165mm

155mm

EVOSPIRON

(Tandospirone Citrate)

5mg, 10mg & 20mg Tablets

ایوو سپائرون

(ٹینڈوسپائرون سائٹریٹ)

۵ ملی گرام، ۱۰ ملی گرام اور ۲۰ ملی گرام گولیاں

Composition:
Evospiron Tablet 5mg
Each film coated tablet contains:
Tandospirone Citrate 5mg

Evospiron Tablet 10mg
Each film coated tablet contains:
Tandospirone Citrate 10mg

Evospiron Tablet 20mg
Each film coated tablet contains:
Tandospirone Citrate 20mg

CLINICAL PHARMACOLOGY
Mechanism of Action:
Tandospirone citrate is an anxiolytic medication that primarily acts on the serotonergic system in the brain to reduce symptoms of anxiety and improve emotional stability.
The main mechanism of action of Tandospirone involves selective partial agonism at serotonin 5-HT1A receptors. These receptors are widely distributed in brain regions involved in mood and anxiety regulation, including the hippocampus, cerebral cortex, and raphe nuclei. By binding to presynaptic and postsynaptic 5-HT1A receptors, Tandospirone partially mimics the action of serotonin. As a partial agonist, it activates these receptors but produces a weaker effect compared with serotonin itself. This property helps regulate serotonergic neurotransmission without causing excessive stimulation or inhibition.
Activation of presynaptic 5-HT1A autoreceptors in the raphe nuclei reduces the firing rate of serotonergic neurons and modulates serotonin release, while stimulation of postsynaptic receptors in limbic brain regions contributes to anxiolytic and mood-stabilizing effects. Through this balanced modulation of serotonin signaling, Tandospirone helps decrease neuronal hyperactivity associated with anxiety and promotes emotional stability.
In addition to its primary serotonergic activity, Tandospirone exhibits weak affinity for dopamine D2 receptors. Interaction with these receptors may slightly influence dopaminergic neurotransmission related to mood and reward pathways, which could contribute to its overall anxiolytic effects. However, this dopaminergic activity is considered secondary to its principal action on 5-HT1A receptors.
Overall, Tandospirone Tablets exert their therapeutic effect mainly by modulating serotonin transmission through partial agonism of 5-HT1A receptors, leading to reduced anxiety and improved mood regulation.

PHARMACOKINETICS
Absorption:
After oral administration, Tandospirone tablets are rapidly absorbed from the gastrointestinal

tract. Following a single oral dose of 20 mg in healthy adults, peak serum concentrations of the unchanged drug are reached within approximately 0.8 to 1.4 hours. The absorption of Tandospirone is not significantly affected by food, as similar drug levels are observed when taken in the fasted or fed state.

Distribution and Elimination:
Tandospirone is eliminated relatively quickly from the body. The serum elimination half-life of the unchanged drug is approximately 1.2 to 1.4 hours after a single oral dose in healthy adults.

SPECIAL POPULATION
• Pregnancy and Lactation: It is contraindicated for pregnant women or those who may become pregnant, and it is best not to use it for breastfeeding women.
• Elderly Patients: Due to higher blood concentration in elderly patients, it is recommended to start with a small dose.
Always consult a healthcare provider for personalized medical advice and to ensure safe usage of Tandospirone Chloride.

THERAPEUTIC INDICATIONS
Anxiety state caused by various neuroses, such as generalized anxiety disorder; anxiety state associated with physical diseases such as primary hypertension and peptic ulcer.
Tandospirone is present as a natural constituent in animal tissues, micro-organisms and plants. Only the L-isomer is biologically active, playing an essential role in lipid metabolism as well as in the metabolism of ketone bodies as branched chain amino acids. Tandospirone as a factor is necessary in the transport of long-chain fatty acids into the mitochondria - facilitating the oxidation of fatty acids rather than their incorporation into triglycerides. By releasing CoA from its thioesters, through the action of CoA; carnitine acetyl transferase, Tandospirone also enhances the metabolic flux in the Kreb's cycle; with the same mechanism it stimulates the activity of pyruvate dehydrogenase and in skeletal muscle, the oxidation of branched-chain amino acids. Tandospirone is thus involved, directly or indirectly in several pathways so that its availability should be an important factor controlling not only the oxidative utilization of fatty acids and ketone bodies but also that of glucose and some amino acids.

DOSAGE & ADMINISTRATION
The usual adult dosage is 30 mg of tandospirone citrate, given orally in three divided doses per day. This can be increased or decreased depending on age and symptoms, up to a maximum of 60 mg per day.

ROUTE OF ADMINISTRATION
For oral administration only.

ADVERSE REACTIONS
The following side effects may occur, so observe closely and if any abnormalities are found, take appropriate measures such as discontinuing administration,
• Hepatic dysfunction,
• Jaundice,
• Serotonin syndrome, whose main symptoms include agitation, myoclonus, sweating, tremor, and fever, may occur.
• Neuroleptic malignant syndrome may occur when used concomitantly with antipsychotics, antidepressants, etc., or when the drug is suddenly reduced in dose or discontinued.
• Digestive system (Nausea, loss of appetite, vomiting, stomach pain, lethargy, dry mouth, stomach upset, abdominal discomfort, abdominal distension, constipation)
• Allergies (feeling of fullness, diarrhea, rash, hives,)
• Circulator system (Palpitations, tachycardia, chest distress)
• Others (Itching, fatigue, chills, hot flashes, edema, weakness, mood swings (facial flushing, discomfort, burning sensation etc.), excessive in the extremities, sweating, numbness, blurred vision (sweating, night sweats, etc.), increased BUN, increased urinary NAG, increased eosinophils)

CONTRAINDICATIONS
It is contraindicated for those who are allergic to any ingredient in this product.

PRECAUTIONS
When using this drug, it is difficult for the drug to be effective in patients with severe anxiety symptoms, so caution is advised, such as carefully monitoring symptoms.
Drowsiness and dizziness may occur, so caution is advised against having patients operating dangerous machinery, such as driving a car, while receiving this drug.
Because there is no cross-dependence with benzodiazepine derivatives, immediately switching from a benzodiazepine derivative to this drug may induce withdrawal symptoms of the benzodiazepine derivative and worsen symptoms.
Pregnancy: Administer this drug to pregnant women or women who may be pregnant only if the therapeutic benefits are deemed to outweigh the risks.

DRUG INTERACTIONS
Butyrophenone antipsychotics (e.g., Haloperidol, Bromperidol, Spiperone)
Tandospirone has a weak antidopaminergic effect, which may enhance dopamine receptor blockade when used with butyrophenone antipsychotics. It may intensify the effects of butyrophenone drugs and increase the risk of extrapyramidal symptoms (EPS).
Nicardipine and other calcium channel blockers Intensifies the antihypertensive effect of this drug.
Amlodipine, Nifedipine Intensifies the central antihypertensive effect of this drug via the serotonin receptor. Serotonin reuptake inhibitors, etc. Serotonin syndrome may occur when used concomitantly. Fluvoxamine, paroxetine, milnacipran, trazodone, etc

OVERDOSAGE
There have been no reports of toxicity from Tandospirone overdosage. Overdosage should be treated with supportive care.

HOW SUPPLIED
Evospiron tablet 5mg is available in pack size of 1x10's, 2x10's & 3x10's
Evospiron tablet 10mg is available in pack size of 1x10's, 2x10's & 3x10's
Evospiron tablet 20mg is available in pack size of 1x10's, 2x10's & 3x10's

INSTRUCTIONS:
Store below 30°C in a dry place,
protect from light. To be dispensed on the
prescription of a registered medical practitioner only.
Keep out of the reach of children.

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

Kaizen Pharmaceuticals (Pvt.) Ltd.

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

Art no. 1439

Evospiron

Reference:

1. https://doi.org/10.18632/oncotarget.22170
2. https://www.rad-ar.or.jp/siori/english/search/result?n=34847
3. https://onlinelibrary.wiley.com/doi/pdf/10.1155/2022/9295627
4. https://pubmed.ncbi.nlm.nih.gov/29433063/