreted into human milk, risk to the breastfeeding child cannot be excluded. Animal data showed no effect on fertility, sperm quality or mating performance. Human case reports with some SSRIs have shown an effect on sperm quality is reversible. Impact on human fertility has not been observed. Please refer to SPC for more detail.
Warnings & Precautions: Closely supervise patients, especially those at high risk, for suicide-related behaviours during first few weeks of treatment and during dose changes. Use with caution in patients at risk of hyponatraemia; with a history of mania/hypomania; undergoing ECT; with unstable epilepsy (discontinue if seizures begin for the first time or increase in frequency); with bleeding tendencies/disorders, taking anticoagulants or medicines affecting platelet function; in patients on lithium or tryptophan; with increased intraocular pressure, or those at risk of acute narrow angle glaucoma. Monitor patients for appearance of serotonin syndrome or neuroleptic malignant syndrome and discontinue if occurs. Patients may experience feelings of aggression, anger, agitation and irritability. Patients/caregivers should seek medical advice if such behaviour emerges or aggravates. SSRIs/SNRIs may increase the risk of postpartum haemorrhage. Brintellix tablets contain sodium (<1mmol/tablet).
Drug interactions: Alcoholic drinks not advisable. Vortioxetine is extensively metabolised in the liver. Potential for interactions with: MAOIs, MAO-A and MAO-B inhibitors; serotonergic medicines (including opioids and triptans); St John's wort; products which may lower the seizure threshold, e.g. antidepressants, neuroleptics, mefloquine or bupropion. Lower dose may be considered if a strong CYP2D6 inhibitor is added to treatment depending on patient response. Effect may be greater in patients who are poor metabolisers of CYP2D6. Dose adjustment may be considered if a broad cytochrome P450 inducer is added to treatment. Reports of false positive results in urine enzyme immunoassays for methadone in patients taking vortioxetine. Exercise caution in interpreting positive drug screen results.
Effects on ability to drive and operate machines: No or negligible influence, dizziness has been reported; use caution at the start of treatment or when the dose is changed.
Adverse events: Most common adverse reaction is nausea, usually mild or moderate, transient and occurs within the first two weeks of treatment. The following have been reported in clinical trials and during post-marketing use: *Very common* (≥1/10 patients): nausea. *Common* (≥1/100 to <1/10): abnormal dreams, dizziness, diarrhoea, constipation, vomiting, dyspepsia, pruritus, including generalised pruritus, hyperhidrosis. *Uncommon* (≥1/1,000 to <1/100): tremor, blurred vision, flushing, night sweats. *Rare* (≥1/10,000 to <1/1,000): mydriasis (which may lead to acute narrow-angle glaucoma). *Not known:* anaphylactic reaction, hyperprolactinaemia in some cases associated with galactorrhoea, hyponatraemia, insomnia, agitation, aggression, serotonin syndrome, headache, akathisia, bruxism, trismus, restless leg syndrome, haemorrhage (including contusion, ecchymosis, epistaxis, gastrointestinal or vaginal bleeding), angioedema, urticaria, rash, discontinuation syndrome. *Sexual dysfunction:* 20mg dose was associated with increase in sexual dysfunction. Post-marketing cases of sexual dysfunction have also been reported with doses below 20mg. *Class effect:* Studies in patients ≥50 years of age, show an increased risk of bone fractures in patients receiving SSRIs and TCAs. Not known if relevant to vortioxetine. *Paediatrics:* Higher incidences reported in adolescents than in adults, for abdominal pain-related events and suicidal ideation. *Discontinuation symptoms* have been reported in the post-marketing period, including dizziness, headache, sensory disturbances (including paraesthesia, electric shock sensations), sleep disturbances (including insomnia), nausea and/or vomiting, anxiety, irritability, agitation, fatigue and tremor. These may occur within the first week of vortioxetine discontinuation. Prescribers should consult the full SPC in relation to other side effects.
Overdose: Management consisting of treating clinical symptoms and relevant monitoring.
Legal category: POM. Brintellix Tablets, blisters of:

5mg NI (EU/1/13/891/002), GB (PLGB00458/0300), 28 tablets, £27.72;

10mg NI (EU/1/13/891/010), GB (PLGB00458/0296), 28 tablets, £27.72.

20mg NI (EU/1/13/891/028), GB (PLGB00458/0298) 28 tablets, £27.72.

Further information available from: Lundbeck Limited, Iveco House, Station Road, Watford, Hertfordshire, WD17 1ET. Tel: 01908 649966. **Date of last revision of PI:** August 2023. **Reference:** UK-BRIN-1442
Brintellix® is a Registered Trade Mark.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Lundbeck Limited, Medical Information, on: 01908 638972 or Email: SafetyLuUnitedKingdom@lundbeck.com