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With,

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Etizolam 0.5 mg and 1 mg Tablets

ETIBLISS™-ES 5 10

Etizolam with Escitalopram Tablets 0.5 mg & 5 mg / 0.5 mg & 10 mg

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Background:

Anxiety is arguably an emotion that predates the evolution of man. Its ubiquity in humans, and its presence in a range of anxiety disorders, makes it an important clinical focus.

In moderation, anxiety stimulates an anticipatory and adaptive response to challenging or stressful events. In excess, anxiety destabilizes the individual and dysfunctional state results. Anxiety is considered excessive or pathological when it arises in the absence of challenge or stress, when it is out of proportion to the challenge or stress in duration or severity, when it results in significant distress, and when it results in psychological, social, occupational, biological, and other impairment. [1]

Depression is a common mental disorder and is the leading cause of disability worldwide, and is a major contributor to the overall global burden of disease.

Prevalence:

- WHO -2015: Globally, approximately 350 million people of all ages suffer from depression.
- Global worldwide prevalence of anxiety disorder – ranges from 7.3% to 10. 4% [2]
- In 2013 – There were 8.2 mn. Cases of Anxiety reported in the UK [3]
- Anxiety disorders rank sixth, accounting for 4% of all Years lived in Disability in Europe [4]
- WHO 2011: 1 out of 7 people in India suffers from Anxiety & Depression
- World mental health 2014 survey indicates - 10-15% people experience major depression at least once in their lifetime. [5]
- Lifetime prevalence of all depressive disorders is over 20% worldwide (1 in 5 individuals) [6]
- 11% population in Low Income Countries are likely to get depression over lifetime [7]

Presence of both disorders is linked to poorer outcome, greater disability, poorer quality of life (QoL) and greater costs compared with either MDD or anxiety disorder alone [8]

Reference

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4- WHO Europe : Global Health Estimates 2014 Summary Tables
5 & 6- Journal of the association of physicians of India • vol 62
7- Cross-National Epidemiology of DSM-IV Major Depressive Episode. BMC Medicine, July 2011
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Etizolam and Escitalopram: Molecules of Choice.

Etizolam second most commonly prescribed benzodiazepine in the Neurotic, stress-related and somatoform disorders patients in India [1]

Title - Comparison of the effect of alprazolam, bromazepam and etizolam in generalized anxiety disorder [2]

Scale	Day 14 versus baseline	Day 28 versus baseline	Day 28 versus day 14
Hamilton's rating scale for Anxiety	- Alprazolam=bromazepam - Etizolam = alprazolam - Etizolam =bromazepam	- Alprazolam=bromazepam - Etizolam > alprazolam' - Etizolam = bromazepam	- Alprazolam=bromazepam - Etizolam > alprazolam - Etizolam > bromazepam
Hamilton's rating for Depression	- Alprazolam >bromazepam - Etizolam > alprazolam - Etizolam > bromazepam	- Alprazolam > bromazepam - Etizolam > alprazolam - Etizolam > bromazepam	- Alprazolam = bromazepam - Etizolam = aprazolam - Etizolam = bromazepam

Escitalopram –is the first choice judged by combined efficacy and tolerability [3]

				Results			
Trial/ Meta analysis objectives	**Indication and Participants**	**Drugs involved (& placebo where available)**	**Duration**	**Escitalopram**	**Paroxetine**	**Sertraline**	**References**
Efficacy & Tolerability	MDD (325)	Escitalopram 10-20 mg and 20-40 mg	8 weeks, then19 weeks maintenance, then 1-2 weeks withdrawal	Similar efficacy overall for escitalopram and paroxetine groups; but in severely depressed patients, escitalopram showed superiority	Higher withdrawal rate due to lack of efficacy; more discontinuation symptoms	-	Baldwin *et al. (2006)*
Efficacy	Severe MDD (459)	Escitalopram 20 mg and paroxetine 40 mg	24 weeks	Escitalopram group showed greater improvement and greater remission rate (75% vs. 67%) than paroxetine group	Higher withdrawal rate than escitalopram (32 vs. 19%); higher withdrawal rate due to adverse events than escitalopram (16 vs. 8%)	-	Boulenger *et al. (2006)*
Tolerability (Perspective follow-up study)	MDD (1251)	Sertraline and paroxetine	-	-	Tolerability: Sertraline (14%) is associated with higher rate of diarrhoea than Paroxetine and other SSRI's (7%) (P<0.05)	-	Meijer *et al. (2002)*
Sexual dysfunction (Meta-Analysis)	MDD	Escitalopram Paroxetine sertraline other antidepressants	Mostly 4-12 weeks	-	Total rate of treatment emergent sexual dysfunction~70%	Total rate of treatment emergent sexual dysfunction~80%	Serretti and Chiesa (2009)
Blood BDNF levels	MDD	-	-	Decreased blood BDNF levels predict treatment response	-	-	Wolkowitz *et al. (2011)*

1- Indian J Psychiatry. 2014 Jul-Sep; 56(3): 253-264.
2- The Journal of International Medical Research 1989; 17: 455 – 460
3- Int Clin Psychopharmacol. 2014 Jul; 29(4): 185–196.

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Description:

ETIBLISS is a film coated tablet containing etizolam molecule which is a benzodiazepine analog. The etizolam molecule differs from a benzodiazepine in that the benzene ring has been replaced by a thiophene ring, making the drug a thienodiazepine. It possesses amnesic, anxiolytic, anticonvulsant, hypnotic, sedative and skeletal muscle relaxant properties.

ETIBLISS-ES is a film coated tablet with a combination of etizolam with escitalopram molecules. Escitalopram is a selective serotonin reuptake inhibitors (SSRIs) and Etizolam is thienotriazolodiazepine and has pharmacological effects similar to those of the model benzodiazepine diazepam.

Mechanism of Action:

Etizolam:
Etizolam acts on the benzodiazepine site of the $GABA_A$ receptor. Mainly acts on Limbic system and ascending reticular formation in the CNS and binds to BZD receptor. The binding will facilitates GABA mediated chloride channel opening and produce hyperpolarization. This will produce an increase in the concentration of the inhibitory neurotransmitter GABA and chloride ions and decrease firing rate of neuron. These in turn alters normal function of the body.

Escitalopram:
The antidepressant, anti-obsessive-compulsive, and antibulimic actions of escitalopram are presumed to be linked to its inhibition of CNS neuronal uptake of serotonin. Escitalopram blocks the reuptake of serotonin at the serotonin reuptake pump of the neuronal membrane, enhancing the actions of serotonin on 5HT1A autoreceptors. SSRIs bind with significantly less affinity to histamine, acetylcholine, and norepinephrine receptors than tricyclic antidepressant drugs.

Indications:
- Major Depressive Disorder
- Sleep disorder

Dosage:
- Anxiety disorder: 0.25-0.5 mg twice daily
- Panic disorder: 0.5 mg twice daily
- Insomnia: 1-2 mg daily
- Maximum daily dosage: 3 mg

Administration: Taken by mouth as directed by physician with food, usually once daily.

Presentation: Available as strip of 10 tablets.

Storage: Store protected from light and moisture, at a temperature not exceeding 30 °C

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