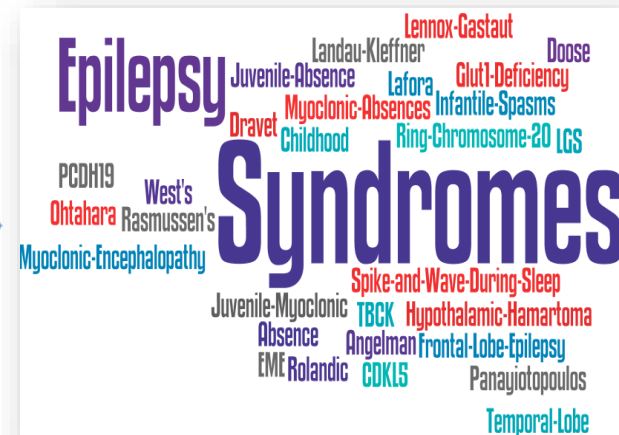
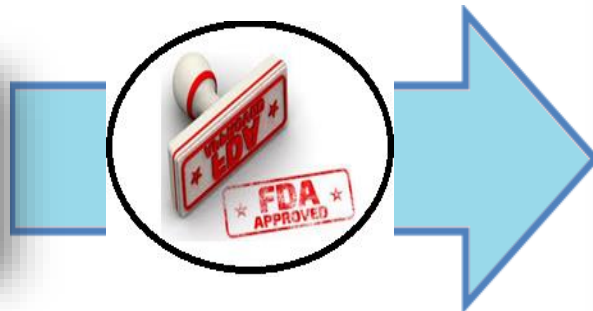


US FDA approves Epidiolex first ever drug derived from marijuana to treat rare, severe forms of Epilepsy approved on 25th June 2018



About Epidiolex (1)

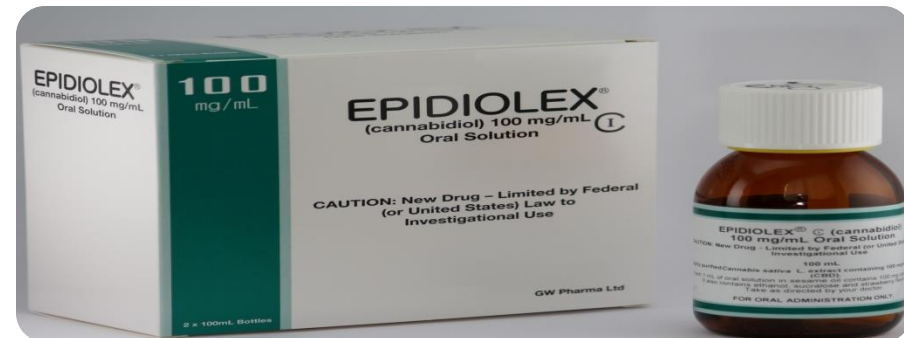
About the GW Pharmaceuticals and Epidiolex

- GW Pharmaceuticals (**Is a British Biopharmaceutical Company**) plc and its U.S. Subsidiary Greenwich Biosciences Announce FDA Approval of EPIDIOLEX® (cannabidiol) oral solution – the First Plant-derived Cannabinoid Prescription Medicine.
- An EMA decision on whether to recommend approval is expected in the first quarter of 2019.
- Epidiolex could soon have competition from **Zogenix**.



Brief on Epidiolex

- EPIDIOLEX is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) in patients 2 years of age and older.
- **Dosage form AND Strength:** 100 mg/ ml (**Oral Solution**)
- **Adverse Reactions:** somnolence; decreased appetite; diarrhea; transaminase elevations; fatigue, malaise, and asthenia; rash; insomnia, sleep disorder, and poor quality sleep; and infections
- Dosage adjustment is recommended for patients with moderate or severe hepatic impairment.
- It is not known if EPIDIOLEX is safe and effective in children under 2 years of age.



About Epidiolex (2)

Product information

➤ Composition:

Active ingredient: cannabidiol

Inactive ingredients: dehydrated alcohol, sesame seed oil, strawberry flavor, and sucralose

EPIDIOLEX does not contain gluten (wheat, barley or rye).

➤ **Administration:** EPIDIOLEX is to be administered orally.

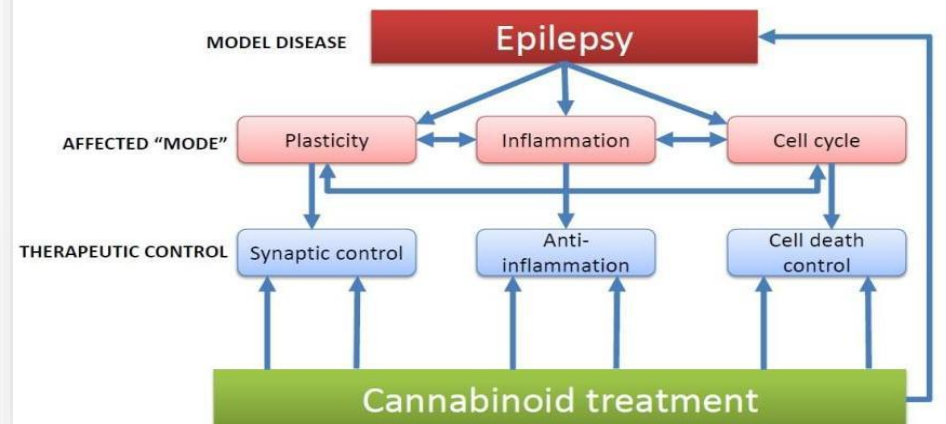
➤ **Dose:** The recommended starting dosage is 2.5 mg/kg taken twice daily (5 mg/kg/day). After one week, the dosage can be increased to a maintenance dosage of 5 mg/kg twice daily (10 mg/kg/day).

Epidiolex, it will be the first plant-derived medication patients will be able to use nationwide.

Mechanism of action

The precise mechanisms by which EPIDIOLEX exerts its anticonvulsant effect in humans are unknown. Cannabidiol does not appear to exert its anticonvulsant effects through interaction with Cannabinoid receptors.

Cannabinoids are effective in Models of Epilepsy



Epilepsy Disease Burden

What is Epilepsy?

- A disorder in which nerve cell activity in the brain is disturbed, causing seizures.
- **General symptoms or warning signs of a seizure can include:**

Staring; Jerking movements of the arms and legs; Stiffening of the body; **Loss of consciousness**; Breathing problems or stopping breathing; Loss of bowel or bladder control; Falling suddenly for no apparent reason; especially when associated with **loss of consciousness**.

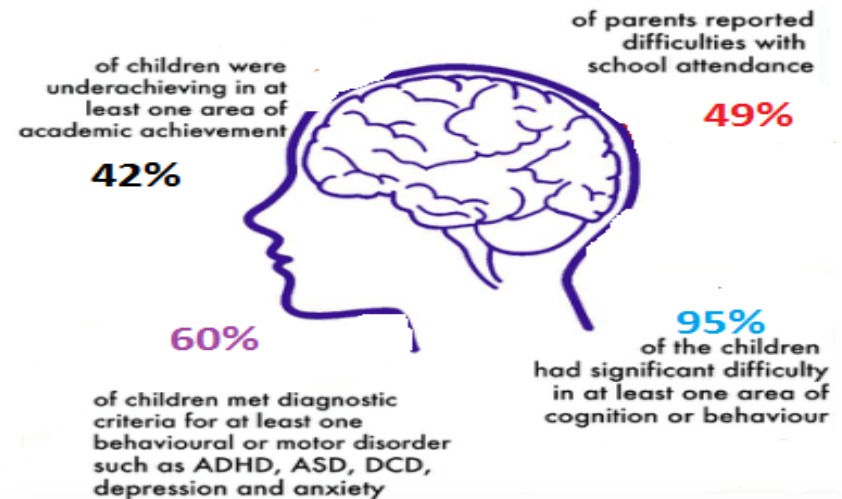
DRAVET SYNDROME

+

LENNOX-GASTAURT SYNDROME

Epidiolex (generic name Cannabidiol or CBD for short) is an experimental medication granted orphan drug designation for use in treating children with Dravet syndrome and Lennox-Gastaut Syndrome. Rare and severe form of infantile-onset, genetic, drug-resistant epilepsy syndrome.

Facts and Figures



Source: - https://www.google.com/search?newwindow=1&safe=active&ei=tk0_W6WwAoH1rQGpireYCA&q=symptoms+of+epilepsy+in+children&oq=symptoms+of+epilepsy&gs_l=psy-ab.1.6.0i67k1l2j0l4j0i67k1j0l3.112259.119515.0.124005.27.23.0.0.0.275.3073.0j18j1.20.0....0...1.1.64.psy-ab..7.19.3063.0..0i13k1.145.HpoJuRMmkuU

https://www.google.com/search?newwindow=1&safe=active&ei=pU0_W6zsK46b9Q0i6L_YAg&q=epilepsy&oq=epilepsy&gs_l=psy-ab.3..0i67k1l2j0l2j0i67k1l3j0l3.11671.13682.0.14705.23.11.0.0.0.361.1970.0j4j0j4.8.0....0...1.1.64.psy-ab..20.3.860...0i22i30k1.0.YsD80TV-zVQ

Competitive Landscape - Epilepsy

Current Treatment options

Combination of - **Ethosuximide, Lamotrigine or Sodium Valproate.**



Global Epilepsy Drugs Market Size To Reach \$5.47 Billion By 2024

EPIDIOLEX®

Sales are predicted to reach \$960M

Top Competitive landscape for Epidiolex

ONFI (Clobazam)

Banzel (Rufinamide)

ZX-008 (Low-dose Fenfluramine)

Fycompa (Perampanel)



Source:

<https://www.owler.com/company/gwpharm> <https://www.grandviewresearch.com/press-release/global-epilepsy-drugs-market>
https://www.google.com/search?newwindow=1&safe=active&ei=-GVAW5CXLYLorQGF_YjoAg&q=+treatment+guidelines+for+epilepsy+in+children&oq=+treatment+guidelines+for+epilepsy+in+children&gs_l=psy-ab.3...44426.59007.0.59717.26.25.1.0.0.0.190.3835.0j25.25.0...0...1.1.64.psy-ab..0.0.0...0.wSQMO
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