

## Medical Authorizations for Cannabis-Based Products in Canada: Sante Cannabis Data on Patient's Safety and Treatment Profiles

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**Abstract :** Introduction: Santé Cannabis (SC), a Canadian medical cannabis-specialized group of clinics based in Montreal and in the province of Québec, has served more than 5000 patients seeking cannabis-based treatment prescription for medical indications over the past five years. Within a research frame, data on the use of medical cannabis products from all the above patients were prospectively collected, leading to a large real-world database on the use of medical cannabis. The aim of this study was to gather information on the profiles of both patients and prescribed medical cannabis products at SC clinics and to assess the safety of medical cannabis among Canadian patients. Methods: Using a retrospective analysis of the database, records of 2585 patients who were prescribed medical cannabis products for therapeutic purposes between 01-November 2017 and 04-September 2019 were included. Patients' demographics, primary diagnosis, route of administration, and chemovars recorded at the initial visits were investigated. Results: At baseline: 9% of SC patients were female, with a mean age of 57 (SD= 15.8, range= [18-96]); Cannabis products were prescribed mainly for patients with a diagnosis of chronic pain (65.9% of patients), cancer (9.4%), neurological disorders (6.5%), mood disorders (5.8 %) and inflammatory diseases (4.1%). Route of administration and chemovars of prescribed cannabis products were the following: 96% of patients received cannabis oil (51% CBD rich, 42.5% CBD:THC); 32.1% dried cannabis (21.3% CBD:THC, 7.4% THC rich, 3.4 CBD rich), and 2.1% oral spray cannabis (1.1% CBD:THC, 0.8% CBD rich, 0.2% THC rich). Most patients were prescribed simultaneously, a combination of products with different administration routes and chemovars. Safety analysis is undergoing. Conclusion: Our results provided initial information on the profile of medical cannabis products prescribed in a Canadian population and the experienced adverse events over the past three years. The Santé Cannabis database represents a unique opportunity for comparing clinical practices in prescribing and titrating cannabis-based medications across different centers. Ultimately real-world data, including information about safety and effectiveness, will help to create standardized and validated guidelines for choosing dose, route of administration, and chemovars types for the cannabis-based medication in different diseases and indications.

**Keywords :** medical cannabis, real-world data, safety, pharmacovigilance

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