DULOREN™

Duloxetine Gastro Resistant 20 mg ,30 mg and 40 mg Tablets

DESCRIPTION:

Duloren (Duloxetine) is a selective serotonin and norepinephrine reuptake inhibitor (SSNRI) for oral administration. Its chemical name is (+)-(S)-N-methyl-γ-(1-naphthyloxy)-2-thiophenepropylamine hydrochloride primarily targets major depressive disorder (MDD), generalized anxiety disorder (GAD), pain related to diabetic peripheral neuropathy and in some countries stress urinary incontinence (SUI) available as delayed release tablets.

MECHANISM OF ACTION:

Duloxetine is a potent inhibitor of neuronal serotonin and norepinephrine reuptake and a less potent inhibitor of dopamine reuptake. The antidepressant and pain inhibitory actions of duloxetine are believed to be related to its potentiation of serotonergic and noradrenergic activity in the CNS.

INDICATIONS:

» Depression
» Anxiety Disorder
» Also used for managing pain caused by fibromyalgia and diabetic peripheral neuropathy (DPNP)

DOSAGE:

The recommended dose: Initially: 20 mg/day, twice daily orally.
Maintenance dose: 40 mg/day twice daily
Maximum dose: 60 mg/day twice daily

ADMINISTRATION:

To be taken by mouth. It is usually taken once or twice a day with or without food.

PRESENTATION:

Available as strip of 10 tablets.

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I am.....
Call me on.....
Mail me at.....

Discard the undesired disruption

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BACKGROUND:

» A spectrum of mood disorders is characterized by depressed or sad mood, diminished interest in activities which used to be pleasurable, weight gain or loss, psychomotor agitation or retardation, fatigue, inappropriate guilt, difficulties concentrating, as well as recurrent thoughts of death.

» The DSM-IV (APA 1994) defines “major depressive episode” by a cluster of symptoms, including somatic symptoms, representing a change from previous functioning and which must be present for at least 2 weeks.

» This cluster includes either 1) depressed mood or 2) loss of interest or pleasure, and five of nine depressive symptoms – depressed mood; anhedonia; appetite or weight change; sleep difficulties; psychomotor agitation or retardation; fatigue or decreased energy; concentration difficulties; feelings of worthlessness or guilt; and recurrent thoughts of death or suicide.

» Painful physical symptoms (PPS), generally present as unexplained headache, pain in the joints or abdomen, or pains in the chest, neck, or shoulder areas, are frequently encountered physical symptoms. PPS is linked with poorer clinical outcomes and contribute to the overall burden of Major depressive disorder (MDD).

» Prevalence of fatigue and low energy is high among patients with MDD, and these symptoms are clinically relevant for patients seeking treatment for MDD.

PREVALENCE:

» MDD affects more than 350 million people, of all ages, worldwide and is a significant contributor to the global burden of disease.[1]

» Depression - become the second - leading cause of disability by 2020, and untreated depression may lead to increased morbidity and mortality.[2]

» The World Mental Health Survey conducted in 17 countries found that on average about 1 in 20 people reported having an episode of depression in the previous year.[3]

» Depression would be the leading cause of disability in industrialized countries by 2030 and accounts for 4.5% of all human disabilities.[3]

» Most of the mental disorder cases reported in the age group of 30-44 years followed by - age group of 18-29 years - due to stress and strain.[3]

» World Health Organization, unipolar depressive disorders were ranked as the third leading cause of the global burden of disease in 2004 and will move into the first place by 2030.[3]

» The burden of depression is 50% higher for females than males. In fact, depression is the leading cause of disease burden for women in both high-income and low- and middle-income countries.[3]

Reference:

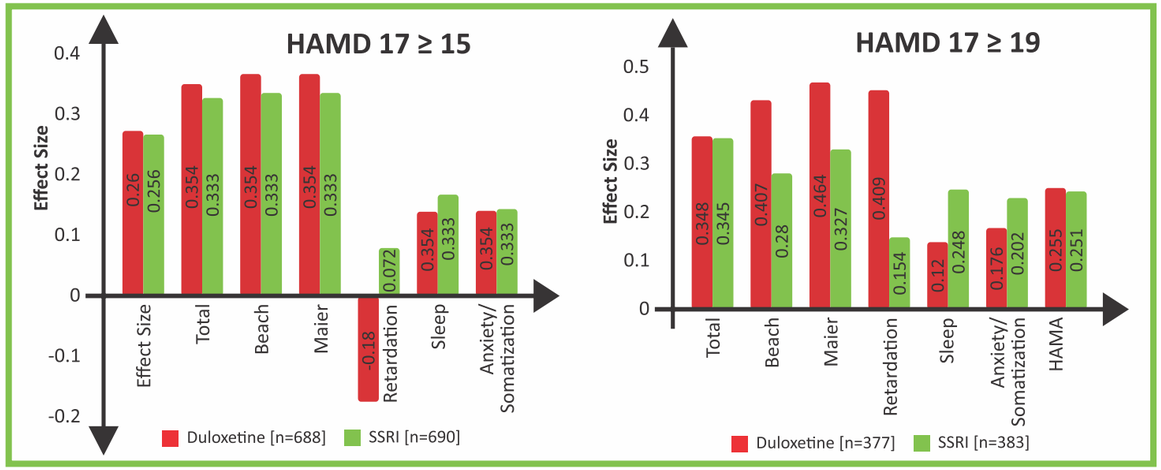
1) http://www.who.int/mediacentre/factsheets/fs369/en/last accessed on 04 march 2016.
2) Neuropsychiatric Disease and Treatment 2016:12 89–97.
3) WHO; 2012 available at: http://www.who.int/mental_health/management/depression/wfmh_paper_depression_wmhd_2012.pdf

DULOXETINE DRUG OF CHOICE:

CLINICAL EFFECTIVENESS:

1) As per Neuropsychiatric Disease and Treatment 2015 Journal:

Pooled data analysis of four randomized, double-blind, placebo-controlled study of duloxetine verses selective serotonin reuptake inhibitors (SSRI) {paroxetine 20 mg/day or escitalopram 10 mg/day} suggests that duloxetine and SSRI have comparable efficacy but duloxetine improves loss of energy and interest.

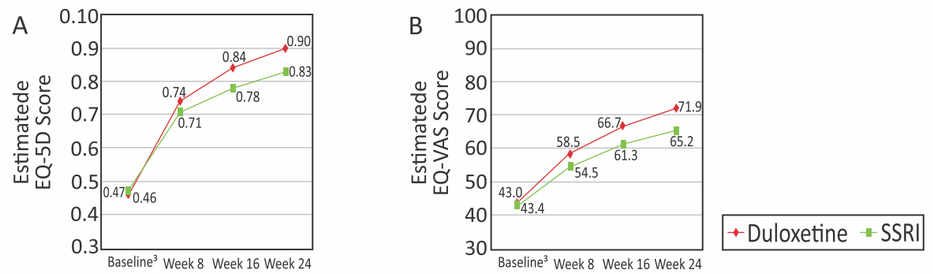


Effect sizes for duloxetine and SSRIs versus placebo in mean changes on HAMD17 total score, subscale score, and HAMA total score at week 8. Total population ($15) and more severe population ($19)
Abbreviations: HAMA, Hamilton Anxiety Rating Scale; HAMD17, 17-item Scale for Depression; SSRIs, selective serotonin reuptake inhibitor

» In the total population, HAMD17 total score effect sizes for duloxetine and SSRI versus placebo were comparable (0.260 and 0.256, respectively) but the differences in some HAMD17 subscale scores indicate an advantage for duloxetine over SSRIs.

2) Patient Preference and Adherence; 2015 Journal suggest that:

» In actual clinical practice, patients treated with duloxetine achieved higher levels of health-related QoL in comparison to SSRIs treated patients for the management of MDD.



The estimated mean levels of QoL during follow-up by treatment cohorts.
Notes: (A) EQ-5D scores by treatment cohorts. (B) VAS scores by treatment cohorts. P<0.05 for all comparisons between the duloxetine cohort and the SSRI cohort at each postbaseline visit. aThe baseline scores are raw mean values.
Abbreviations: SSRI, selective serotonin reuptake inhibitor; QoL, quality of life; 5D, EuroQoL-5 Dimensions; VAS, Visual Analog Scale., painful physical symptoms; SSRI, selective serotonin reuptake inhibitor; QoL, quality of life; EQ-5D, EuroQoL-5 Dimensions; VAS, Visual Analog Scale.

Conclusion:

Both duloxetine and SSRIs improve patient's QoL in the treatment of MDD, the effect of duloxetine is likely greater than that of SSRIs. These findings are consistent with other treatment outcomes. The mean EQ-5D score increased from 0.46 at study entry to 0.90 (estimated mean) at 24 weeks in duloxetine-treated patients and from 0.47 at study entry to 0.83 (estimated mean) at 24 weeks in SSRI-treated patients.