

Medicinal cannabis:

Multiple sclerosis

This fact sheet summarises the evidence and clinical guidance in the Therapeutic Goods Administration's (TGA) <u>Guidance for the use of medicinal cannabis in the treatment of multiple sclerosis in Australia</u>.

There has been increasing interest in recent years regarding medicinal cannabis*. However, there is a limited body of evidence to support its efficacy and safety in clinical practice.¹⁻³

While anecdotal reports, animal data and some research on human subjects have suggested some therapeutic potential, there is insufficient evidence from high quality studies, such as randomised controlled trials (RCTs), for most conditions.²

In response the TGA has published <u>guidance documents</u> to assist health professionals and patients in the use of medicinal cannabis, including the document for multiple sclerosis (MS).

Note that medicinal cannabis is not recommended as a first line treatment in any condition. Prescribing should always be considered on a case-by-case basis and once all other standard approved treatments have been unsuccessful.

Evidence⁴

About the TGA Guidance for the use of medicinal cannabis in the treatment of multiple sclerosis in Australia:

- ▶ a systematic review of 11 systematic reviews of symptoms associated with MS including pain, spasticity, bladder spasm, ataxia and tremor, quality of life, sleep, disability and disease progression.
- ▶ 32 studies (29 RCTs, 3 case series) included: GRADE (grading of recommendations, assessment, development and evaluation) approach to assess quality of the studies found one high quality RCT and the remainder of RCTs were moderate to low quality. The case series were very low quality.

Efficacy

The systematic review found low to moderate quality evidence that pharmaceutical-grade (medical-grade) delta-9 tetrahydrocannabinol (THC), such as dronabinol (synthetic THC) or THC extract from plant (neither is TGA-registered),^{5,6} is effective for treating symptoms of pain.

It also found some evidence (although inconsistent) that nabiximols (TGA-registered combination of THC:CBD (cannabidiol) product,^{5,6} may reduce pain and spasticity, and improve patient quality of life.

Findings were mixed as to whether medicinal cannabis (as a class of products) assisted in improving bladder function, sleep, quality of life and ataxia/tremor. There is no evidence of an effect on disability and disease progression.

There is no evidence comparing medicinal cannabis (as a class of products) to first-line treatments for pain and spasticity in MS, including baclofen, dantrolene, and benzodiazepines.

Adverse events

Commonly reported adverse events included dizziness, somnolence dysphoria, euphoria, feeling 'high', diarrhoea, and vertigo, with most reviews classifying them as mild or well tolerated. In one meta-analysis of adverse events, serious adverse events found included relapse of multiple sclerosis, convulsion and severe dizziness.

THC:CBD extracts from plants may attenuate adverse events associated with THC alone.

*NPS MedicineWise has adopted the term 'medicinal cannabis', which is used by the TGA, many health departments and affiliated organisations. Variations include cannabis medicines, cannabinoids, cannabis-based products (CBP).

Drug-drug interactions

There is no evidence to provide guidance on drug-drug interactions. More research is needed on drug-drug interactions in MS.

Clinical guidance⁴

- ▶ Medicinal cannabis is not recommended as a first-line treatment or monotherapy for pain and spasticity in patients with MS due to the absence of evidence comparing it to first-line treatments.
- ▶ The place in therapy for medicinal cannabis is as an adjunctive treatment if pain and spasticity in MS patients are not controlled by standard therapies.
- ▶ If deciding to prescribe medicinal cannabis, nabiximols, dronabinol or THC extract are recommended products.
- ▶ Be aware of the common adverse events and consider whether they are likely to interfere with quality of life.
- ▶ In the absence of strong evidence for dosing and specific preparations for products (other than nabiximols), if treatment is commenced, assess response after 4 to 6 weeks.
- ▶ If treatment is likely to be long term, it is important that any side-effects from medicinal cannabis are not greater than the side effects experienced with other first-line treatments.

Prescribing guidance

The NSW Cannabis Medicines Prescribing Guidance is a suite of resources intended to assist medical practitioners in their prescribing and management of cannabis medicines (for NSW patients within current regulatory frameworks and clinical practice).

Visit the <u>Australian Centre for Cannabinoid Clinical and Research Excellence</u> (ACRE) to download the documents.

Further information

Studies included in the TGA guidance document are found here.

National sources:

NPS MedicineWise

Office of Drug Control

TGA

State and territory health departments:

ACT

Northern Territory

NSW

Queensland

South Australia

Tasmania

Victoria

Western Australia

References

- 1. Therapeutic Goods Administration. Guidance for the use of medicinal cannabis in Australia Overview. Canberra: Government of Australia, Department of Health, 2017. https://www.tga.gov.au/publication/ guidance-use-medicinal-cannabis-australia-overview (accessed 10 May 2020).
- 2. Queensland Health. Clinical Guidance: for the use of medicinal cannabis products in Queensland. 2016. https://www.health.qld.gov.au/ data/assets/pdf file/0023/634163/med-cannabis-clinical-guide.pdf (accessed 10 May 2020).
- 3. Martin JH, Bonomo Y, Reynolds AD. Compassion and evidence in prescribing cannabinoids: a perspective from the Royal Australasian College of Physicians. Med J Aust 2018;208:107-9. https://www.ncbi.nlm.nih.gov/ pubmed/29438641.
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- 5. Therapeutic Goods Administration. Guidance for the use of medicinal cannabis in the treatment of chronic non-cancer pain in Australia. Canberra: Government of Australia, Department of Health, 2017. https://www.tga.gov.au/sites/default/files/guidance-use-medicinal-cannabis-treatment-chronic-non-cancerpain-australia.pdf (accessed 10 May 2020).
- 6. Therapeutic Goods Administration. Guidance for the use of medicinal cannabis in Australia Patient information. Canberra: Government of Australia, 2017. https://www.tga.gov.au/sites/default/files/guidance-usemedicinal-cannabis-australia-patient-information.pdf (accessed 10 May 2020).

nps.org.au/medicinal-cannabis

