Nytenso™

Vortioxetine Hydrobromide

Presentation

Nytenso™ 5: Each tablet contains Vortioxetine Hydrobromide INN equivalent to Vortioxetine 5 mg.

Nytenso™ 10: Each tablet contains Vortioxetine Hydrobromide INN equivalent to Vortioxetine 10 mg.

Nytenso™ 20: Each tablet contains Vortioxetine Hydrobromide INN equivalent to Vortioxetine 20 mg.

Description

Vortioxetine is a serotonin modulator and stimulator. The precise mechanism of action of Vortioxetine is unknown, but is thought to be related to increase the level of serotonin (5-HT).

Indications and usage

Vortioxetine is indicated for treatment of major depressive disorder (MDD) in adults.

Dosage and administration:

- The recommended starting dose is 10 mg administered orally once daily without regard to meals.
- Then, the dose can be increased to 20 mg/day, as tolerated.
- Consider 5 mg/day for patients who do not tolerate higher doses.
- Vortioxetine can be discontinued abruptly. However, it is recommended that doses of 15 mg/day or 20 mg/day be reduced to 10 mg/day for one week prior to full discontinuation if possible.

Adverse reactions

The most common adverse reactions of Vortioxetine are nausea, constipation and vomiting.

Contraindications

Vortioxetine is contraindicated in patients with a known hypersensitivity to Vortioxetine. Use of MAOIs with Vortioxetine or within 21 days of stopping treatment with Vortioxetine or use of Vortioxetine within 14 days of stopping an MAOI is contraindicated. In addition, administration of Vortioxetine in a patient who is being treated with linezolid or intravenous methylene blue is also contraindicated.

Precautions

Caution should be exercised when Vortioxetine is prescribed in patients with:

- SSRIs, SNRIs, and triptans- increase risk of serotonin syndrome
- Concomitant use of aspirin, nonsteroidal anti-inflammatory drugs and other antiplatelet drugs, angle closure glaucoma, hyponatremia and sexual dysfunction can occur when a patient is treated with an antidepressant.

Drug interactions

Vortioxetine should be used with caution in combination with:

- Strong inhibitors of CYP2D6- Vortioxetine dose should be by half when coadministered
- Strong CYP Inducers: Vortioxetine dose should be increased when coadministered for more than 14 days. The maximum recommended dose should not exceed 3 times the original dose

Use in specific population

Pregnancy & Lactation: Third trimester use may increase risk for persistent pulmonary hypertension and withdrawal in the newborn. There is no information regarding the presence of vortioxetine in human milk, the effects on the breastfed infant, or the effects on milk production.

Pediatric use: The safety and effectiveness of Vortioxetine have not been established in pediatric patients for the treatment of MDD.

Geriatric use: No dose adjustment is recommended on the basis of age.

Overdose

The most frequently reported symptoms with overdoses up to 80 mg (four times the maximum recommended daily dose) were nausea and vomiting.

Storage

Do not store above 30 ºC. Keep away from light and out of the reach of children.

Commercial Pack

Nytenso™ 5: Each box contains 3 blister strips of 10 tablets.
Nytenso™ 10: Each box contains 3 blister strips of 10 tablets.
Nytenso™ 20: Each box contains 3 blister strips of 10 tablets.

Manufactured by
Incepta Pharmaceuticals Ltd
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™ Trademark