

**Summer Training at
Micro Labs Pvt. Ltd.**

**Brand Launch Strategies and Marketing Plan of Sodium Valproate and
Topiramate**

**By
Anshuka Nailwal**

**Under the guidance of
Mr. Abhishek Dadhich**

**MBA Pharmaceutical Management
2017-2019**

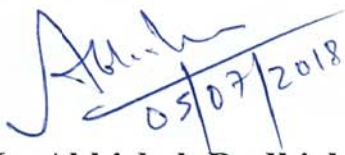
 **IIHMR UNIVERSITY**
School of Pharmaceutical Management
**The IIHMR University, Jaipur
2018**

CERTIFICATE

This is to certify that **Ms Anshuka Nailwal** has undergone summer training at **Micro Labs Pvt Ltd** on '**Brand launch strategies and Marketing plan of Sodium Valproate and Topiramate**' from 4th April 2018 to 5th May 2018.

The candidate herself completed the project assigned to her during summer training. Her approach to the project was sincere and proactive. This summer training is in partial fulfillment of the course requirement recommended for the award of MBA in Pharmaceutical Management.

I wish her success in all her future endeavors.

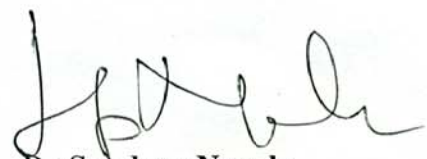


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MICRO LABS LIMITED

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22nd June, 2018

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Ms Anshuka Nailwal, student of IIHMR University, Jaipur has successfully completed summer internship from 4th April – 5th May, 2018 at Micro Labs Limited.

It was pleasure to have you as management trainee at Micro Labs Limited, Gurgaon offer for *maximising* learning.

You did well & we appreciate your efforts in the areas of:

- Openness to learning.
- Commitment & adaptation on understanding the business concept & translating into project.
- Office administration & corporate etiquettes.
- Effectively prepared brand campaign under the guidance of the supervising executive.

We wish you success for your future assignments.

With best wishes,

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ABSTRACT

This report is based on the summer internship 2018 at Micro Labs Limited. It covers all the tasks which are accomplished from 4th April 2018 to 5th May 2018.

In my summer internship, I got two molecules Sodium Valproate and Topiramate as my topic and to these molecules I had given the name ECIPILIM and TOPILEPSY respectively. The molecules are used mainly in the treatment of Epilepsy. I have learnt to do the branding of a product which includes Marketing Campaign, Action Plan, Input Planning, Business goals, Expense Ratio, Visual Aid, Literature Review and Detailing. Moreover with this, I have also covered corporate profile of Micro Labs Limited, Corporate Etiquettes and Netiquettes, Professional communication and Writing Business Letters.

OBJECTIVE

To study the successful launch of the brands ECIPILIM (Sodium Valproate) and TOPILEPSY (Topiramate) in the market.

METHODOLOGY

Research Design: Descriptive Study

Type of data: Secondary Study

Duration: 5 Weeks

Disease Information and Brand Plan

Disease:- EPILEPSY

**Molecule Name: SODIUM
VALPROATE**

Brand Name: ECIPILIM

SEIZURE

- “A seizure is a sudden, uncontrolled electrical disturbance in the brain”.
- “It can cause changes in the behaviour, movements, feelings and in levels of consciousness”.
- “Most seizures last from 30 seconds to two minutes. A seizure that lasts longer than five minutes is a medical emergency”.

Types of seizures

- 1) **Partial seizure:** A partial seizure means the epileptic activity took place in just part of the patient's brain. There are two types of partial seizure:-
 - **Simple partial seizure-** “In this, the patient is conscious during the seizure. In most cases, the patient is also aware of their surroundings, even though the seizure is in progress”.
 - **Complex partial seizure-** “In this, the patient's consciousness is impaired. The patient will generally not remember the seizure, and if they do, their memory will be vague.”
- 2) **Generalized seizures :** “Seizures that appear to involve all areas of the brain are called generalized seizures. Different types of generalized seizures include”:-
 - **“Absence seizures-** Absence seizures, previously known as petit mal seizures, often occur in children and are characterized by staring into space or by subtle body movements, such as eye blinking or lip smacking. These seizures may occur in clusters and cause a brief loss of awareness”
 - **Tonic seizures-** “Tonic seizures cause stiffening of your muscles. These seizures usually affect muscles in your back, arms and legs and may cause you to fall to the ground”.
 - **Atonic seizures-** “Atonic seizures, also known as drop seizures, cause a loss of muscle control, which may cause you to suddenly collapse or fall down”.
 - **Clonic seizures-** “Clonic seizures are associated with repeated or rhythmic, jerking muscle movements. These seizures usually affect the neck, face and arms”.
 - **Myoclonic seizures-** “Myoclonic seizures usually appear as sudden brief jerks or twitches of your arms and legs”.

- **Tonic-clonic seizures-** “Tonic-clonic seizures, previously known as grand mal seizures, are the most dramatic type of epileptic seizure and can cause an abrupt loss of consciousness, body stiffening and shaking, and sometimes loss of bladder control or biting your tongue”.

3) Secondary generalized seizures: “A secondary generalized seizure occurs when the epileptic activity starts as a partial seizure, but then spreads to both halves of the brain. As this development happens, the patient loses consciousness”.

EPILEPSY

Epilepsy is also defined as having "two or more unprovoked seizures," according to Johns Hopkin Medicine.

Symptoms of Epilepsy

“The main symptom of epilepsy is repeated seizures. If one or more of the following symptoms are present, the individual should see a doctor, especially if they recur”:

- “a convulsion with no temperature”
- “short spells of blackout, or confused memory”
- “for a short period, the person is unresponsive to instructions or questions”
- “the person becomes stiff, suddenly, for no apparent reason”
- “repetitive movements that seem inappropriate”
- “nightmares”
- “repetitive movements that seem inappropriate”

Causes of Epilepsy

- “Inherited genetic factors”
- “Brain conditions, including stroke or tumour”.
- “Infectious diseases, for instance, AIDS and viral encephalitis”.
- “Prenatal injury, or brain damage that occurs before birth”.
- “Developmental disorders, for instance, autism and neurofibromatosis”:

Types of Epileptic Seizures

There are three diagnoses a doctor might make when treating a patient with epileptic seizures:

- **Idiopathic**- There is no apparent cause.
- **Cryptogenic**- The doctor thinks there is most probably a cause, but cannot pinpoint it.
- **Symptomatic**- The doctor knows what the cause is.

Anti-epileptic drugs (AEDs)

The majority of AEDs are taken orally. The type of seizure the patient is having will decide which drug the doctor may prescribe. All patients do not react in the same way to drugs, but AEDs appear to help control seizures in 70 percent of cases.

Drugs commonly used to treat epilepsy include:

- “Sodium Valproate”
- “Carbamazepine”
- “Lamotrigine”
- “Levetiracetam”

Some drugs may stop seizures in one patient, but not in another. Even when the right drug is found, it can take some time to find the ideal dose.

SODIUM VALPROATE

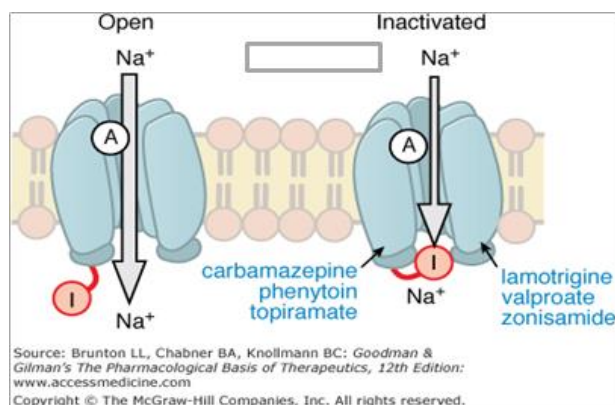
- “It is the medication primarily used to treat epilepsy and bipolar disorder and to prevent migraine headaches”.
- “It can be given intravenously or by mouth”.
- “Long and short acting formulations of tablets exist”.

Valproate: Pharmacokinetics

- **Absorption:** “Sodium Valproate is quickly converted to Valproic acid after oral administration”.
- **Distribution:** “It is very widely distributed in the body in protein bound form”.
- **Metabolism:** “It is extensively metabolised in the liver”.
- **Excretion:** “It is excreted mainly in urine and small amount in faeces, exhaled air and breast milk”.
- **Onset of Action:** “Within 1 hour”.
- **Duration of Action:** 12 hours.
- **Half Life:** 15 hour

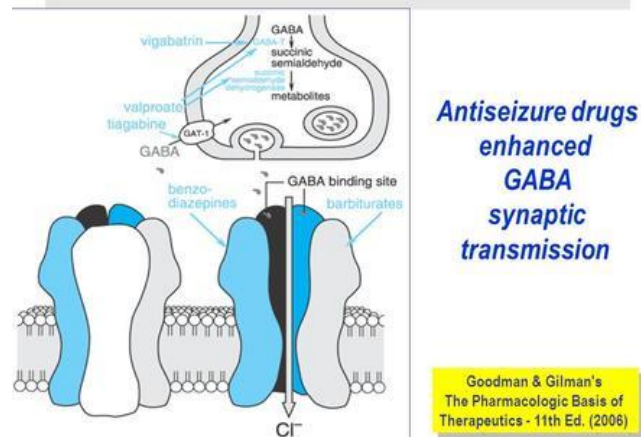
Mechanism of Action

a) It blocks Sodium channels.



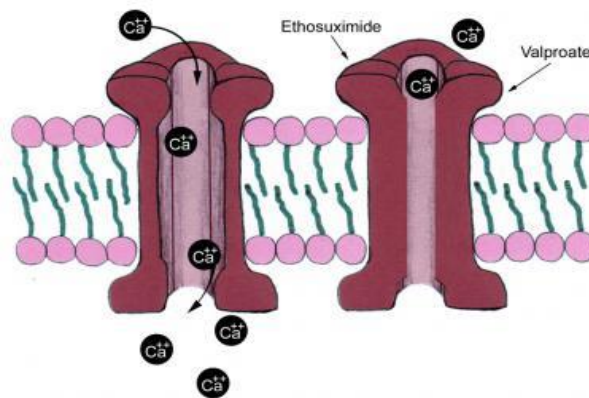
b) Enhance GABA (increase synthesis and release).

II. Enhancement of GABA Inhibition



c) Blocks T-type Calcium channels.

Reduced Current through T-Type Calcium Channels

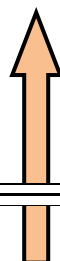


Side Effects

- “Nausea and Vomiting”
- “Impairment of liver enzymes”
- “Liver toxicity”
- “Hair loss”
- “Weight gain”
- “Sedation”
- “Upper abdominal cramps”
- “Abnormal liver function”

Moving Annual Total of Sodium Valproate

- MAT FEB’18 = 99.1 crores



10

CAGR Increased

- MAT FEB'17 = 99.9 crores by 5%
- MAT FEB'16 = 95.6 crores (13.9 crores) from
- MAT FEB'15 = 85.2 crores 2015 to 2018

Unit MAT of Sodium Valproate

- Unit MAT FEB'15 = 21368.25
 - Unit MAT FEB'16 = 23390.20
 - Unit MAT FEB'17 = 23548.82
 - Unit MAT FEB'18 = 25518.29
- CAGR Increased by 6%
from 2015 to 2018

Month wise trend of Sodium Valproate (all values in crores)

YEAR →	2014	2015	2016	2017	2018
MONTHS ↓					
JANUARY		7.3	8.0	7.9	9.1
FEBRUARY		6.9	7.9	8.1	8.4
MARCH	6.4	7.0	7.9	7.9	
APRIL	7.2	8.2	8.5	8.2	
MAY	7.3	7.8	8.7	8.0	
JUNE	6.6	7.9	8.2	7.6	
JULY	7.1	7.9	8.3	6.9	
AUGUST	6.9	7.7	8.9	8.7	
SEPTEMBER	7.3	8.2	8.4	8.5	
OCTOBER	7.2	8.2	8.4	8.3	
NOVEMBER	7.3	8.0	8.1	8.8	
DECEMBER	7.6	8.8	8.4	8.7	

Competitors Overview

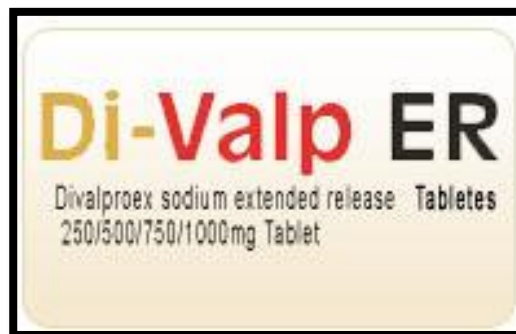
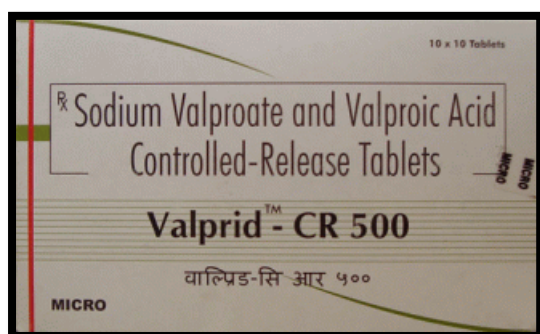
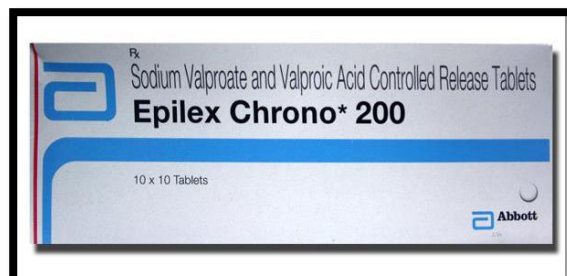
S.NO	BRAND NAME	COMPANY NAME	Price(□) of 10 tablets/ Strip
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1)	DIVAA (500mg)	Intas Pharma	91
2)	VALPROL (400mg)	Intas Pharma	79
3)	DILPRA (250mg)	Emcure	44
4)	VALPEX (750mg)	Alkem	95
5)	ENCORATE (500mg)	Sun	67.51
6)	VALPARIN (200mg)	Sanofi	29.4
7)	EPIVAL (200mg)	Sun	28.87
8)	TORVATE (500mg)	Torrent Pharma	42.7
9)	VALPORIL (300mg)	Reliance Formulaf	45
10)	VALPRID CR (500mg)	Micro Labs	94.7
11)	DILPRA-OD (500mg)	Emcure	108.65
12)	VALP (500mg)	Orchid Pharma	27.37
13)	EPIMA (200mg)	Zydus Cadila	35

Packshot of the Competitors Brand





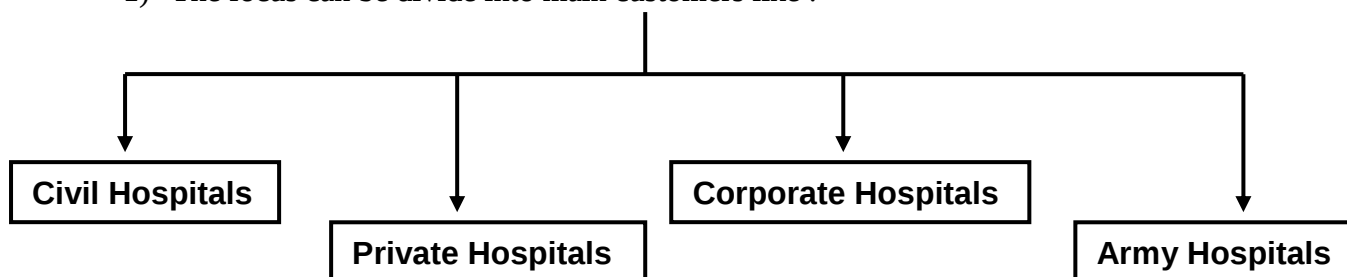


SWOT Analysis of Sodium Valproate

<u>STRENGTH</u> • It shows rapid action. • It has a wider therapeutic index. • It has better tolerability. • It has 3 mechanism of action: ✓ blocks Sodium channel. ✓ enhancement of GABA inhibition. ✓ blocks t-type calcium channels.	<u>WEAKNESS</u> • It shows severe side effects. ✓ hair loss ✓ weight gain ✓ upper abdominal cramps ✓ liver toxicity
<u>OPPORTUNITIES</u> • By increasing awareness among the consumers, the market of the molecule can be increased.	<u>THREATS</u> • Regulations by the government. • High cost can result in shift to other molecule.

Marketing Campaign

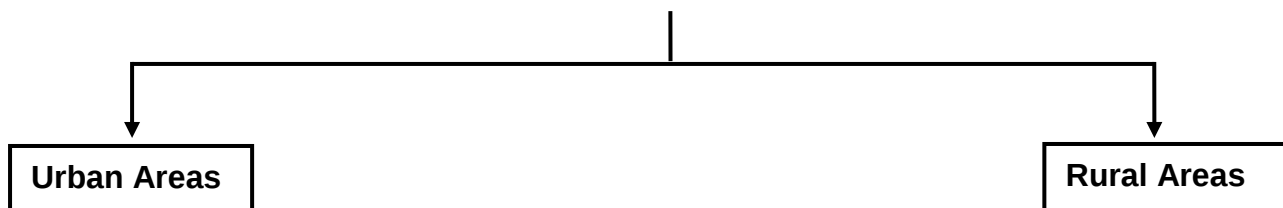
- 1) The focus can be divide into main customers like :



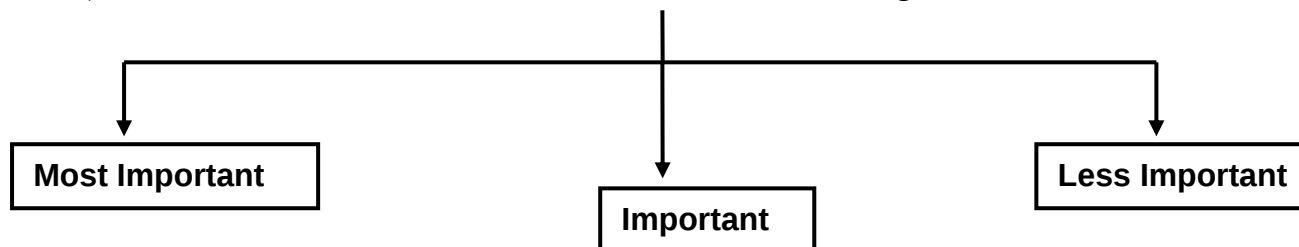
- 2) Awareness and value can be created in the doctor's mind by telling the benefits of the molecule.
- 3) Something related to the molecule can be given to the doctor as a reminder.
- 4) CSR activities can also be performed.

Action Plan

- 1) First, the customers will be targeted geographically.



- 2) In Urban areas, the doctors can be divided into different categories:



- 3) Total 70 doctors in urban area will be taken, which will include 10 most important doctors, 25 Important doctors and 45 Less Important doctors.

- 4) In Rural areas, main hospitals and doctors for the business will be targeted.

Inputs Planning

1) Visual Aid

- It should be attractive.
- The molecule name should be in focus and should be attractive.
- It should have the punch line.
- It should include indications.
- It should also mention the USP.
- It should convey the mechanism of action.
- Dosage should also be mentioned.

2) Literature

- It includes clinical studies.
- It should be in brief language for the better understanding of doctors.
- It should be updated and should be in two folds.

3) Scientific Gifts

The scientific gifts are given as a reminder to the doctors. It can be in different forms like:

- Journals
- Books
- Stethoscope

4) CME Planning

- The list of the doctors who will give us the main business will be made.
- Then, the venue will be booked.
- Invitations to the doctors will be sent.
- Main doctor as our speaker will be chosen.
- Preparation of lunch and tea.
- The decoration of the venue should be according to the theme or molecule.

Business Goals

The Business Goal would be, to achieve a target of 2 crores in one year.

Expense Ratio

Scientific gifts by MR's	☐ 2 lakhs
By Area Sales Manager	☐ 1 lakh
By Regional Sales Manager	☐ 75,000
Digital Marketing	☐ 50,000
CME's	☐ 6 lakhs
Display Items (visual aids, leaflets, reminder cards, journals, pamphlets)	☐ 9.5 lakhs

Ecipilim Dossier:

- Pack Size:- 3*10
- Each bi-layered tablet is coated with S-granulates to avoid the dissolution in stomach
- Each pack should be mentioned with Category H drug, not to be sold without physician prescription
- Shipper Pack:- 20 boxes in each carton
- Colour of each box is similar as per the given instruction on pack

Visual Aid

✓ In India with more than 1 billion population, 6-10 million people suffer from Epilepsy.



✓ 70% - 80% people can be seizure free with anti epileptic drugs.

✓ 1 in 10, will have seizure in lifetime.

✓ 1 in 26, will develop epilepsy.

70-80% patients of Epilepsy have following conditions:-

- Short attention blackouts



- Memory gaps



- Mumbling or no response



- Sudden stomach pain followed by confusion and sleepiness.



In the management of Epilepsy

Rx

ECIPILIM

Sodium Valproate Tablets: 200mg / 500mg

- Used to treat migraine.
- Fast onset of action.
- Bilayered tablet.
- High bioavailability because of micronized particles.

Packshot of Ecipilim



Dosage:
500mg once in a day
200mg twice in a day

SAY HELLO!! TO PERFECT LIFE...

Prescribe it when your patients experience short attention blackouts or memory loss

In the management of Epilepsy
Rx

ECIPILIM

Sodium Valproate Tablets: 200mg / 500mg

Packshot of Ecipilim

Dosage: 500mg once in a day
200mg twice in a day

SAY HELLO!! TO PERFECT LIFE...

Detailing of Visual Aid of Sodium Valproate (ECIPILIM)

Doctor, as you are aware, over 39 million people suffer from epilepsy and 70% - 80% patients of epilepsy have conditions like short attention blackouts, memory gaps, mumbling or no response and sudden stomach pain followed by confusion and sleepiness.

In these conditions, prescribe ECIPILIM, Ecipilim contains Sodium Valporate. Ecipilim is available in the tablet form having 2 strengths of 200mg and 500mg.

Ecipilim is a bilayered tablet having faster onset of action within 15 minutes and does not interact with HCL.

Ecipilim has high bioavailability because of micronized particles.

ECIPILIM can also be used in the treatment of migraine.

Doctor by prescribing Ecipilim “ SAY HELLO TO GOOD LIFE!!”

Ecipilim, is available at Ram Medical Store.

So, doctor with all these benefits can I look forward for your prescriptions of Ecipilim in your next patient of Epilepsy / Migraine.

Literature Review

EPILEPTIC SEIZURES

DO'S

- Move things out of the way.
- Cushion the person's head.
- Turn the person on side.
- Time the seizure.



DONT'S

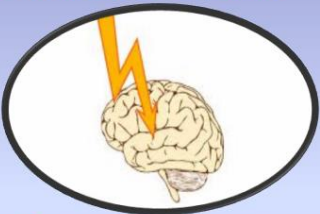
- Don't restrain someone having a seizure.
- Don't give water till fully conscious.
- Don't crowd around the person or get panic.

* The seizure usually subsides in 2 minutes.
Just prevent the person from getting injuries.

1) Evaluation of the efficacy of sodium valproate in convulsive status epilepticus following to ischemic stroke

First Page

Over a lifetime, 1 in 26 people will be diagnosed with Epilepsy.
Only 1 in 5 get specialized care.
50% of patients will be able to stop using their anti-epileptic medicines, after being seizure free for about 2-5 years.

EPILEPSY



Second Page

In the management of Epilepsy
Rx

ECIPILIM

Sodium Valproate Tablets: 200mg / 500mg

Third Page

TABLE: Changes in Biochemical Parameters

	Pretreatment (n = 17)	Post-treatment (48 h) (n = 17)	p-value
Glucose (75-115 mg/dL)	158.88 ± 70.17	117.58 ± 42.40	0.013
WBC (3.5-10.5 billion/L)	9.2 ± 1158	9.3 ± 1254	> 0.05
PLT (150-450 billion/L)	361.82 ± 115.65	336.94 ± 105.59	0.045
ALT (7-55 U/L)	41.05 ± 9.01	55.76 ± 14.57	0.001
AST (7-55 U/L)	40.88 ± 8.29	54.41 ± 19.36	0.003
Ammonia (15-60 mcg/dL)	36.00 ± 13.24	41.58 ± 10.86	0.002
K (3.6-5.5 mmol/L)	4.16 ± 0.68	3.96 ± 0.76	> 0.05
Na (135-145 mEq/L)	141.76 ± 4.17	140.70 ± 3.92	0.015
Amilase (23-85 U/L)	80.88 ± 27.90	83.41 ± 27.46	> 0.05
Soyum Valproat (50-100 mg/L)	-	83.29 ± 18.42	

Fourth Page

In the management of Epilepsy

Rx

ECIPILIM

Sodium Valproate Tablets: 200mg / 500mg

- Sodium Valproate treatment halted status epilepticus in 12 (63.15%) patients.
- Sodium valproate may be also similarly be more effective and safe than phenytoin in the elderly with status epilepticus.
- It is a bilayered tablet.
- It is also used in the treatment of migraine.

PACKSHOT



Reference:- http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0004-282X2015000400293&lng=en&tlng=en

Detailing of Literature Review

Doctor, as you are aware over a lifetime, 1 in 26 people will be diagnosed with Epilepsy. And only 1 in 5 people get specialized care.

Studies shows that, Sodium Valproate halted status epilepticus in 63.15% patients. Sodium valproate may be also similarly be more effective and safe than phenytoin in the elderly with status epilepticus.

Doctor, our brand Ecipilim is used in the management of epilepsy. Ecipilim contains Sodium Valporate. Ecipilim is available in the tablet form having 2 strengths of 200mg and 500mg.

Ecipilim is a bilayered tablet having faster onset of action within 15 minutes and does not interact with HCL.

Ecipilim is also used in the treatment of migraine.

Doctor by prescribing Ecipilim “ SAY HELLO TO GOOD LIFE!!”

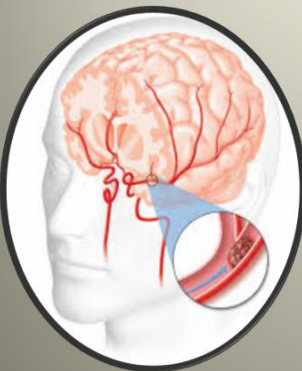
Ecipilim, is available at your nearby medical stores.

So doctor, with all these positive results of Ecipilim, can I expect 2 prescriptions coming from your side every month.

2) The efficacy of intravenous Sodium Valproate and Phenytoin as the first-line treatment in status epilepticus: a comparison study

First Page

65 Million People in World live with Epilepsy
One-Third patients live with Uncontrollable Seizures





**E
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Y**

Second Page

In the management of Epilepsy

Rx **ECIPILIM**

Sodium Valproate Tablets: 200mg / 500mg

Third Page



TABLE: Numbers of antiepileptic drug (AED) used in status epilepticus patients by group

No. AED	Phenytoin group N = 37	Sodium valproate group N = 17
1	13 (35.14)	9 (52.94)
2	14 (37.84)	3 (17.65)
3	9 (24.32)	4 (23.53)
4	1 (2.70)	1 (5.88)

■ The mean doses of AED used in phenytoin and sodium valproate group were 1.95 and 1.82
 ■ The numbers of patients with two or more AED usage were 10 and 5 in the phenytoin and sodium valproate groups, respectively.

Fourth Page

In the management of Epilepsy

Rx

ECIPILIM

Sodium Valproate Tablets: 200mg / 500mg

- ❑ Both intravenous phenytoin and sodium valproate were effective in SE treatment .
- ❑ Intravenous sodium valproate is non-inferior to intravenous phenytoin as the first-line treatment in SE with no significant cardiovascular compromises.
- ❑ It is pocket friendly as compared to other brands.
- ❑ It has fast onset of action.

PACKSHOT



Reference:- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3727978/>

Detailing of Literature Review

Doctor, as you are aware 65 million people in the world live with epilepsy and out of them, one-third patients live with uncontrolled seizures.

As the studies shows, both intravenous phenytoin and sodium valproate were effective in SE treatment . Intravenous sodium valproate is non-inferior to intravenous phenytoin as the first-line treatment in SE with no significant cardiovascular compromises.

Doctor, our brand Ecipilim is used in the management of epilepsy. Ecipilim contains Sodium Valporate. Ecipilim is available in the tablet form having 2 strengths of 200mg and 500mg.

Ecipilim is pocket friendly as compared to other brands. Ecipilim also has fast onset of action.

Doctor by prescribing Ecipilim “ SAY HELLO TO GOOD LIFE!!”

Ecipilim, is avaiable at your nearby medical stores.

So doctor, with all these positive results of Ecipilim, can I expect few prescriptions coming from your side next month.

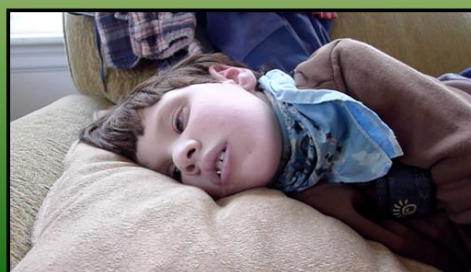
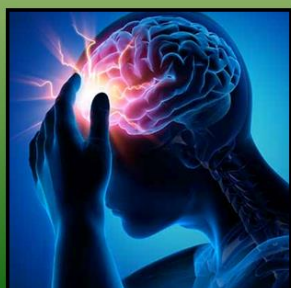
3) Psychological effects of sodium valproate and carbamazepine in epilepsy

First Page

1 in 20 children are affected by Epilepsy.

60% of people will respond positively to the first anti-epileptic drug prescribed to them.

EPILEPSY



Second Page

In the management of Epilepsy

Third Page

Rx

ECIPILIM

Sodium Valproate Tablets:200mg / 500mg

TABLE: Numbers of children in epilepsy and control groups according to treatment and sex

Sex	Children With Epilepsy	Sodium Valproate	Carbamazepine	Controls	TOTAL
Boys	34	20	14	26	60
Girls	29	14	15	21	50
TOTAL	63	34	29	47	110

A total of 110 children were included in the study: 63 children with epilepsy and 47 controls. There were no withdrawals during the course of the investigation.

Fourth Page

In the management of Epilepsy

Rx

ECIPILIM

Sodium Valproate Tablets: 200mg / 500mg

- ❖ Both drugs were effective in most cases at modest dosage without causing notable psychological effects 12 months into treatment.
- ❖ Improved function was the same in children with epilepsy and controls.
- ❖ High bioavailability because of micronized particles.
- ❖ Less side effects as compared to other brands.

PACKSHOT



Reference:- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1793785/pdf/archdisch00632-0012.pdf>

Detailing of Literature Review

Doctor, as you are aware 1 in 20 children are affected by Epilepsy. 60% of people will respond positively to the first anti-epileptic drug prescribed to them.

A total of 110 children were included in the study: 63 children with epilepsy and 47 controls. There were no withdrawals during the course of the investigation. A study shows sodium Valproate is effective in most cases at modest dosage without causing notable psychological effects 12 months into treatment.

Doctor, our brand Ecipilim is used in the management of epilepsy. Ecipilim contains Sodium Valporate. Ecipilim is available in the tablet form having 2 strengths of 200mg and 500mg.

Ecipilim has high bioavailability because of micronized particles. Ecipilim has less side effects as compared to other brands.

Ecipilim is also effective in children.

Doctor by prescribing Ecipilim “ SAY HELLO TO GOOD LIFE!!”

Ecipilim, is available at your nearby medical stores.

So doctor, with all these positive results of Ecipilim, can I expect 2 prescriptions coming from your side every month.

Retailing Survey of Sodium Valproate

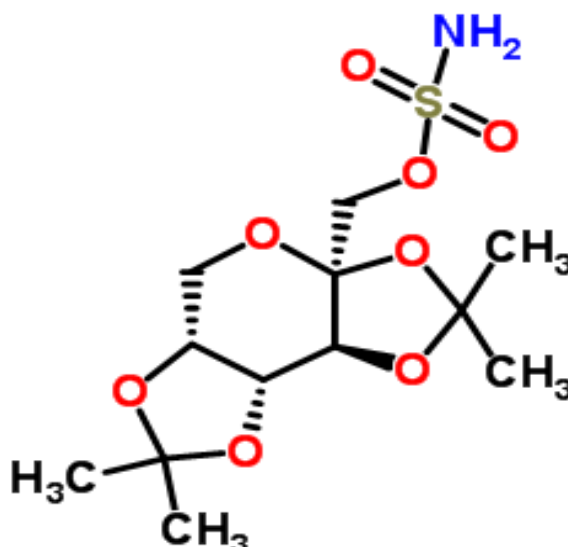
S.No	Brand Name	Company	Price(₹)	Bonus	Strategy
1)	EPILEX CHRONO (Sodium Valproate + Valproic Acid) (333/145mg)	Abbott	127.5	12%	
2)	NAVALIN CHRONO (Sodium Valproate + Valproic Acid) (333/145mg)	Molecule	90	12%	Company Faith
3)	VALPARIN CHRONO (Sodium Valproate + Valproic Acid) (333/145mg)	Sanofi	124	10+2	Company Faith
4)	VALPROMAX (Sodium Valproate + Valproic Acid) (333/145mg)	Invision (Marx)	55	10+2	
5)	VALPROMAX DS (Sodium Valproate + Valproic Acid) (333/145mg)	Invision (Marx)	76	12%	
6)	DEPAKOTE (500mg)	Sanofi	69	12%	
7)	DICORATE (500mg)	Sun Pharma	99	12%	
8)	DESVAL (500mg)	Ranbaxy	110	21% with cash discount	
9)	DIVAA (500mg)	Intas Pharma	91	20%	
10)	DIVALIN (500mg)	Molecule	90	20%	

Molecule Name: TOPIRAMATE

Brand Name: TOPILEPSY

TOPIRAMATE

- Topiramate is used to treat epilepsy in children and adults, and it was originally used as an anticonvulsant.
- In children, it is indicated for the treatment of Lennox-Gastaut syndrome, a disorder that causes seizures and developmental delay.
- The drug is also used to treat migraines due to the effect it has on the blood vessels in the brain.
- This medication was discovered in 1979 by Bruce E. Maryanoff and Joseph F. Gardocki during their research work at McNeil Pharmaceuticals.
- The commercial usage of Topiramate began in 1996.
- Mylan Pharmaceuticals was granted final approval by the FDA for the sale of generic topiramate in the United States and the generic version was made available in September 2006.
- The last patent for topiramate in the U.S. was for use in children and expired on February 28, 2009.



Pharmacokinetics of Topiramate

- **Absorption:** It has rapid absorption with peak plasma concentrations occurring after 2 hours and a bioavailability of 80%.
- **Protein binding:**
 - ✓ 15-41% (over the blood concentration range of 0.5 - 250 mg/mL).

- ✓ The fraction bound decreased as blood concentration increased.
- ✓ Carbamazepine and phenytoin do not alter the binding of immediate-release topiramate.
- ✓ Sodium valproate, at 500 mcg/mL (a concentration 5 to 10 times higher than considered therapeutic for valproate) decreased the protein binding of immediate-release topiramate from 23% to 13%.
- ✓ Immediate-release topiramate does not influence the binding of sodium valproate.
- **Metabolism:**
 - ✓ Not extensively metabolized, 70% of the dose is eliminated unchanged in the urine.
 - ✓ The other 30% is metabolized hepatically to six metabolites (formed by hydroxylation, hydrolysis, and glucuronidation), none of which constitute more than 5% of an administered dose.
 - ✓ There is evidence of renal tubular reabsorption of topiramate.
- **Route of elimination:** It is not extensively metabolized and is primarily eliminated unchanged in the urine (approximately 70% of an administered dose).
- **Half life:** 19 to 23 hours.
- **Clearance:**
 - ✓ Plasma clearance (CL/F) =20-30 mL/min [in humans following oral administration].
 - ✓ Pediatric patients on adjunctive treatment exhibited a higher oral clearance compared to those on monotherapy.
- **Toxicity/ Overdose:**
 - ✓ Abdominal pain
 - ✓ Agitation
 - ✓ blurred vision
 - ✓ Convulsions
 - ✓ Depression
 - ✓ Dizziness
 - ✓ double vision
 - ✓ Drowsiness

- ✓ Impaired mental activity
- ✓ Low blood pressure
- ✓ Severe diarrhea
- ✓ Speech problems

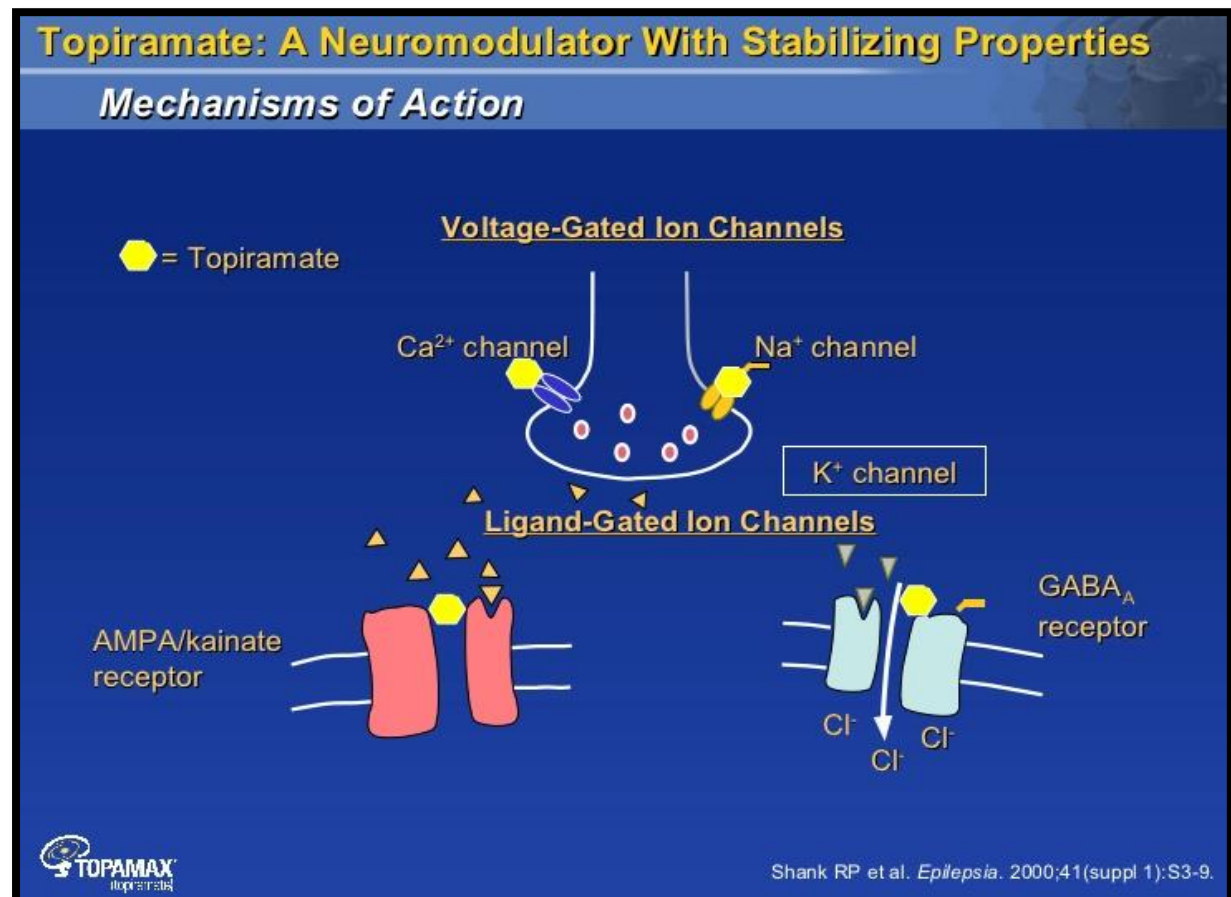
Pharmacodynamics of Topiramate

- It enhances GABA-activated chloride channels.
- In addition, topiramate inhibits excitatory neurotransmission, through actions on kainate and AMPA receptors.
- It has a specific effect on GluR5 kainate receptors.
- It is also an inhibitor of carbonic anhydrase, particular subtypes II and IV.

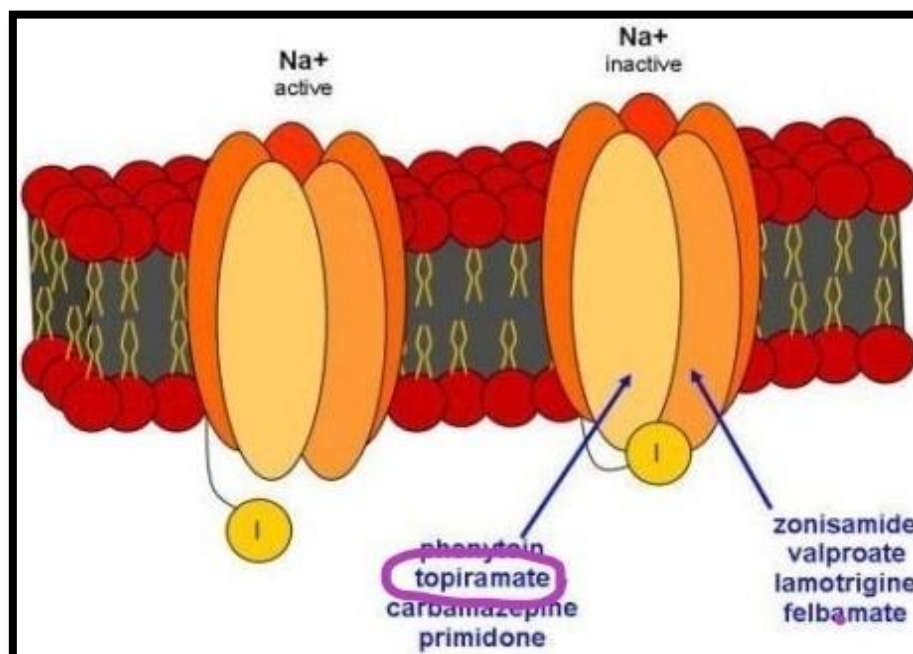
Drug Interactions

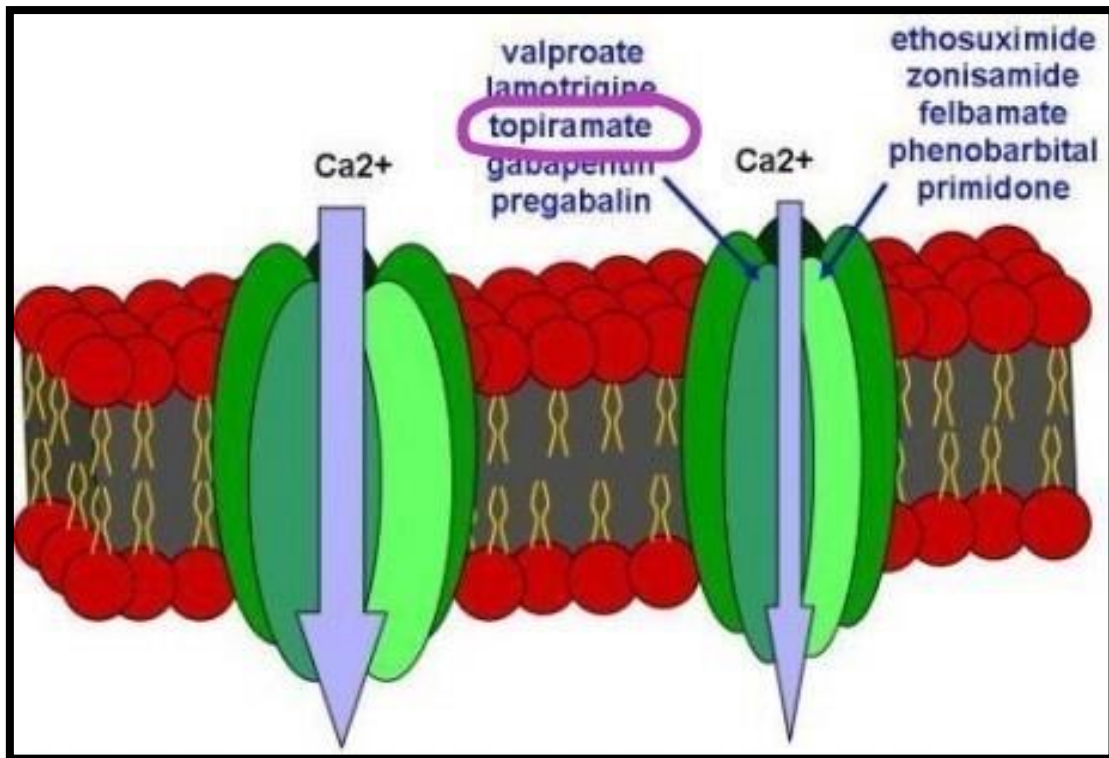
S.NO	DRUG	INTERACTION
1)	Acenocoumarol	The metabolism of Acenocoumarol can be decreased when combined with Topiramate.
2)	Aclidinium	The risk or severity of adverse effects can be increased when Aclidinium is combined with Topiramate.
3)	Adinazolam	The metabolism of Adinazolam can be decreased when combined with Topiramate.
4)	Amoxicillin	The metabolism of Amoxicillin can be decreased when combined with Topiramate.
5)	Antipyrine	The metabolism of Antipyrine can be decreased when combined with Topiramate.

Mechanism of Action



1) Blocks Sodium channels and Calcium channels

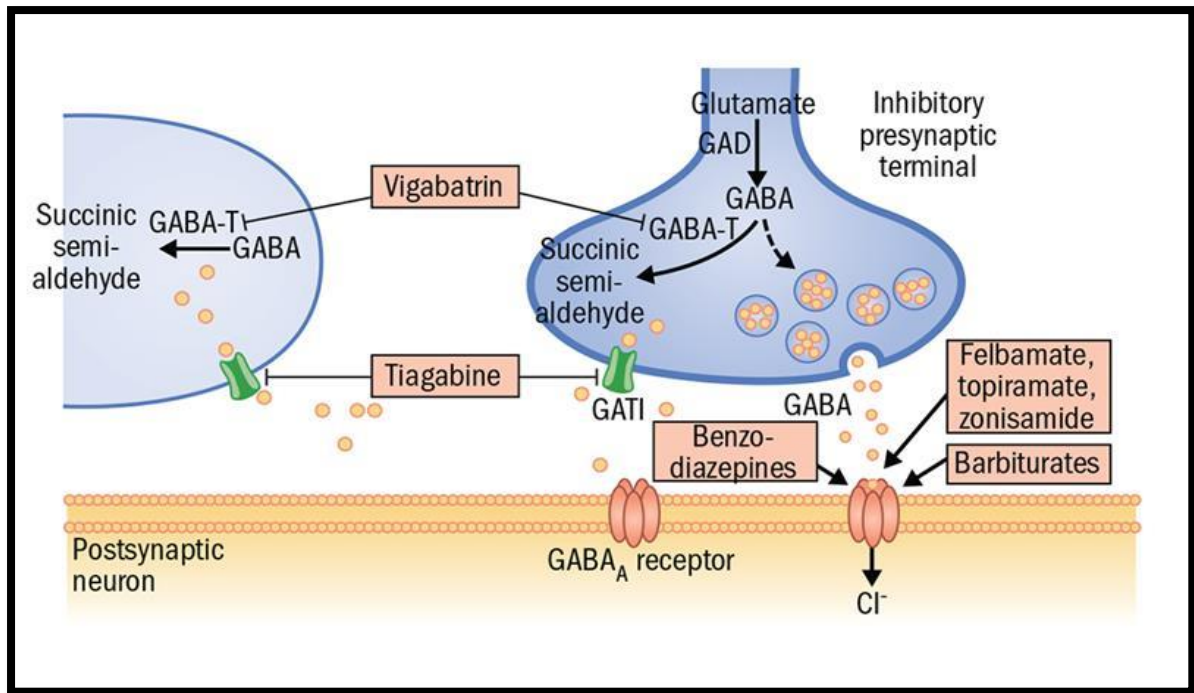




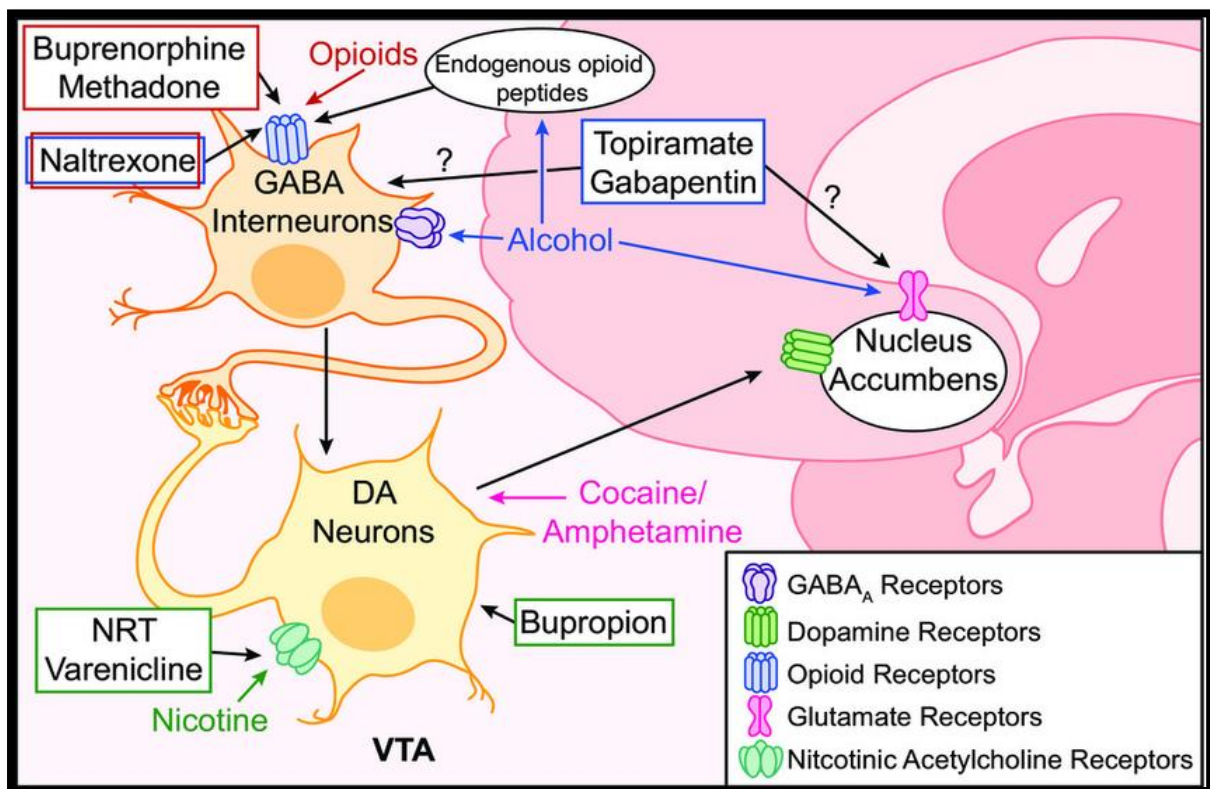
2) Increases the actions of GABA at GABA-A receptors

GABA A RECEPTOR

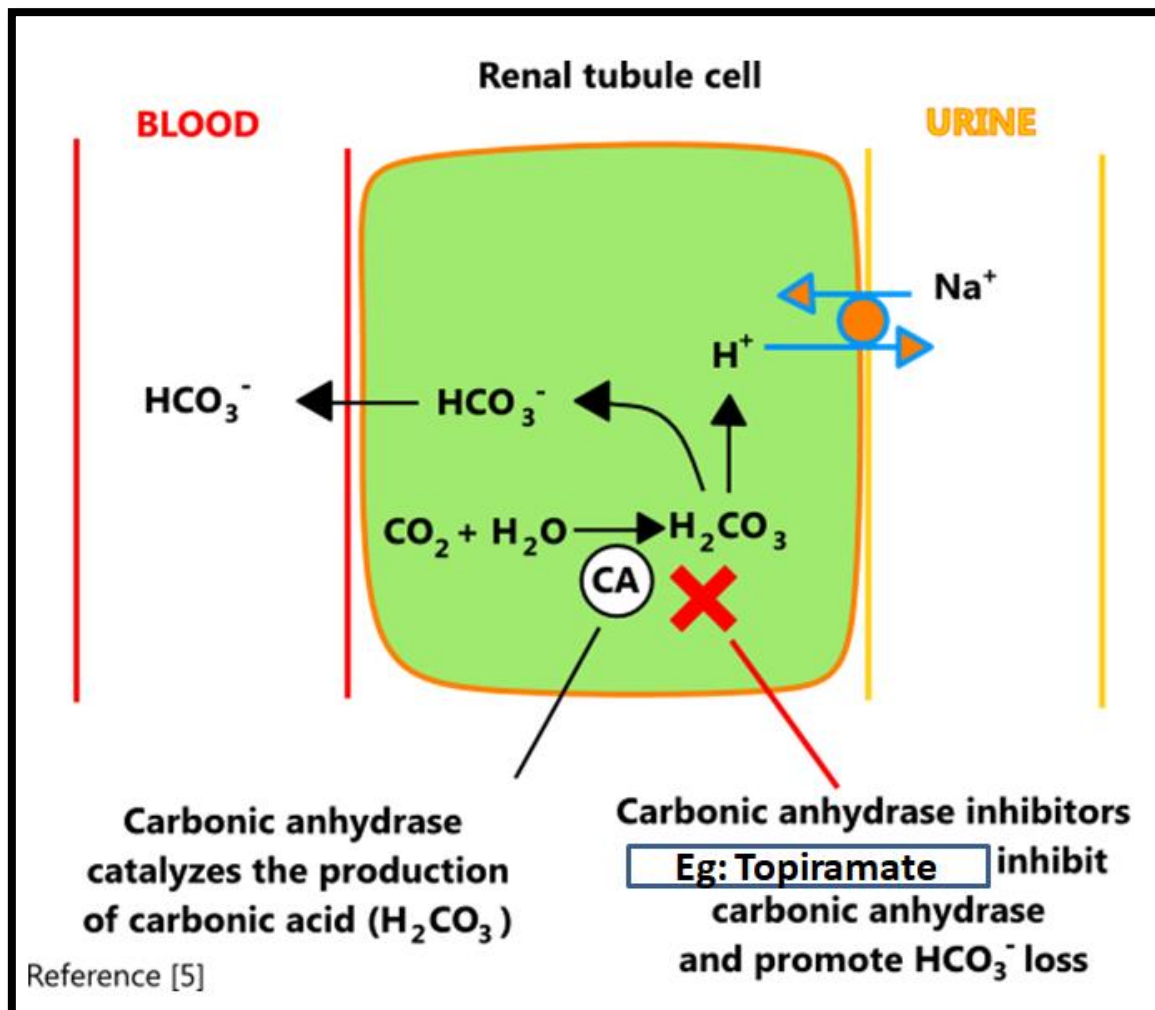
- It has pentameric structure
- It has structural similarity & functional similarity with ligand-gated ion channels
- Each GABA A receptor subunit contains two alpha subunit, two beta subunit & one gamma subunit



3) Antagonizes glutamate receptors



4) Inhibits carbonic anhydrase (isozymes II & IV)



Indications of Topiramate

FDA labeled indications

- Epilepsy in patients above 2 years of age
(Both monotherapy and adjunctive therapy)
- Seizures associates with Lennox-Gastaut Syndrome (above and equal to 2 years)
- Migraine headaches
- Chronic weight management (in combination with phentermine)

Off-label indications

- Alcoholism

- Eating disorder
- Essential tremor
- Obesity
- Type 2 diabetes mellitus in obese patients (adjunct)

Side Effects

More Common

- Blurred vision
- Confusion
- Drowsiness
- Speech or language problems

Common

- Abdominal or stomach pain
- Fever, chills, or sore throat
- Loss of appetite
- Weight loss

Rare

- Blood in the urine
- Pale skin
- Swelling
- Trouble breathing

Moving Annual Total of Topiramate

- MAT FEB'18= 54.1 crores
 - MAT FEB'17= 52.9 crores
 - MAT FEB'16= 47.5 crores
 - MAT FEB'15= 44.1 crores
- 
- CAGR Increased
by 7%
(13.9 cores) from
2015-2018

Unit MAT of Topiramate

- Unit MAT FEB'15 = 7507 crores
 - Unit MAT FEB'16 = 7785.2 crores
 - Unit MAT FEB'17 = 8136.5 crores
 - Unit MAT FEB'18 = 7685.8 crores
- 
- CAGR Increased by 1%
from 2015-2018

Month wise trend of Topiramate (all values in crores)

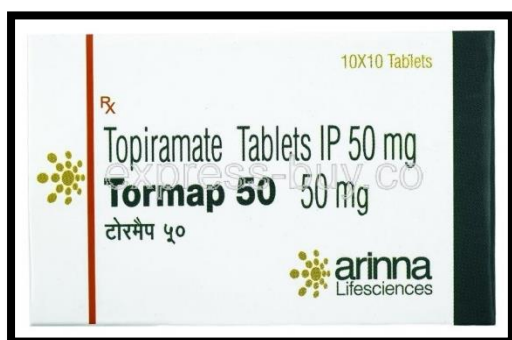
YEAR 	2014	2015	2016	2017	2018
MONTHS 					
JANUARY		3.9	4.1	4.7	4.6
FEBRUARY		3.7	4.1	4.5	4.3
MARCH	3.2	3.6	4.1	4.6	
APRIL	3.7	4.1	4.4	4.7	
MAY	3.7	3.5	4.2	4.7	
JUNE	3.4	3.5	4.3	4.2	
JULY	3.7	4.5	4.4	3.9	
AUGUST	3.7	4.0	4.4	4.8	
SEPTEMBER	3.7	4.1	4.5	4.6	
OCTOBER	3.6	4.0	4.4	4.7	
NOVEMBER	3.8	3.8	4.3	4.7	
DECEMBER	4.0	4.2	4.9	4.5	

Competitors Overview

S.NO	BRAND	COMPANNY	Price (₹) of 10 tablets/ Strip
1)	EPITOP (50mg)	Micro Labs	70.5
2)	NEXTOP (25mg)	Torrent Pharma	55.40
3)	TOPAZ (100mg)	Intas Pharma	253.50
4)	TOPIROL (100mg)	Sun	199
5)	LEPTOMATE (50mg)	La Renon Healthca.	73
6)	TMATECAD (50mg)	Cadila Pharma	57.13
7)	TOPAMAC (50mg)	Janssen	162
8)	TOPAMATE (25mg)	Cipla	40.28
9)	TOPAMED (50mg)	Icon Lifesciences	100
10)	TOPATE (50mg)	Tas Med	70.48
11)	TOPEMA (25mg)	Alkem	47
12)	TOPIRATE (50mg)	Pulse Pharma	97.50
13)	TOPSE (50mg)	Crescent Pharma	85.43
14)	TORMAP (50/100mg)	Arinna Lifescience	74/142

Packshot of competitors brand



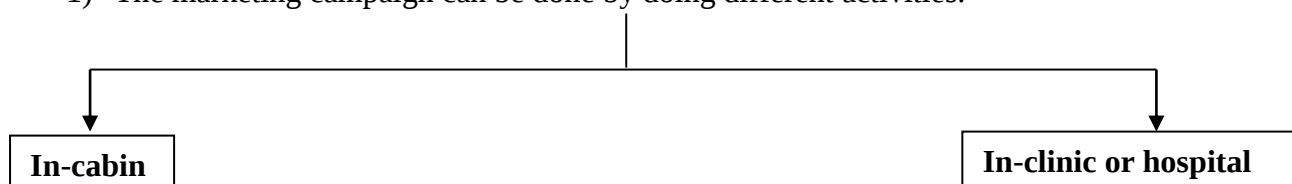


SWOT Analysis of Topiramate molecule

<u>STRENGTH</u> • It is used in two types of seizures. ✓ Partial Seizure ✓ Generalized Seizures • It is used to treat migraine. • Other than seizure it is also used in weight loss therapy in combination with Phenanthrene.	<u>WEAKNESS</u> • If patients are taking Topiramate for a long term then, it can lead to eye problems and if left untreated, then it can cause permanent vision loss. • It causes side effects like: ✓ Aggression ✓ Depression ✓ Agitation ✓ Apathy
<u>OPPORTUNITIES</u> • It has high chances of growth, as people are not much aware about it.	<u>THREATS</u> • As this is the new brand, so it is difficult to convince doctors to prescribe it. • Due to its severe side effects, people are becoming reluctant.

Marketing Campaign

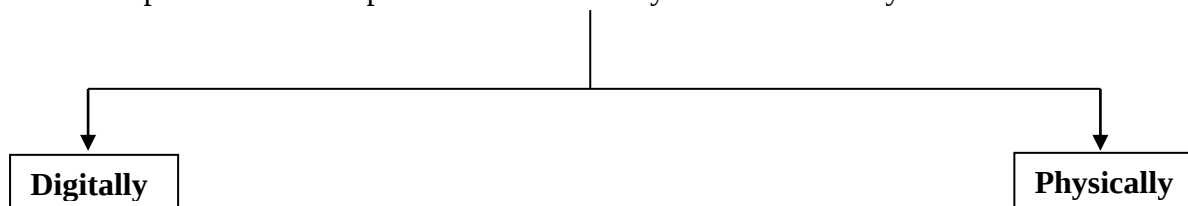
- 1) The marketing campaign can be done by doing different activities.



- 2) In-cabin activities can be done by showing videos to the doctors related to the product.
- 3) In-clinic or hospital activities can be done by performing activities related to the product for the staff members and the people around.
- 4) It can be done by arranging CME's.
- 5) It can also be done by providing free samples to the doctors.

Action Plan

- The promotion of the product can be done by two different ways:

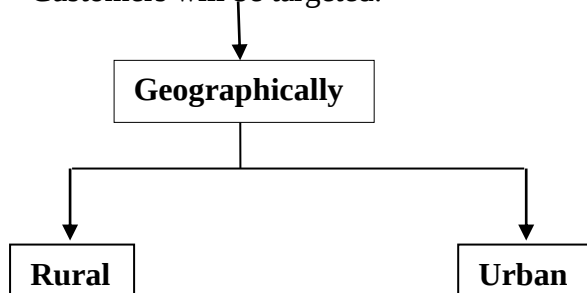


DIGITALLY

- : At first, a page will be created on some social network site where doctors are available.
- Then, the doctors which are key opinion leaders will be targeted more.
- Emails will be sent to all the doctors.
- Those emails will have the link of the content related to the molecules, which will be beneficial to the doctors also.
- This way, the doctor will show interest towards the product.

PHYSICALLY

Customers will be targeted:-



- In rural areas, the focus will be on the doctors who are the most popular.
- In urban areas, the focus will be on the doctors who are the key opinion leaders.

Inputs Planning

1) Visual Aid

- Visual aid should be in 3-4 pages.
- The first page should contain some facts related to the product with some pictures.
- The second page should have the storyline regarding the disease.
- The third page can contain the indications with some pictures
- The fourth page must have the brand name, strengths available, USP's, dosage, some related images, packshot image and the tag line.
- The fifth page will have the closing line for the doctors with brand name, strengths available, related image, packshot image, dosage and a tag line.

2) Literature

- The literature should be in 2 folds.
- It should have four sides.
- The literatures are made for 6 months, one for each month.
- The first page contains some facts regarding the drug and the disease with some pictures
- The second and the third page contain the brand name, strengths available, and the results mostly in the form of table which are concluded from the articles.
- The fourth page contains the brand name, strengths available, result findings, related image, packshot image and the reference.

3) Scientific Gifts

Scientific gifts are given to the doctor as a reminder of the product. These can be in different forms:

- Stethoscope
- Books
- Journals

4) CME Planning

- The list of doctors giving the major business will be made.
- Finalisation of the venue will be done.
- Invitation to the doctors will be sent.
- Selection of the speaker will be done.
- The venue will be decorated according to the theme.

Business Goal

Our business goal would be to achieve the target of 1 crore in 1 year.

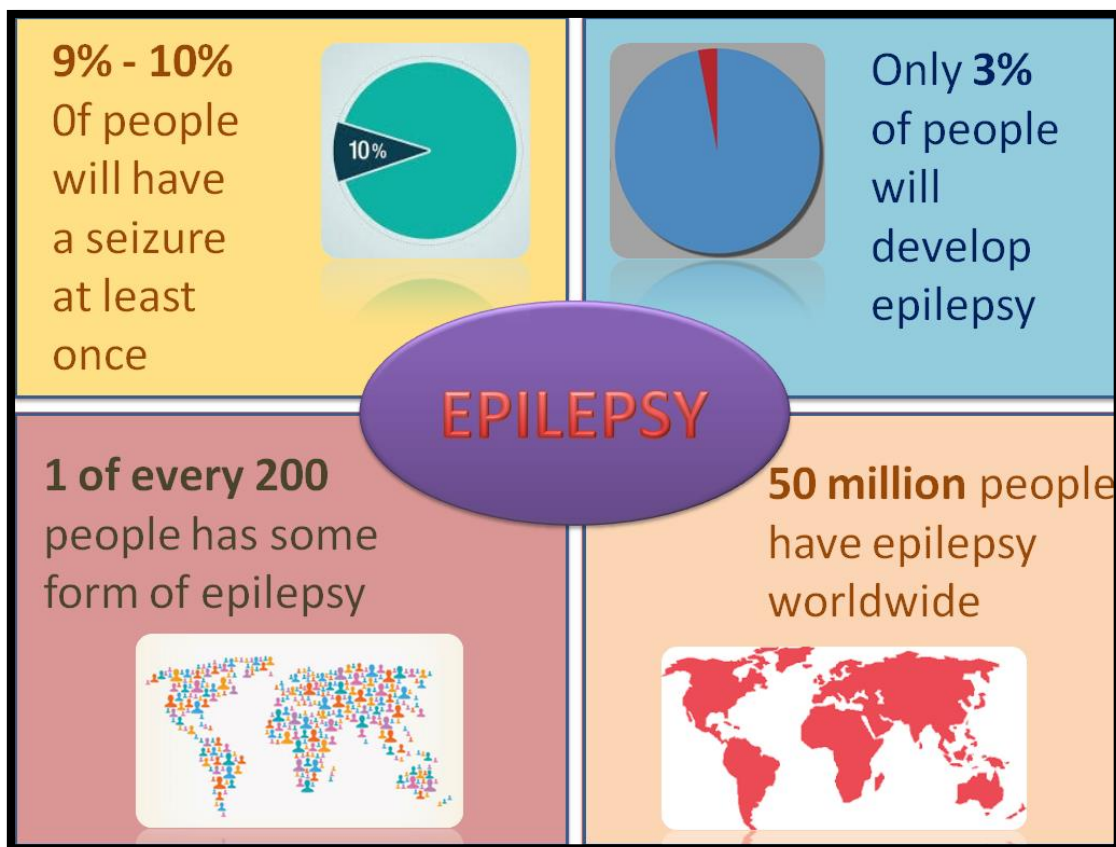
Expense ratio

Scientific gifts and Sampling	
i. For MR's	☐ 3 Lakhs
ii. For ASM's	☐ 2 Lakhs
iii. For RSM's	☐ 1 Lakh
Digital Marketing	☐ 20,000
Visual aids, Leaflets, Reminder cards	☐ 8,000
CME's and Company meetings	☐ 3 Lakhs

Topilepsy Dossier:

- Pack Size:- 3*10
- Each bi-layered tablet is coated with S-granulates to avoid the dissolution in stomach
- Each pack should be mentioned with Category H drug, not to be sold without physician prescription
- Shipper Pack:- 20 boxes in each carton
- Colour of each box is similar as per the given instruction on pack

Visual Aid



EPILEPSY

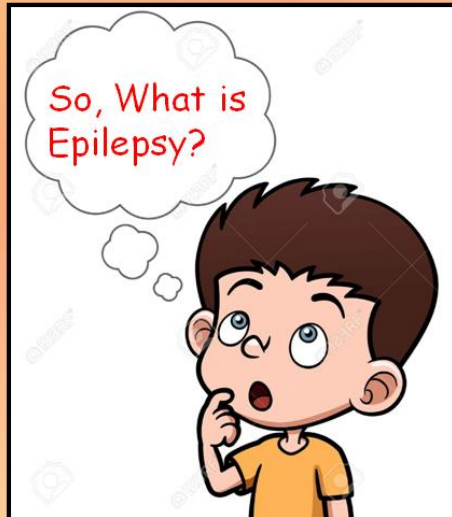
@Epilepsy is a group of neurological disorders characterized by different types of seizures.

@Some types of Epilepsy are more serious than others.

@Epilepsy can vary from staring into space to severe shaking fits.

@Many physical injuries can occur from epilepsy.

@Over 39 million people suffer from epilepsy.



In the management of Epilepsy

Rx **TOPILEPSY**

Topiramate Tablet: 25mg / 50mg / 100mg

- Used in both Partial and Generalised seizures
- Effective in less dose
- Sustain Release Tablet
- Wider therapeutic index



PACKSHOT

DOSAGE: 25mg twice in a day
50mg once in a day
100mg once in a day

LIVE A HAPPY LIFE!!

Prescribe it when your patient experience temporary confusion or loss of consciousness or awareness

In the management of Epilepsy

Rx **TOPILEPSY**

Topiramate Tablet: 25mg / 50mg / 100mg

PACKSHOT

DOSAGE: 25mg twice in a day
50mg once in a day
100mg once in a day

LIVE A HAPPY LIFE!!

Detailing of Visual Aid of Topiramate (TOPILEPSY)

Doctor, as you are aware 9% - 10% Of people will have a seizure at least once in life and 1 of every 200 people has some form of epilepsy. Many physical injuries can occur from epilepsy.

Our brand Topilepsy is used in the treatment of epilepsy. Topilepsy contains Topiramate. Topilepsy is available in the tablet form having 3 strengths of 25mg, 50mg and 100mg.

Topilepsy is used in both Partial and Generalised seizure. Topilepsy is effective in less dose. Topilepsy is a sustain release tablet. Topilepsy has wider therapeutic index.

Topilepsy can also be used in the treatment of migraine.

Doctor, by prescribing Topilepsy your patient will “LIVE A HAPPY LIFE!!”

Topilepsy, is available at Payal Medical Store.

So, doctor with all these benefits can I look forward for your prescriptions of Topilepsy in your next patient of Epilepsy / Migraine.

Literature Review

1) Assessment of topiramate's efficacy and safety in epilepsy

First Page

20% of all persons with epilepsy have their first seizure before the age 10

Seizures medication works on about 65% of people with epilepsy

EPILEPSY



Second Page

In the management of Epilepsy

Third Page

Rx **TOPILEPSY**

Topiramate Tablet: 25mg / 50mg / 100mg

TABLE: Doses of topiramate in relation to responders

Topiramate dosage	N (%)				
	100 mg	200 mg	300 mg	400 mg	Total
Responders	11 (68.8)	35 (87.5)	12 (85.7)	4 (66.7)	62 (71.26)
Nonresponders	5 (31.2)	5 (12.5)	3 (14.3)	2 (33.3)	15 (17.24)
Total	16 (100)	40 (100)	15 (100)	6 (100)	87 (100)
Z test	2.121	6.708	3.286	1.154	7.173
P	<0.05	<0.001	<0.05	>0.05	<0.001

Best response to TPM therapy in terms of percentage responders was noted with TPM dose of 200 mg/day. The difference in number of responders with a dose of 200 mg/day was most highly significant followed by significant responses of 100 and 300 mg/day but the dose of 400 mg/day was not significant statistically.

Rx

TOPILEPSY

Topiramate Tablet: 25mg / 50mg / 100mg

- Topiramate is rapidly absorbed from the gastrointestinal tract and its absorption is unaffected by food.
- Topiramate was found as a significantly effective add-on anticonvulsant with some limitation or mild side effects.
- Used in both Partial and Generalised seizures.
- Effective in less dose.

PACKSHOTReference: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4064179/>

Detailing Of Literature Review

Doctors, as you are aware 20% of all persons with epilepsy have their first seizure before the age 10. Seizures medication works on about 65% of people with epilepsy.

The studies shows, topiramate is rapidly absorbed from the gastrointestinal tract and its absorption is unaffected by food. Topiramate was found as a significantly effective add-on anticonvulsant with some limitation or mild side effects.

Our brand TOPILEPSY contains molecule Topiramate. Topilepsy is used in both Partial and Generalised seizures. Topilepsy is effective in less dose.

Doctor by prescribing Topilepsy, your patient will “LIVE A HAPPY LIFE!!”

Topilepsy, is available at your nearby medical stores.

So doctor, with all these positive results of Topilepsy, can I expect few prescriptions coming from your side next month.

2) Comparison of the Effectiveness of Topiramate and Sodium Valproate in Pediatric Migraine

First Page

10% of people worldwide suffer from migraine.



Migraine is in the top 20 of the world's most disabling illnesses.

MIGRAINE



Second Page

In the management of Epilepsy

Third Page

RX **TOPILEPSY**

Topiramate Tablet: 25mg / 50mg / 100mg

TABLE: Comparison of Headache Frequency, Intensity, and Duration in Migraine Patients Before and After Treatment With Valproate and Topiramate

Treatment group	Headache frequency	Headache intensity	Duration of migraine episode	pedMIDAS
<u>Topiramate</u>				
Baseline	15.3 (10.1)	6.8 (1)	10.2 (9.4)	36 (29.5)
After therapy	4.4 (5.5)	3.2 (1.8)	2.4 (3.1)	4.6 (6.5)
Differences	6.7 (7.6-14.3)a	9.8 (2.85-4.35)a	5 (4.65-10.98)a	5.49 (19.61-43.02)a
<u>Sodium Valproate</u>				
Baseline	20.1 (10.2)	7.1 (1)	7 (12)	20.5 (16.1)
After therapy	6.6 (8.6)	3.4 (2.1)	1.4 (2.5)	5.5 (9.2)
Differences	6.2 (9.0-18.1)a	7.5 (2.71-4.78)a	2.3 (0.60-10.49)b	3.64 (6.41-23.68)a

Fourth Page

In the management of Epilepsy

RX

TOPILEPSY

Topiramate Tablet: 25mg / 50mg / 100mg

- ❖ Frequent headache can cause a significant impact on disability and quality of life, prompting the need for early recognition and treatment.
- ❖ Valproate and Topiramate seem to be able to manage successfully childhood migraine without substantial differences in efficacy.
- ❖ Less side effects as compared to other brands.
- ❖ Wider therapeutic index.

PACKSHOT

Reference:

<http://journals.sagepub.com/doi/pdf/10.1177/0883073808318547>



Detailing of Literature Review

Doctor as you are aware, 10% of people worldwide suffer from migraine. Migraine is in the top 20 of the world's most disabling illnesses.

As the studies show, frequent headache can cause a significant impact on disability and quality of life, prompting the need for early recognition and treatment. Topiramate seem to be able to manage successfully childhood migraine without substantial differences in efficacy.

Our brand TOPILEPSY contains molecule Topiramate. Topilepsy has less side effects as compared to other brands. Topilepsy has wider therapeutic index.

Doctor by prescribing Topilepsy, your patient will "LIVE A HAPPY LIFE!!"

Topilepsy, is available at your nearby medical stores.

So doctor, with all these positive results of Topilepsy, can I expect 3 prescriptions coming from your side next month.

3) Efficacy and safety of topiramate in infants according to epilepsy syndromes

First Page

Seizures in upto 30% of people with epilepsy do not respond to available medications.

More than 30% of people with epilepsy experience generalized seizures.

After trying 2 medications, the chance that a 3rd medication will control seizure is less than 5%.



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Y



Second Page

In the management of Epilepsy

Third Page

Rx **TOPILEPSY**

Topiramate Tablet: 25mg / 50mg / 100mg

TABLE: Efficacy of Topiramate according to epilepsy syndromes

Epilepsy syndromes	No. of patients	Responders (seizure-free)	3) Generalized	23	9 (5)
1) Localization-related epilepsy	22	14 (3)	Cryptogenic		
Idiopathic			Infantile spasms	6	4 (4)
Early-onset occipital seizure	1	NR	Symptomatic		
Benign partial complex seizure	1	1 (0)	Infantile spasms	13	4 (1)
Cryptogenic	7	5 (1)	Ohtahara syndrome	1	NR
Symptomatic	12	7 (1)	Myoclonicepilepsy and MSNE	1	NR
Bathing epilepsy	1	1 (1)	Others	2	1 (0)
2) Dravet's syndrome	6	2 (0)	4) Unclassifiable	8	3 (0)

Fourth Page

In the management of Epilepsy

Rx

TOPILEPSY

Topiramate Tablet: 25mg / 50mg / 100mg

- ❑ Topiramate was more effective in localization-related epilepsy than in generalized epilepsy.
- ❑ The most frequently reported adverse effects were drowsiness, irritability, hyperthermia, and anorexia.
- ❑ Its a sustain release tablet.
- ❑ Effective in case of infants.

PACKSHOT



Reference: [https://www.seizure-journal.com/article/S1059-1311\(05\)00023-3/fulltext](https://www.seizure-journal.com/article/S1059-1311(05)00023-3/fulltext)

Detailing Of Literature Review

Doctor as you are aware, seizures in upto 30% of people with epilepsy do not respond to available medications. More than 30% of people with epilepsy experience generalized seizures. After trying 2 medications, the chance that a 3rd medication will control seizure is less than 5%.

As the studies show, Topiramate is more effective in localization-related epilepsy than in generalized epilepsy. The most frequently reported adverse effects were drowsiness, irritability, hyperthermia, and anorexia.

Our brand TOPILEPSY contains molecule Topiramate. Topilepsy is a sustain release tablet. Topilepsy is effective in case of infants.

Doctor by prescribing Topilepsy, your patient will “LIVE A HAPPY LIFE!!”

Topilepsy, is available at Sharma medical stores.

So doctor, with all these positive results of Topilepsy, can I expect 2 prescriptions coming from your side every month.

Retailing survey of Topiramate

S.No	Brand Name	Company	Price (₹)	Bonus	Strategy
1	EPITOP (100mg)	Micro Labs	108	20%	
2	NEXTOP (100mg)	Torrent Pharma	159	20%	Oldest brand and approved by the regulatory body
3	NEUROMATE (100mg)	Invision	60	20%	
4	TOPAZ (100mg)	Intas Pharma	231	20%	
5	TOPMAC (100mg)	Janseen	275	10+3	
6	TOPEMA (25mg)	Alkem	40	20%	
7	TOPIRAIN (50mg)	Unichem	85	20%	
8	TOPIROL (100mg)	Sun Pharma	175	20%	

References

https://pubchem.ncbi.nlm.nih.gov/compound/Sodium_valproate#section=Drug-and-Medication-Information

<https://www.medicineindia.org/pharmacology-for-generic/241/sodium-valproate>

https://www.researchgate.net/publication/277437258_The_new_generation_of_GABA_enhancers

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3696515/>

file:///C:/Users/Micro/Downloads/Review_of_Sodium_Valproate_Clinical_and_Biochemica.pdf

<http://cochranelibrary-wiley.com/doi/10.1002/14651858.CD010611/full>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3727978/>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1793785/pdf/archdisch00632-0012.pdf>

<http://www.bioline.org.br/pdf?pt05030>

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<https://www.drugbank.ca/drugs/DB00273>

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