MIRNITE Meltab (Mirtazapine melt-in-mouth tablet)

Available as mouth dissolving tablets: 7.5 mg, 15 mg, 30 mg

(1) Indications (for elderly): treatment of major depressive disorder

(2) Recent trials:

Abstract 1

Effect of mirtazapine orally disintegrating tablets on health-related quality of life in elderly depressed patients with comorbid medical disorders: a pilot study.

Varia I, Venkataraman S, Hellegers C, Gersing K, et al.
Psychopharmacol Bull. 2007;40(1):47-56.

BACKGROUND: There is a need for additional studies on the quality of life (QOL) of elderly depressed subjects with medical comorbidity.

METHOD:We conducted a 10-week, open trial of mirtazapine orally disintegrating tablets in 16 elderly subjects with major depressive disorder and one or more serious medical illnesses. Quality of life was measured by the Medical Outcomes Study Short Form-36 Health Status Survey (SF- 36).

RESULTS: Treatment with mirtazapine was associated with significant reductions in clinical global impressions-severity of illness scale (CGI-S) score, the Hamilton rating scale for anxiety (HAM-A) total score, the 17-item Hamilton rating scale for depression (HAM-D) total score and the Beck depression inventory (BDI) total scores. The SF-36 "physical functioning", "role limitation physical", "vitality", "social functioning", "role limitation emotional", and "mental health" domains improved significantly. The mean mirtazapine dose at endpoint was 35 mg per day. The drug was relatively well tolerated except for three subjects who dropped out because of side effects. No drug-drug interactions or significant changes in blood pressure or heart rate occurred.

CONCLUSION: Mirtazapine orally disintegrating tablets may improve depression, insomnia, anxiety, somatic symptoms, and certain quality-of-life measures in elderly depressed subjects with medical disorders. A randomized, placebo-controlled study is warranted to confirm these promising findings.

Abstract 2

The efficacy of mirtazapine in agitated patients with Alzheimer's disease: A 12-week open-label pilot study.

Cakir S, Kulaksizoglu IB.
Neuropsychiatr Dis Treat. 2008 Oct;4(5):963-6.

Agitation is one of the most devastating behavioral symptoms in demented patients but there is little evidence about effective and safe pharmacotherapy. We aimed to determine the effectiveness and safety of mirtazapine in treatment of agitated patients with Alzheimer's disease (AD). The consecutive patients with AD who have significant agitation were assigned to a 12-week open-label, prospective study. Patients received mirtazapine 15-30 mg/day. The changes in Cohen-Mansfield Agitation Inventory-Short form (CMAI-SF) scores were primary outcome measurement. The change in Clinical Global Impression-Severity scale (CGI-S) scores and tolerability-safety profile were the secondary efficacy variables. Thirteen of 16 (81.25%) patients completed the study. There was a significant reduction in CMAI-SF and CGI-S between the pre- and post-treatment with mirtzapaine ($p < 0.001$). The mean baseline score was 26.54 (+/- 5.4) and mean reduction was 10.6 (+/- 7.5) in CMAI-SF. **There was no significant side effect and cognitive deterioration. The results of this open-label pilot study suggest that mirtazapine may be an effective choice for treatment of agitated patients with AD.**

Abstract 3

Mirtazapine is associated with less anxiolytic use among elderly depressed patients in long-term care facilities.

Gardner ME, Malone DC, Sey M, Babington MA.
J Am Med Dir Assoc. 2004 Mar-Apr;5(2):101-6.

BACKGROUND: Depression is a common, treatable disorder among nursing facility residents. OBJECTIVE: The purpose of this study was to examine medication use and cost between two groups of patients: (1) persons treated with mirtazapine, as compared with (2) persons taking other antidepressants.

DESIGN: This study was a retrospective chart review of long-term care patients. Consultant pharmacists collected data on patients who were receiving selective serotonin reuptake inhibitors (SSRIs), venlafaxine, nefazodone, or mirtazapine.

SETTING: Nursing facilities that were geographically dispersed throughout the United States.

PARTICIPANTS: We studied patients greater than 65 years of age with major depressive disorder or a depression-related diagnosis and receiving antidepressant treatment for at least 3 months. Patients with bipolar-induced depression were excluded as well as those receiving tricyclic antidepressants.

RESULTS: The two groups were similar in terms of age, but those receiving mirtazapine had lower body weight and body mass index. Patients on mirtazapine were less likely to

be taking a sedative/hypnotic (P = 0.006). This was primarily the result of fewer patients in the mirtazapine group taking lorazepam (P = 0.03). There was no difference between the two groups regarding their use of other psychotropic medications, including multiple antidepressants, antipsychotics, anticonvulsants, acetylcholinesterase inhibitors, or appetite stimulants. Monthly medication costs were less for those patients receiving mirtazapine ($82.83) as compared with other antidepressants ($97.03) (P <0.0001).

CONCLUSIONS: The results of this study suggest that patients receiving mirtazapine are less likely to be on anxiolytic/hypnotic agents. The findings also suggest that medication costs are less when mirtazapine is used compared with other antidepressants

(3) Dosage in elderly:

The recommended starting dose for MIRNITE Meltab is 15 mg/day, administered in a single dose, preferably in the evening prior to sleep. The effective dose range is generally 15-45 mg/day.

Pharmacokinetic studies revealed a decreased clearance in the elderly. Caution is indicated in administering MIRNITE Meltab to elderly patients

Elderly patients are more likely to have decreased renal function, care should be taken in dose selection as this drug is known to be substantially excreted by the kidney (75%). the risk of decreased clearance of this drug is greater in patients with impaired renal function.

MIRNITE Meltab has an elimination half-life of approximately 20-40 hours; therefore, dose changes should not be made at intervals of less than one to two weeks in order to allow sufficient time for evaluation of the therapeutic response to a given dose.

Sedating drugs may cause confusion and over-sedation in the elderly. No unusual adverse age-related phenomena were identified in this group.

(4) Common side effects:

MIRNITE may cause somnolence and nausea. Other side effects which may occur during treatment include increased appetite, weight gain, constipation, asthenia, flu syndrome and dizziness.