

### Midodrine efficacy

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I would like to raise attention to the inaccurate representation of midodrine efficacy in the [new drug comment on midodrine for orthostatic hypotension](#).<sup>1</sup>

The pivotal study in the regulatory submission reported that the three-times-a-day regimen demonstrated a clinically and statistically significant benefit to patients in the treatment group and that the benefits of midodrine were sustained throughout the treatment period.<sup>2</sup> Further, the efficacy and safety of midodrine was supported by 11 clinical studies and two meta-analyses from which the Therapeutic Goods Administration (TGA) concluded evidence exists in support of the cardiovascular benefit and symptomatic improvement in the target population.

The new drug comment leads physicians to believe the efficacy and clinical benefit of midodrine has not been established. It is essential physicians are exposed to information that accurately reflects the totality of the evidence supporting the clinical efficacy of midodrine while making their decision to prescribe to the target demographic who would most benefit. That midodrine was once supplied under the Special Access Scheme is demonstrable of the medicine meeting an important unmet need in the Australian community.

Midodrine was approved by the US Food and Drug Administration (FDA) in September 2010 following the receipt of postmarketing confirmatory trial results demonstrating the medicine's clinical benefit. It is also noted the decision to reverse the

FDA's proposal to withdraw midodrine was at the appeal of professional organisations, healthcare professionals, and indeed patients.


The clinical benefits of midodrine in the management of orthostatic hypertension symptoms are acknowledged globally, the medicine being approved in the USA, European Union and New Zealand.

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### REFERENCES

1. Midodrine for orthostatic hypotension. *Aust Prescr* 2021;44:31. <https://doi.org/10.18773/austprescr.2020.081>
2. Low PA, Gilden JL, Freeman R, Sheng K, McElligott MA. Efficacy of midodrine vs placebo in neurogenic orthostatic hypotension: a randomized, double-blind multicenter study. *JAMA* 1997;277:1046-51. <https://doi.org/10.1001/jama.1997.03540370036033>

### The Editor John Dowden comments:

 The new drug comment on midodrine prepared by the Editorial Executive Committee took into consideration the clinical evaluation report prepared for the Therapeutic Goods Administration. That report is reflected in the published Australian Public Assessment Report (AusPAR).<sup>1</sup>

While the AusPAR reports a haemodynamic benefit and symptom improvement with midodrine, it also comments that the clinical dossier does not provide compelling evidence of efficacy.<sup>1</sup> Readers are encouraged to look at the evidence in the AusPAR and draw their own conclusions about the clinical effectiveness of the drug.

### REFERENCE

1. Therapeutic Goods Administration. Australian Public Assessment Report for midodrine hydrochloride. Canberra: Commonwealth of Australia; 2021. <https://www.tga.gov.au/auspar/auspar-midodrine-hydrochloride> [cited 2021 Oct 15]