

EVORTIOX[®]

[Vortioxetine]

Evortiox 10mg Tablets
Each film coated tablet contains:
Vortioxetine Hydrobromide (Mfg. specs)
Eq. to Vortioxetine 10mg
Product complies as per innovator's specifications.

Evortiox 20mg Tablets
Each film coated tablet contains:
Vortioxetine Hydrobromide (Mfg. specs)
Eq. to Vortioxetine 20mg
Product complies as per innovator's specifications.

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

- Increased risk of suicidal thinking and behavior in children, adolescents, and young adults taking antidepressants.
- Monitor for worsening and emergence of suicidal thoughts and behaviors.
- Evortiox has not been evaluated for use in pediatric patients.

INDICATIONS AND CLINICAL USE

Evortiox is indicated for the treatment of major depressive episodes in adults.

DOSAGE AND ADMINISTRATION

The starting and recommended dose of Vortioxetine 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.

Paediatric population

The safety and efficacy of Vortioxetine in children aged 7 to 11 years have not been established. No data are available. Vortioxetine should not be used in adolescents aged 12 to 17 years with major depressive disorder (MDD) because efficacy has not been demonstrated.

Renal or hepatic impairment

No dose adjustment is needed based on renal or hepatic function.

Method of administration

Vortioxetine is for oral use.
The film-coated tablets can be taken with or without food.

CONTRAINDICATIONS

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. Concomitant use with nonselective monoamine oxidase inhibitors (MAOIs) or selective MAO-A inhibitors.

Special Populations

There are limited data from the use of vortioxetine in pregnant women. Studies in animals have shown reproductive toxicity

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 (see section 5.3). A risk to the breastfeeding child cannot be excluded.
A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Vortioxetine treatment taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

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(وورٹیو آکسٹین)
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Fertility

Fertility studies in male and female rats showed no effect of vortioxetine on fertility, sperm quality or mating performance (see section 5.3).
Human case reports with medicinal products from the related pharmacological class of antidepressants (SSRIs) have shown an effect on sperm quality that is reversible. Impact on human fertility has not been observed so far.

Effects on ability to drive and use machines

Vortioxetine has no or negligible influence on the ability to drive and use machines. However, as adverse reactions such as dizziness have been reported, patients should exercise caution when driving or operating hazardous machinery, especially when starting treatment with vortioxetine or when changing the dose.

PHARMACODYNAMIC 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-HT_{1D} receptor antagonist, 5-HT_{1B} receptor partial agonist, 5-HT_{1A} receptor agonist and inhibitor of the 5-HT transporter.

PHARMACOKINETIC PROPERTIES

Absorption

Vortioxetine is slowly, but well absorbed after oral administration and the peak plasma concentration is reached within 7 to 11 hours. Following multiple dosing of 5, 10, or 20 mg/day, mean C_{max} values of 9 to 33 ng/mL were observed. The absolute bioavailability is 75%. No effect of food on the pharmacokinetics was observed (see section 4.2).

Distribution

The mean volume of distribution (V_{ss}) is 2,600 L, indicating extensive extravascular distribution. Vortioxetine is highly bound to plasma proteins (98 to 99%) and the binding appears to be independent of vortioxetine plasma concentrations.

Biotransformation

Vortioxetine is extensively metabolised in the liver, primarily through oxidation catalysed by CYP2D6 and to a minor extent CYP3A4/5 and CYP2C9, and subsequent glucuronic acid conjugation.

No inhibitory or inducing effect of vortioxetine was observed in the drug-drug interaction studies for the CYP isozymes CYP1A2, CYP2A6, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2D6, CYP2E1, or CYP3A4/5 (see section 4.5). Vortioxetine is a poor P-gp substrate and inhibitor. The major metabolite of vortioxetine is pharmacologically inactive.

Elimination

The mean elimination half-life and oral clearance are 66 hours and 33 L/h, respectively. Approximately 2/3 of the inactive vortioxetine metabolites are excreted in the urine and approximately 1/3 in the faeces.
Only negligible amounts of vortioxetine are excreted in the faeces. Steady-state plasma concentrations are achieved in approximately 2 weeks.

DOSAGE FORMS AND STRENGTHS:

Tablets: 10 mg & 20 mg (SCORED TABS)

Packsize :

10 mg 20's, 14's

20 mg 20's, 14's

STORAGE CONDITIONS AND OTHER INFORMATION

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and on the blister after EXP.
- Do not throw away any medicines via wastewater or household waste

ہدایات:

- خوراک ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
- دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر روشنی سے بچا کر خشک جگہ پر رکھیں۔
- صرف رچرڈ ڈاکٹر کے نسخے پر ہی فروخت کریں۔
- بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:

Kaizen Pharmaceuticals (Pvt.) Ltd.,
E-127-129, North Western Industrial Zone,
Bin Qasim, Karachi-75020, Pakistan.

Art no: 670/1