



Utah Department of Health

Guidance on the Suggested Use of Medical Cannabis

Autism

About this document: The following information on the use of medical cannabis serves as a suggested use guide for those participating in the Utah Medical Cannabis Program. The intended audience for this document includes qualified medical providers, pharmacy medical providers, patients intending to use medical cannabis, and caregivers of patients intending to use medical cannabis.

This document details the guidance on the use of medical cannabis for chronic pain. This document does not include general instructions on the use of medical cannabis, contraindications, warnings, precautions and adverse reactions to using cannabis and drug-to-drug interactions which could be found in the extended guidance document titled *Guidance on the Suggested Use of Medical Cannabis*. The extended guidance document can be found on the Utah Department of Health Center for Medical Cannabis website (www.medicalcannabis.utah.gov).

About the authors: This document was authored by the Utah Cannabinoid Product Board and Utah Department of Health staff.

About the Utah Cannabinoid Product Board: Under Utah Health Code 26-61-201, the Cannabinoid Product Board is a board of medical research professionals and physicians who meet on a voluntary basis to review and discuss any available scientific research related to the human use of cannabis, cannabinoid product or an expanded cannabinoid product that was conducted under a study approved by an Institutional Review Board (IRB) or was conducted and approved by the federal government.

DISCLAIMER

The following information on the use of medical cannabis serves as a suggested use guide for those participating in the Utah Medical Cannabis Program. This document has been vetted and approved by the Utah Cannabinoid Product Board under Utah Health Code 26-61-202.

This document is a summary of available peer-reviewed literature concerning potential therapeutic uses and harmful effects of cannabis and cannabinoids. With the ongoing nature of cannabis and cannabinoid research, it is not meant to be complete or comprehensive and should be used as a limited complement to other reliable sources of information. This document is not a systematic review or meta-analysis of the literature and has not rigorously evaluated the quality and weight of the available evidence. There is a lack of controlled clinical trials yielding high level evidence of predictable therapeutic benefit for any given condition other than those for FDA approved formulations. This document includes warnings and risks related to the use of cannabis including cannabis use disorder, potentially irreversible brain damage/mental illness, and legal liability for DUI and potential for adverse work-related consequences.

All patrons participating in the Utah Medical Cannabis Program are advised to use this document and any such document produced from this original document as informational and educational. The use of medical cannabis is at one's own risk. **Medical cannabis is NOT a first line therapy for most medical conditions.**

The information in this document is intended to help as far as available data allows Utah health care decision-makers, health care professionals, health systems leaders, and Utah Medical Cannabis patients to make well-informed decisions and thereby improve the quality of health care outcomes in patients using medical cannabis use. While patients and others may access this document, the document is made available for informational purposes only and no representations or warranties are made with respect to its fitness for any particular purpose. The information in this document should not be used as a substitute for professional medical advice or as a substitute for the application of clinical judgment in respect of the care of a particular patient or other professional judgment in any decision-making process.

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IMPORTANT NOTE: As always, in the event of significant side effects, stop use of medical cannabis until side effects have resolved, and then reduce to previous, best-tolerated dose. To avoid unwanted psychoactive side effects, “**start low and go slow**” especially when using cannabis products for the first time or using new dosages or types of products.

There is insufficient evidence to support or refute the conclusion that medical cannabis or cannabinoids are an effective or ineffective treatment for symptoms of autism or autism spectrum disorder.

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The medical literature as of 2019, is devoid of results from randomized blinded placebo-controlled clinical trials to guide the use of cannabis or cannabinoids in children or adults for the treatment of autism spectrum disorder (ASD). There are however three recently-published short-duration uncontrolled observational studies from Israel that show possible benefit from the use of a CBD-predominant (chemotype III) cannabis extract in the treatment of ASD (Aran et al., 2018; Schleider et al., 2019; Barchal et al., 2019). Patients treated in these three studies included children and young adults (age range 4-22 years) with behavioral problems that were refractory to standard treatments. Treatment consisted of concentrated cannabis extract with a CBD:THC ratio of 20:1 administered sublingually and titrated up based on effect. Measured outcomes were generally favorable and included reductions in anxiety, disruptive behaviors, hyperactivity, rage attacks, self-injury, and seizures. Improvements were noted in mood, quality of life, self-care, and sleep. Some patients did not experience clinical improvements. Reported adverse events were generally mild involving somnolence, appetite, and were non-life threatening.

These three studies suggest the possibility of favorable outcomes from use of CBD-predominant cannabis extract (chemotype III) in the treatment of co-morbid and behavioral challenges associated with ASD but they are limited due to their observational nature as they do not include randomized untreated control groups and hence, **causation as to the benefits and risks of using CBD-predominant or CBD-enriched cannabis extract in the treatment of ASD cannot be established nor excluded based on these studies.** Long-term safety and efficacy likewise cannot be determined based on the short-duration of these three observational studies. Why all 3 studies used CBD-predominant cannabis extract with a CBD/THC ratio of 20:1 is not stated but may be based on pre-clinical experience of the researchers doing the studies. It should be noted that there were no children in any of these observational studies who were under the age of 4 years.

Managing behavioral challenges associated with ASD can be very difficult. Currently there is no randomized placebo-controlled trial to guide the use of cannabis or phytocannabinoids as in the treatment of ASD. However, there may be clinical situations where FDA-approved medications and interventions are causing substantial adverse reactions or are not adequately controlling behaviors of concern associated with ASD. In such situations and after careful consideration of

all possible treatment alternatives, a clinician may decide that the potential benefits of using medicinal cannabis may outweigh the potential risks of medicinal cannabis and/or the potential risks of leaving the individual's severe behaviors unmanaged. This would generally happen after failed attempts using interventions that have positive clinical trial data to support their use and been approved by the FDA.

If medicinal cannabis is recommended by a qualified medical provider, the following general dosing suggestions (based on observations made in the above three reports from Israel) may be a helpful starting point:

- **Suggested chemotype:** Chemotype III, CBD predominant – 20:1 CBD: THC
- **Dose form:** Cannabis extract prepared for oral or sublingual use
- **Route:** Sublingual drops
- **Starting Dose:** CBD 15mg/THC 0.75mg administered sublingually three times per day followed by careful titration based on individual response to dosage increases. Lower starting doses should be considered in younger children.
- **Titration:** Dose range for efficacy is likely quite variable depending on unknown or unpredictable individual patient factors and may be as high as 10mg CBD/kg/day.

References

1. Aran, A., Cassuto, H., & Lubotzky, A. (2018). Cannabidiol Based Medical Cannabis in Children with Autism- a Retrospective Feasibility Study (P3.318). *Neurology*, 90(15).
2. Schleider, L. B.-L., Mechoulam, R., Saban, N., Meiri, G., & Novack, V. (2019). Real life Experience of Medical Cannabis Treatment in Autism: Analysis of Safety and Efficacy. *Scientific Reports*, 9(1). doi: 10.1038/s41598-018-37570-y
3. Barchel, D., Stolar, O., De-Haan, T., Ziv-Baran, T., Saban, N., Fuchs, D. O., ... Berkovitch, M. (2019). Oral Cannabidiol Use in Children With Autism Spectrum Disorder to Treat Related Symptoms and Co-morbidities. *Frontiers in Pharmacology*, 9. doi: 10.3389/fphar.2018.01521