

Epidiolex: Everything You Need to Know About the New CBD Drug

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What does Epidiolex contain?

Cannabidiol.

What are the possible side effects of Epidiolex?

Insomnia, infections, fatigue, sleepiness, reduction in appetite, diarrhea, rash, and increased liver enzymes leading to possible liver injury.

What does Epidiolex treat?

Lennox-Gastaut and Dravet Syndrome—two types of severe childhood epilepsy.

How much will Epidiolex cost?

\$32,500 per year (without insurance).

When will Epidiolex be released?

Scheduled fall of 2018.

How much will each bottle of Epidiolex contain?

Each package will contain two 100ml bottles.

How Epidiolex Will Help Patients

Improved quality of life for over 30 percent of patients living with medically refractory, treatment-resistant or pharmacoresistant epilepsy is likely with Epidiolex® as an additional treatment option. This is the first FDA approved medication in its therapeutic classification.

The medical management of two rare forms of childhood epilepsy has generated positive outcomes with a cannabis-based anti-epileptic regimen. Children with the severe pediatric seizure disorders, Lennox-Gastaut syndrome and Dravet syndrome, can have multiple generalized seizures or 'drop attacks' a day. The onset of the syndrome typically occurs between the ages of one and eight years old. The disorder affects development and has an increased risk of death.

Pharmacology of Epidiolex

Our body's natural endocannabinoid system has been difficult to target. The therapeutic effects of dronabinol (treatment for chemotherapy-t induced nausea), nabilone (appetite enhancer for patients living with AIDS), and Sativex®, (neuropathic pain and multiple sclerosis) do not easily separate from the effects of THC. Namely, the THC producing high, potential addictiveness, and other unwanted brain chemistry consequences.

According to the National Institutes of Health, influencing the endocannabinoid system by using the pharmacology of external cannabinoids may prove to be valuable and beneficial for many medical conditions. This system includes two primary receptors, CB1 and CB2. What is unique is cannabidiol (CBD) stimulates activity without directly binding to them which causes indirect effects. These effects are enhanced overall activity in the body. The implications in medicine are a growth of the continuing number of ailments CBD may be helpful.

The CBD signaling system is unraveling and researchers are meeting the challenges to create safe and effective treatment possibilities. In doing so, we face a reduction in safety problems and increasing efficacy, even with the serious complexities.

Expected in the fall of 2018, Epidiolex (cannabidiol) 100mg per ml is formulated as an oral solution and packaged in 2-100 ml bottles. Epidiolex is extracted from marijuana. The active substance cannabidiol (CBD) is actually found in small amounts of the raw marijuana plant. For many years it has produced interest due to its anti-seizure therapeutic effects.

Since it is developed from marijuana, the drug has a Schedule I status of 'no currently accepted medical use". However, the FDA approved the purified drug substance and will be reclassified to Schedule 2, 3, 4, or 5.

"We don't have a choice on that," DEA public affairs officer Barbara Carreno told Business Insider in June. "It absolutely has to become Schedule 2, 3, 4, or 5."

Study Evidence

Peripheral and Central Nervous System Drugs Advisory Committee of the FDA evaluated the study design and conclusions of randomized and well-controlled investigations. In all, 516 children with either Lennox-Gastaut syndrome or Dravet syndrome were studied in three randomized clinical trials. Participants ranged in age from 1 year to 30 years old, had intractable, childhood-onset, treatment-resistant epilepsy. Administered with other medications, Epidiolex® was better than placebo at seizure reduction. The findings demonstrated that Epidiolex® was effective in reducing overall seizure activity and frequency by up to 36% from baseline.

“The New England Journal of Medicine reports roughly 43% of the children in that study who got the drug saw their number of seizures cut in half, and 5% stopped having seizures entirely. In comparison, children who got a placebo had barely any noticeable change in their symptoms.”

Risk of Side Effects vs. Efficacy of Treatment

Lennox-Gastaut syndrome and Dravet syndrome are life-altering and life-threatening conditions; therefore, the efficacy appears to outweigh the side effects and risks. A patient Medication Guide will be dispensed to educate on the possibility of insomnia, infections, fatigue, sleepiness, reduction in appetite, diarrhea, rash, and increased liver enzymes leading to possible liver injury. Signs to watch for are nausea, abdominal pain, vomiting, dark urine, and jaundice.

Epidiolex and CBD products

British-based GW Pharmaceuticals specializes cannabinoid-based products, have set the cost price point compared to other standard epilepsy drug treatment regimens of \$32,500 per year.

It is estimated that many will turn to or remain with alternative compounded CBD oils, in that they do not require a physician’s prescription and are currently cheaper. Yet, all may not be as it seems as dispensary-grade CBD products have not been well studied or well-controlled.

In addition, CBD oils are not regulated, may contain contaminants, and dosage control may not be accurate. With the lack of pharmaceutical grade oversight and validation, researchers and advocates are guarded as to whether they contain pharmaceutical-grade CBD.

“What’s different with [Epidiolex] is that this is a well-studied and well-controlled product,” , the chief scientific officer of a nonprofit called Cure that funds epilepsy research, told Business Insider in April.

The Journal of American Medical Association published a 2017 report, which cited the testing of 84 products purchased from 31 variable online CBD vendors. Seven out of 10 products did not contain the levels of CBD branded on the label. More than 50% had higher levels of CBD

and 25% had lower levels of CBD than specified. In addition, 18 products were positive for THC that was not on their label.

Due to research-based evidence as a foundation, Epidiolex, when available, will be a safer, consistent product, as compared to product variations from marijuana dispensaries or the Internet. Furthermore, once insurance companies and coverage enter the mix Epidiolex could be a more cost-effective, dependable option.

“The cost of co-pay [for Epidiolex] is significantly – or could be significantly – less onerous and burdensome than the cost of the product either over the internet or from dispensary,” Gangolli said.

For now many are taking a wait and see position. If past history and system behaviors are any indications, Epidiolex® is a landmark touch point to securing safe and effective, evidence-based cannabinoid treatments for numerous medical disorders.

“This approval serves as a reminder;” Scott Gottlieb, the FDA commissioner, said in a statement on Monday, “that advancing sound development programs that properly evaluate active ingredients contained in marijuana can lead to important medical therapies.”

As the industry finds its footing with growing financial interests, regulation, specialized, individually customized compounding, and the surrounding governmental bureaucracies, politics, and policies, we are in the midst of a sea of change. Researchers and the CBD industry are energized with the expanded horizon of other marijuana-based components that offer hope for the future.

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