Healer Respite: Clinician Guide

Introduction

In people with dementia, the beneficial cannabinoid compounds found in cannabis and hemp can address a variety of symptoms, including anxiety, agitation, aggression, anorexia, apathy, and sleep disturbance, as well as comorbidities such as chronic pain and gastrointestinal symptoms. On the basis of pre-clinical research and limited human clinical evidence, cannabinoids may also exert neuroprotective effects that could slow or even reverse progression of the condition. Given the frequent off-label use of Beer's Criteria medications in people with dementia, cannabinoids are an appealing alternative that is proving to be safer and more effective for addressing behavioral and psychological symptoms in dementia.

Several factors frequently prevent the effective use of cannabinoid-based solutions in people with dementia, including legal and policy concerns, product quality and reliability, and clinicians' unfamiliarity with the process of implementing a cannabinoid trial.

Based on clinical research and experience, cannabinoid expert Dr. Dustin Sulak designed Healer Respite Gummies as a safe and easy-to-implement solution for both clinicians, caregivers and individuals with dementia.

Federally-Legal, Non-Prescription Product

Healer's Respite Gummies are a hemp-based supplement, compliant with the 2018 Farm Bill and third-party lab tested with less than 0.3% (by weight) naturally hemp-derived, non-synthetic Δ-9-THC. The low amounts of Δ-9-THC present in these products, in combination with other hemp-derived cannabinoids, are intentionally similar to levels of Δ-9-THC associated with beneficial effects and minimal adverse effects in clinical trials.

Because Healer Respite Gummies are considered a hemp supplement and blister packaged, extended care facilities can store and administer them like other over-the-counter nutritional supplements. They can be purchased by families, shipped across state lines[1], and administered by facilities with an attending clinician's order (see Healer Respite Order Template).

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[1] Not available in the following states: AZ, IA, ID, MN, NE, NY, OR, SD, VA.

Healer Respite Gummies are also an excellent alternative for people who have been successfully treated with dronabinol (Δ-9-THC) capsules but can no longer access the medication due to a drug supply shortage.[2]

Product Design:

Healer Respite Gummies are designed to be administered three times daily; the morning and afternoon gummies are identical, while the evening gummy is intended to be better suited for addressing nighttime symptoms and promoting restful sleep. Healer Respite comes in two stages, enabling an individual to start with a low-potency product (Stage 1) and subsequently titrate to a stronger low-potency product (Stage 2) if needed.

The gummies include naturally derived, non-synthetic cannabinoids from hemp grown in the U.S. and organic ingredients. They come in 30 quantity blister packages with clear labeling for easy administration and tracking. Each batch is tested by third-party labs (ISO accredited) for consistency and freedom from contaminants, and each product includes a QR code linked to the results.

Stage 1:**Starting product (90 ct.)**

- Morning and afternoon: CBD 8 mg CBD + THC 2 mg (0.04% THC)
- Evening: CBG 5 mg CBG + THC 2.5 mg (0.05% THC)

Stage 2: Recommended for those who do not respond to Stage 1 after 21 days. (90 ct.)

- Morning and afternoon: CBD 5 mg + THC 5 mg (0.1% THC)
- Evening: CBG 10 mg + THC 5 mg (0.1% THC)

Pharmacological targets of the three primary cannabinoids included in Healer Respite:

- Δ 9-tetrahydrocannabinol (THC), a partial agonist at the CB1 and CB2 receptors, mimics endocannabinoids, modulates neuropsychiatric symptoms by enhancing the homeostatic control of neurotransmitters, reduces neuroinflammation, and provides analgesia. These benefits are typically achievable at doses below the threshold of impairment or euphoria.
- Cannabidiol (CBD) acts as a negative allosteric modulator of CB1, often improving the adverse effect profile of THC when co-administered. It also acts as an anxiolytic and analgesic via the serotonin and adenosine systems.
- Cannabigerol (CBG) has relaxing effects via inhibition of GABA reuptake and stimulation of the alpha-adrenoceptor.

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[2] "Drug Shortage Detail: Dronabinol Capsules." www.ashp.org, www.ashp.org/drug-shortages/current-shortages/drug-shortage-detail.aspx?id=1013&loginreturnUrl=SSOCheckOnly. Accessed 16 June 2024.

Supporting Clinical Evidence

Several small clinical trials have demonstrated the safe and effective use of cannabinoids, in amounts similar to those found in Healer Respite, in people with dementia:

- A placebo-controlled crossover study on 15 patients with probable Alzheimer's disease who were refusing food received 2.5 mg of dronabinol (THC) or a placebo every morning and at noon for 6 weeks. Dronabinol decreased the severity of disturbed behavior and improved body weight. Adverse reactions observed more commonly during the dronabinol treatment than during placebo periods included euphoria, somnolence, and tiredness, but these did not require discontinuation of therapy.[3]
- A retrospective systematic chart review of 40 inpatients from the McLean Hospital Geriatric Neuropsychiatry Inpatient Unit diagnosed with dementia demonstrated significant decreases in all domains of the Pittsburgh Agitation Scale and significant improvements in Clinical Global Impression (CGI) scores, sleep duration, and percentage of meals consumed during treatment with dronabinol. The average total daily dose was THC 7 mg. Adverse effects were mild and did not result in discontinuation of treatment.[4]
- In an Israeli open-label pilot study, 11 patients with Alzheimer's disease and severe agitation or aggressive behavior were given cannabis oil containing 2.5 mg of THC twice daily, titrated up to a maximum of 7.5 mg of THC twice daily (seven of the patients remained at the 2.5 mg dose), and followed for 4 weeks. Patients experienced a significant reduction in CGI severity score (from 6.5 to 5.7; $p < .01$) and NPI score (from 44.4 to 12.8; $p < .01$). Adverse effects were minimal.[5]
- In an Italian open-label study of 30 patients with AD experiencing agitation and weight loss, treatment with THC-dominant cannabis oil (THC 5-10 mg twice daily) for 12 weeks was associated with a significant improvement in behavioral and cognitive symptoms, and an improvement in caregiver distress, with minimal adverse effects.[6]
- In a Swiss open-label study of 19 patients with dementia and behavioral symptoms followed for an average 10 months, treatment with cannabis oil was associated with significant and sustained improvements in neuropsychiatric symptoms and quality of life. The average total daily dose of THC ranged from 7 to 13 mg during the study.[7]

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[3] Volicer, L., Stelly, M., Morris, J., McLaughlin, J., & Volicer, B. J. (1997). Effects of dronabinol on anorexia and disturbed behavior in patients with Alzheimer's disease. *International journal of geriatric psychiatry*, 12(9), 913-919

[4] Woodward, M. R., Harper, D. G., Stolyar, A., Forester, B. P., & Ellison, J. M. (2014). Dronabinol for the treatment of agitation and aggressive behavior in acutely hospitalized severely demented patients with noncognitive behavioral symptoms. *The American Journal of Geriatric Psychiatry*, 22(4), 415-419.

[5] Shelef, A., Barak, Y., Berger, U., Paleacu, D., Tadger, S., Plopsky, I., & Baruch, Y. (2016). Safety and efficacy of cannabis oil for behavioral and psychological symptoms of dementia: an-open label, add-on, pilot study. *Journal of Alzheimer's disease*, 51(1), 15-19.

[6] Palmieri, Beniamino, and M. Vadalà. "Oral thc: cbd cannabis extract in main symptoms of Alzheimer disease: agitation and weight loss." *La Clinica Terapeutica* 174.1 (2023).

[7] Pautex, Sophie, et al. "Cannabinoids for behavioral symptoms in severe dementia: Safety and feasibility in a long-term pilot observational study in nineteen patients." *Frontiers in Aging Neuroscience* 14 (2022): 957665.

Adverse Effects, Cautions and Interactions

The adverse effect profile of appropriately dosed cannabinoids are well within the range of, and often superior to that of, many commonly used drugs used for behavioral symptoms associated with dementia.

In a review of 10 clinical studies on cannabinoids in people with dementia, the most common adverse effect was sedation,[8] which is typically a result of excessive doses of THC. Other common adverse effects include dizziness and dry mouth. While appropriately-dosed THC typically relieves anxiety, confusion, agitation, and nausea, excessive doses can cause paradoxical effects and trigger or exacerbate these symptoms.

The amounts of THC included in Healer Respite Stage 1 are very unlikely to cause any adverse effects. If adverse effects do occur, the amount can be reduced by cutting the gummies in half.

While cannabinoids can cause cardiovascular adverse effects, including tachycardia, hypotension, and triggering arrhythmia, these are most likely to occur with inhaled high-potency cannabis and are very unlikely to occur with the amounts of cannabinoids in Healer Respite.

An increase in fall risk has not been identified in any studies of cannabis or cannabinoids in people with dementia. One study found that THC 1.5 mg given twice daily did not significantly alter gait in 18 people with dementia – the treatment was well-tolerated with no difference in adverse effects compared to placebo.[9]

Other cautions:

- THC can have both mild anticholinergic and procholinergic activities. Clinical evidence suggests that adults who combine cannabinoids with anticholinergic medications may have an increased likelihood of adverse effects – this may be more likely in the elderly.
- Cannabinoids have mild antihypertensive effects which may be additive when administered with other medications for hypertension.
- Cannabinoids can alter the effects of warfarin but are not likely to impact other anticoagulants.

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[8] Peprah, Kwakye, and Suzanne McCormack. "Cannabis for the treatment of dementia: a review of clinical effectiveness and guidelines." Canadian Agency for Drugs and Technologies in Health, Ottawa (2019).

[9] van den Elsen, Geke AH, et al. "Effects of tetrahydrocannabinol on balance and gait in patients with dementia: a randomized controlled crossover trial." *Journal of psychopharmacology* 31.2 (2017): 184-191.

Common drug interaction checkers can be used to evaluate potential pharmacokinetic interactions between cannabinoids and other medications, though these interactions are not likely to be clinically-relevant considering the low amounts of cannabinoids present in Healer Respite. If the interaction checker does not include cannabinoids as a medication, you can enter “dronabinol” for THC and “epidiolex” for CBD. THC and CBG are mainly metabolized by CYP2C9 and CYP3A4, and CBD by CYP2C19 and CYP3A4.

Combining with Sedating Medications

Healer Respite can be safely combined with antipsychotic, benzodiazepine, and opioid medications – the most common interaction is increased sedation, which is likely to occur after reaching a therapeutic dose of cannabinoids. In most cases, Dr. Sulak recommends adding Healer Respite stage 1 to the existing treatment and observing for symptomatic improvement and for increased sedation. Should increased sedation occur, the other medication(s) can be subsequently tapered until the sedation improves. If the patient is eventually switched to Healer Respite stage 2, there may be the need for an additional tapering of the other medications, should the sedation recur.

Questions and Assistance

For more information, assistance or to schedule a call with Dr. Dustin Sulak, please contact us at (207) 271-9333 or Help@HealerCBD.com.

Medication Orders for Healer Respite Gummies

Patient name: _____ DOB: _____

Note: Healer Respite Gummies are a hemp-based supplement, compliant with the 2018 Farm Bill and third-party lab tested with less than 0.3% (by weight) naturally hemp-derived, non-synthetic Δ-9-THC. They can be stored and administered similarly to over-the-counter nutritional supplements.

Healer Respite gummies can be given with or without food, but this may alter the speed of onset and overall effect. For best results, adhere to a consistent schedule of administration with or without food.

Stage 1 Respite Gummies:

- ☐ Administer one “Stage 1: Day” gummy (CBD 8mg + THC 2mg) by mouth twice daily in the morning and afternoon, at least 4 hours apart.
- ☐ Administer one “Stage 1: Night” gummy (CBG 5mg + THC 2.5mg) by mouth once daily in the evening, at least 4 hours after the previous dose of a Healer Respite gummy.

Stage 2 Respite Gummies:

- ☐ Administer one “Stage 2: Day” gummy (CBD 5mg + THC 5mg) by mouth twice daily in the morning and afternoon, at least 4 hours apart.
- ☐ Administer one “Stage 2: Night” gummy (CBG 10mg + THC 5mg) by mouth once daily in the evening, at least 4 hours after the previous dose of a Healer Respite gummy.

Observation:

- ☐ Administer and record the facility-specific measure of behavioral/psychological symptoms prior to starting Healer Respite and once weekly for the next 4 weeks.
- ☐ Administer and record the Healer Respite Response Tracker (attached) prior to starting Healer Respite and once weekly for the next 4 weeks.
- ☐ Observe for any potential adverse effects or signs of medication interactions, e.g. sedation. Report any findings to the attending clinician and hold the subsequent dose of Healer Respite if adverse effects are suspected.
- ☐ Measure and record heart rate and blood pressure daily for 1 week after starting Healer Respite (recommended for patients taking antihypertensive medications). Report abnormal readings to the attending clinician.

Clinician name: _____

Signature: _____ Date: _____

Healer Respite Response Tracker

Rating scale: **0** = no symptoms **1** = infrequent mild symptoms **2** = frequent mild symptoms
3 = moderate symptoms **4** = infrequent severe symptoms **5** = frequent severe symptoms

Symptom	Date				
	Before Use	**Week 1**	**Week 2**	**Week 3**	**Week 4**
Enter Date:					
Irritability and Restlessness: Impatient, cranky, mood swings, pacing, rocking, wandering and exit seeking, difficulty coping with delays or waiting for planned activities					
Hallucinations and Paranoia: Seeing and/or hearing things that no one else can see or hear, acting suspicious without good reason					
Indifference and Social Withdrawal: Loss of interest in his/her usual activities or in the activities and plans of others					
Sleep Problems: Trouble sleeping at night, awakening caregivers in the night, rising too early in the morning, excessive napping during the day					
Impairment in Activities of Daily Living: Getting dressed, bathing, grooming, using the toilet, or eating					
How difficult is it to provide care for this individual? 1 = not difficult at all, 5 = extremely difficult					
Total Score					