Drug & Poison Information Center Bulletin
Faculty of Pharmacy - Tanta University

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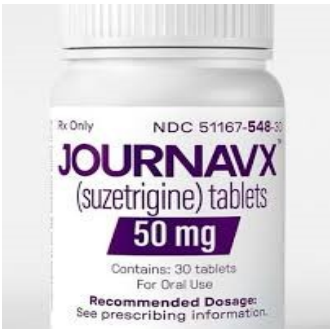
First drug approved in new class of non-opioid pain medicines

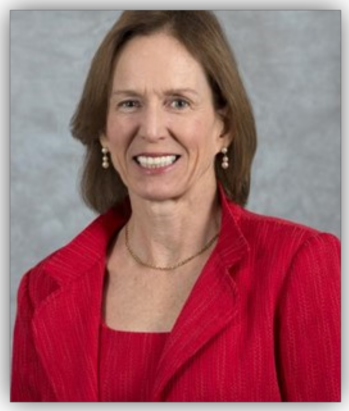


On January 30, 2025, the U. S. Food and Drug Administration (FDA) approved Journavx (suzetrigine) 50 mg tablets as the first non-opioid drug of its kind to treat moderate to severe acute pain in adults. It works by blocking sodium channels in the peripheral nervous system, stopping pain signals before they reach the brain.

Key points:

- **Significance:** Journavx is a groundbreaking non-opioid analgesic, offering a new alternative to opioid-based pain treatments.
- **Pain Management Context:** Acute pain, often caused by injury or surgery, is typically treated with opioids, but the FDA is encouraging safer, non-opioid alternatives.
- **Clinical Trials:** Journavx showed significant pain relief in two surgical pain trials, outperforming placebo, with ibuprofen allowed as rescue medication.
- **Safety Profile:** In trials with 874 participants, common side effects of Journavx included itching, muscle spasms, and rash. It should not be used with strong CYP3A inhibitors, and grapefruit products must be avoided.
- **FDA's Commitment:** Journavx's approval supports the FDA's overdose prevention framework, reinforcing the agency's focus on promoting non-opioid pain treatment options.

Quote



This approval offers a valuable option for managing acute pain while mitigating the risks associated with opioids.

Jacqueline Corrigan-Curay
Acting director of the FDA's Center for Drug Evaluation and Research

References:

- *International association for the study of pain. FDA approves non-opioid treatment for moderate to severe acute pain. Available at: https://www.iasp-pain.org/publications/iasp-news/fda-approves-non-opioid-treatment-for-moderate-to-severe-acute-pain/. Accessed in March 16, 2025.*
- *U.S. Food and Drug Administration . FDA approves novel non-opioid treatment for moderate to severe acute pain. Available at: https://www.fda.gov/news-events/press-announcements/fda-approves-novel-non-opioid-treatment-moderate-severe-acute-pain. Accessed in March 16, 2025.*

Ph. Bassant M. Mahboub. M.Sc., PhD. Cand.

New early findings highlight CBD's role in pediatric autism support

Autism spectrum disorder (ASD) involves social and behavioral difficulties, with limited success from traditional medications. A new meta-analysis presented at the 2025 European Psychiatric Association (EPA) Congress suggests cannabidiol (CBD), a non-psychoactive compound from Cannabis sativa, may offer therapeutic benefits for children and adolescents with ASD. The analysis reviews current evidence, potential mechanisms, and clinical implications, while stressing the need for further research.

Overview:

ASD affects approximately 1 in 36 children worldwide, with rising prevalence. While behavioral therapies are primary, medications like risperidone and aripiprazole are used for symptoms like irritability but may cause significant side effects. CBD is emerging as a potential alternative, valued for its anxiolytic, antipsychotic, and neuroprotective properties in managing ASD-related symptoms.

Mechanism of Action: CBD acts through the endocannabinoid system (ECS), which influences mood, behavior, and brain development. Unlike tetrahydrocannabinol (THC), CBD is non psychoactive. It indirectly affects CB1 and CB2 receptors and also interacts with serotonin (5-HT1A), TRPV1, and GPR55 receptors, potentially explaining its calming and anti aggressive effects.

Recent Clinical Findings: A meta-analysis by researchers from the University of São Paulo, presented on April 8, 2025 at the EPA , assessed CBD's efficacy and safety in children and adolescents with ASD, highlighting its emerging therapeutic potential.

Clinical Trial Details: The meta-analysis combined data from three randomized clinical trials with 276 participants aged 5–21 years, 78.3% of whom were male. The trials used CBD-rich oil (5–167 mg/mL) with CBD-to-THC ratios from 9:1 to 20:1. Doses started at 1 mg/kg/day and increased up to 10 mg/kg/day.

Key Findings: The meta-analysis found that CBD led to moderate improvement in social responsiveness (SMD: -0.75) and a small but significant reduction in disruptive behaviors (SMD: -0.36), without an increase in adverse effects compared to placebo. However, CBD showed no significant benefit for anxiety or sleep problems. Overall, CBD was well-tolerated and may provide clinical value for managing core and associated ASD symptoms, though larger, long-term studies are needed to validate these results.

Dosing and Formulation Considerations: There is no standardized CBD dosing protocol for pediatric ASD. Most studies have used oral formulations with high CBD-to-THC ratios (typically 20:1), with doses ranging from 1 to 20 mg/kg/day. Pure CBD formulations like Epidiolex have also been used off-label. CBD is generally well-tolerated, with common side effects including drowsiness, reduced appetite, and gastrointestinal issues. Clinicians should be cautious of potential drug interactions, especially with anticonvulsants and serotonergic medications.

Future Directions

Future research should focus on larger randomized controlled trials, explore optimal dosing strategies, and identify ASD subgroups most likely to benefit from CBD. Long-term safety monitoring and biomarker development are also essential to move this emerging therapy toward mainstream clinical use.

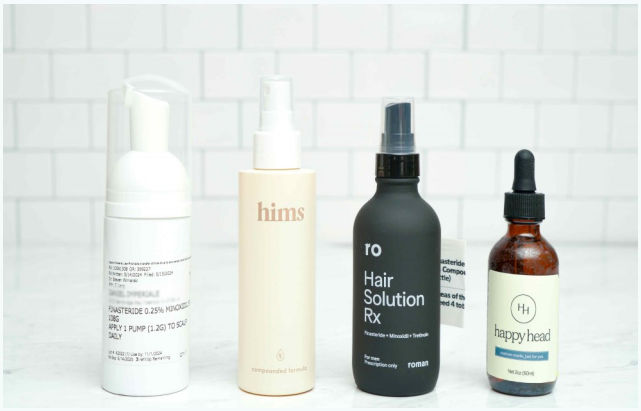
Conclusion: Cannabidiol appears to be a promising adjunctive treatment for managing behavioral symptoms, anxiety, and sleep disturbances in pediatric ASD. The new data from the EPA 2025 meta-analysis add weight to the growing body of evidence supporting its therapeutic potential. However, the field remains in early stages, and clinicians must continue to approach CBD use with cautious optimism.

References

- *Early data suggest CBD may help pediatric autism. Available at: https://www.staging.medscape.com/viewarticle/early-data-suggest-cannabidiol-may-help-pediatric-autism-2025a10008sw. Accessed in April, 2025.*
- *Stolar, O. et al. Medical cannabis for the treatment of comorbid symptoms in children with autism spectrum disorder: An interim analysis of biochemical safety. (2022) doi:10.3389/fphar.2022.977484.*
- *Aran, A. et al. Cannabinoid treatment for autism: a proof-of-concept randomized trial. Mol. Autism 12, 1–11 (2021).*

Ph. Mai Mousa, PharmD., M.Sc., PhD. Cand.

FDA warns of risks linked to compounded topical finasteride



The U.S. Food and Drug Administration (FDA) has received multiple reports of adverse events linked to compounded topical finasteride, a selective type 2 5-α reductase inhibitor that is clinically approved for oral use in the treatment of benign prostatic hyperplasia (BPH) and androgenic alopecia. These adverse events raise significant safety concerns for consumers.

However, some telemedicine platforms and compounders market topical finasteride formulations either alone or combined with other ingredients like minoxidil to treat hair loss despite the lack of FDA approval or safety evaluation for such uses.

No approved topical version available:

The FDA reminds consumers that only two oral finasteride products: Proscar (approved in 1992) and Propecia (approved in 1997), are FDA-approved in the U.S. for specific indications. Currently, no topical finasteride formulation has FDA approval. Compounded topical versions lack approved labeling and may pose serious safety risks.

Discussion:

Between 2019 and 2024, the FDA received 32 reports of adverse events linked to compounded topical finasteride, including symptoms like erectile dysfunction, depression, fatigue, and suicidal ideation similar to those from oral formulations. These side effects often persisted after stopping use, with many patients unaware of the potential risks. Some were misinformed that topical application posed no harm. Additional concerns include local skin reactions (e.g., irritation, burning, and dryness) and risk of unintentional exposure to others, especially pregnant women.

Unlike the FDA-approved oral finasteride, which has protective coatings, compounded topical versions lack such safeguards, increasing the risk of absorption and harm especially in pregnancy, where exposure can cause fetal abnormalities in the male fetus.

Conclusion:

There are currently no FDA-approved topical finasteride products, whether used alone or in combination with other ingredients. Compounded drugs are not FDA-approved, meaning their safety, efficacy, and quality have not been evaluated by the agency. Reports from both consumers and healthcare providers have highlighted adverse events associated with compounded topical finasteride, with many users stating they were unaware of the potential risks prior to use.

FDA recommendations:

- The FDA urges health care providers to educate patients on the potential risks of using compounded topical finasteride, including the danger of inadvertent exposure to females through contact. Topical formulations may pose a greater risk of transfer compared to approved oral products.
- Consumers are advised to consult with healthcare providers and compounders about these risks before starting treatment.
- The FDA also encourages consumers, providers, and compounders to report adverse events or quality issues related to compounded topical finasteride through the MedWatch adverse event reporting program:

References:

- *FDA alerts health care providers, compounders and consumers of potential risks associated with compounded topical finasteride products. Available at: https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-consumers-potential-risks-associated-compounded#:~:text=In%20addition%20to%20safety%20concerns,exposure%20to%20others%2C%20specifically%20females%2C. Accessed in April, 2025.*
- *Finasteride FDA Alerts. Available at: https://www.drugs.com/fda-alerts/1091-0.html. Accessed in April, 2025.*

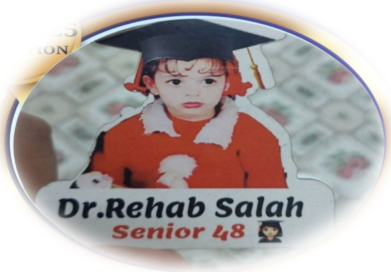
Ph. Marwa El-Sayed, PGCPD, M.Sc. Cand.

From our Activities in 2025

Under the patronage of the dean Prof. Dr. Mona A. El-Aasr, leadership of Prof. Dr. Sahar M. Elhaggar, vice dean for community and environmental development affairs, and the supervision of Ph. Bassant M. Mahboub, executive manager of the Drug and Poison Information Centre, a series of scientific competitions were held on the center's official Facebook page in February, March, and April 2025. These events aimed to enhance the knowledge about drug-related information, and also to raise the awareness in line with the World Kidney Day in March, and the World Immunization Week in April. Winners were chosen based on active participation and accuracy of responses. Join us for more interesting upcoming competitions . ***Facebook page: Drug and Poison Information Center-Faculty of Pharmacy-Tanta University*** .

Congratulations to our winners

Ph. Heba El-Bennawy



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We are on the web

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Vision

The vision of Tanta University DPIC is to improve national healthcare service through provision of evidence-based, unbiased, patient oriented drug information services & adverse drug reporting system.

Mission

* Responding to drug inquiries related to the use of the drug and providing the health care professionals and patients with drug information related to the patient's care to achieve the optimal use of the drug in addition to the provision of other toxicological managing information.
* Educational activities to support the rational optimal use of drugs as well, supporting research activities.
* Continuous medical education and training courses in various fields of pharmacy for students, undergraduates, postgraduate students, and researchers.
* Issuing a Drug Information Bulletin periodically to take a look at medical & pharmaceutical news.
* Supporting the National Pharmaceutical Vigilance Program by following up and monitoring side effects and problems related to use of pharmaceutical preparations within regional hospitals.
* Contributing to the establishment of various treatment protocols and prescription booklet services in regional hospitals.

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