Off-label use of mirtazapine to treat insomnia

Effectiveness unproven, does have adverse effects

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The antidepressant mirtazapine (Remeron®) is increasingly used by patients suffering from insomnia. However, this usage is not based on evidence of effectivity from randomised studies. At best, there are some suggestions, based on its theoretical mode of action. The rationale behind the increased prescription of mirtazapine for insomnia is unclear. Possible reasons could be the fear of addiction that could arise when using benzodiazepine receptor agonists (such as temazepam or zolpidem), or the fact that these drugs are not reimbursed by insurers. But mirtazapine also has problematic adverse effects, such as daytime drowsiness. In view of the possible effect on driving ability due to this drowsiness, the Dutch driving licence authority CBR has special regulations for patients using mirtazapine. From the point of view of rational pharmacotherapy, there is no reason to prescribe mirtazapine off-label for insomnia.

Ge-Bu Indication

• As long as there is no evidence for its effectiveness from randomised studies, there is no reason to prescribe mirtazapine to treat insomnia in patients who have no psychiatric comorbidity.

• Even for patients with depression and insomnia, is there no evidence from randomised studies that mirtazapine is useful against the insomnia. Only in exceptional cases there is a rationale for prescribing mirtazapine in this group of patients.

• Adverse effects like daytime drowsiness and diminished driving ability limit the applicability of mirtazapine.

Literature references


The literature refers to the Dutch text

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