

SUMMER TRAINING

at

Micro Labs Pvt. Ltd.

(International Division)

(01th April 2018 – 31th May 2018)

A Project

Brand Launch Strategies and Marketing Plan of

Uriflo and Solichem

By:

Bhumika Bhatnagar

MBA- Pharmaceutical Management

2018-2020

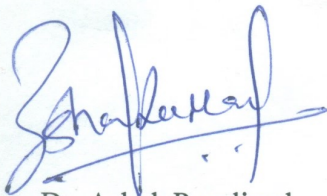


CERTIFICATE

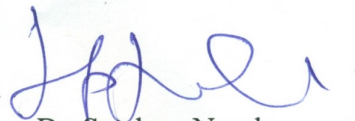
This is to certify that **Bhumika Bhatnagar** has undergone Summer Training at **Micro Labs Limited, Gurugram** from 1st April 2019 to 31st May 2019.

The candidate herself has completed the project assigned to her in summer training. Her approach to 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.

A handwritten signature in blue ink, appearing to read 'Ashok Peepliwal'.

Dr. Ashok Peepliwal
Associate Professor
School of Pharmaceutical Management
IIHMR University, Jaipur

A handwritten signature in blue ink, appearing to read 'Sandeep Narula'.

Dr. Sandeep Narula
Dean-in-charge (Associate Professor)
School of Pharmaceutical Management
IIHMR University, Jaipur



MICRO LABS LIMITED

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REGD. & CORPORATE OFFICE : # 27, Race Course Road, Bangalore-560 001, INDIA. website : www.microlabsltd.com

31/5/2019

To Whom It May Concern

This is to certify that **Ms. Bhumika Bhatnagar** D/o Mr. Mukesh Bhatnagar, a student of **IIHMR**, Jaipur has successfully completed six weeks internship at **Micro Lab Ltd.**, Gurgaon during 1st April to 30th April' 2019 – 15th May to 31st May' 2019 period.

She is found punctual, hard working and deeply involved with the given assignments during her Internship.

We wish her every success in life.

MICRO LABS LTD.
GURGAON

Authorised Signatory

Micro Labs Ltd.

ACKNOWLEDGEMENT

I humbly owe the completion of my Summer intern project to the almighty and my family who always support me in my life.

I would like to extend my sincere gratitude to **Mr. TAVINDER JIT SINGH VASUDEVA, President & Chief Business Officer, Micro Labs Ltd, Gurugram** for providing me this opportunity to develop myself professionally and personally.

I am thankful to my Project Mentor **Mr. SUNEEL BABU BEJJAM**, Brand promotion and business development Manager, Micro Labs Ltd Gurugram, for his valuable suggestions and support throughout the project.

I would like to express my deep gratitude to my Academic mentor and Intern coordinator **PROF. ASHOK PEEPLIWAL , Associate Professor, IIHMR University, Jaipur, Rajasthan.**

I would like to thank him for providing their guidance, their valuable suggestions that helped me to carry out this project.”

I am very much thankful to colleagues of my office for their participation and cooperation. I would like to thank my family for supporting and standing with me in successfully completing the project.

BHUMIKA BHATNAGAR

DECLARATION

I hereby declare that this Summer Intern Project entitled “ **Brand launch and marketing plan of Silodosin and solifenacin**” submitted to IIHMR University, Jaipur in the partial fulfillment of the requirements for the award of degree of MBA Pharmaceutical Management is a bonafide and genuine study carried out by me under the esteemed guidance of **Mr. Tavinder Jit Singh Vasudeva, President & Chief Business Officer, Micro labs, Gurugram.** The extent of information gathered in the study is discussed in this Project report. This work is original and confidential.

BHUMIKA BHATNAGAR

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Brand Name: URIFLO

Disease Information and Brand Plan

Disease:- Benign prostatic hyperplasia

Molecule Name: SILODOSIN



BENIGN PROSTATIC HYPERPLASIA (BPH)

Prostate gland

Prostate gland, a small organ is of the size of a walnut. It is located below the bladder (where urine is stored) , it surrounds the urethra (tube that carries urine from the bladder).

The gland makes the fluid that helps to nourish sperm as part of the semen .

These problems are more common in men at the of age 50 and older.

BPH

“Benign prostatic hyperplasia (BPH) is nonmalignant (noncancerous) enlargement of the prostate gland which is commonly occurs in older men”.

Symptoms of BPH

The severity of symptoms varies from people to people , Common signs and symptoms of BPH include:

- Frequent urination specially at night
- Urgency in urination
- Urine stream becomes weaks
- Inability to completely empty the bladder
- Post Micturition Dribble

Causes of BPH

Prostate gland is located below the bladder. From the center of prostate , a tube passes which transports the urine from the bladder and out of penis (urethra) . When the size of prostate enlarges, it begins to block the flow of urine.

Most of the men have continued prostate growth throughout their life. Sometimes, this continued growth enlarges the prostate gland and cause urinary symptoms and blocks the urine flow.

It is not completely clear what causes the enlargement of prostate .

It might be due to imbalance of sex hormones as men grew older.

Risk factors

Risk factors responsible for enlargement of prostate include:

Aging

Family history

Diabetes and heart disease

Lifestyle.

Treatment

- **Medication**

Alpha blockers

Phosphodiesterase-5 (PDE5) inhibitors

5-alpha-reductase inhibitors

Combinations

- **Surgery**

BPH Market Overview

The **global benign prostatic hyperplasia therapeutics market** was valued at \$10,688.73 million in 2017, and is projected to reach \$20,096.69 million by 2025 at a CAGR of 8.2% from 2018 to 2025.

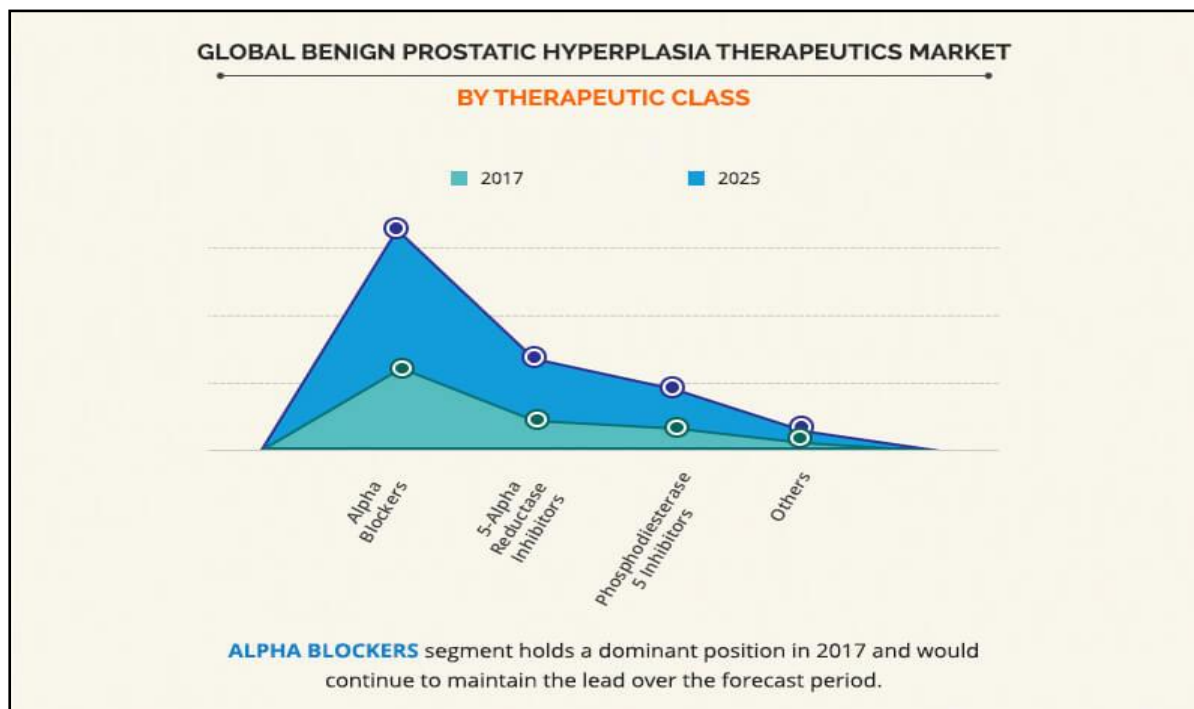
According to reports “**Global prevalence of BPH varies from 20 – 62% in men over 50 years and this includes USA, UK, Japan and Ghana.**”

In South Africa, reports indicate that 1:3 men 45 years old experience LUTS due to BPH and 50% of men at 60 years are facing symptoms of BPH .

The prevalence of increases with increasing age, with the highest prevalence in participants aged 70 and above.

Prevalence of BPH in Ghana is **responsible for 60% acute urine retention.**

Annual sales of Silodosin is \$198.5 million in the US.



URIFLO (SILODOSIN)

Silodosin is a drug which is used in the treatment of BPH .

Description

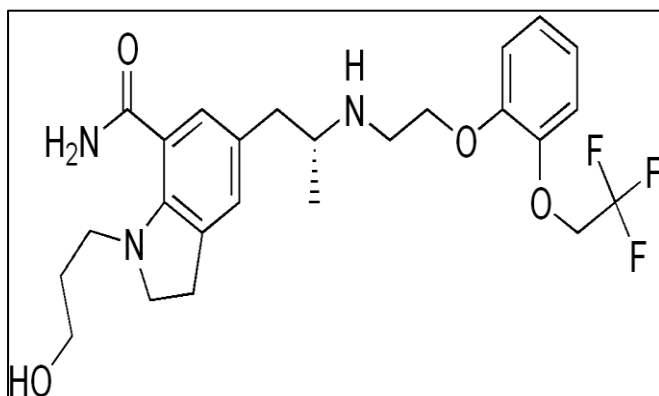
Uriflo which contain silodosin is an $\alpha 1$ -adrenoceptor antagonist , selective for the prostate. It is for symptomatic treatment of benign prostatic hyperplasia which is FDA approved in Oct 9, 2008.

Chemical Formula - $C_{25}H_{32}F_3N_3O_4$

Half life - Silodosin = 13.3 ± 8 hours

Clearance - Plasma clearance = 10 L/h

Volume of distribution - 49.5 L



Indication

Benign Prostatic hyperplasia

Dosage – 8 mg per day with meal

Pharmacodynamic

“Uriflo is **583 times** more selective for human α -1A receptors than α -1B receptors”

Also the drug is **56 times** more selective for human α -1A receptors than α -1D.

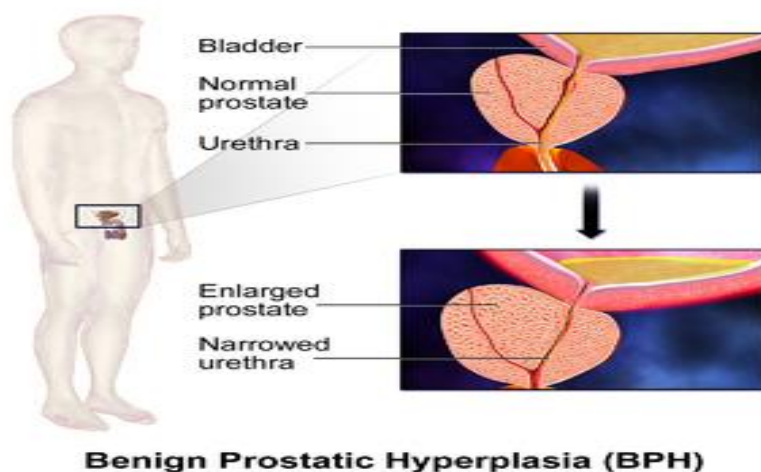
Mechanism of action

Uriflo is highly uroselective for the alpha (1A) receptors which is located in the prostate.

When the alpha receptor gets block it relaxes the smooth muscles, resulting in an improvement of urine flow and also reduce the symptoms of BPH.

The selective binding of drug with the alpha (1A) receptors is greater than the binding with the alpha (1B) receptors and in this way it maximizes target organ activity while minimizing the potential for blood pressure effects.

Uriflo (Silodosin) is alpha 1A-adrenoceptor selective antagonist which inhibits sympathetic nerve stimulation and relaxation of smooth muscle tone in the lower urinary tract which relieves the pressure from contraction of smooth muscle.



Adverse Effects

Diarrhea

Headache

Insomnia

Dizziness

Orthostatic hypotension

Naso pharyngitis

Nasal congestion

Sinusitis

VISION

Our vision is to become a leader in the pharmaceutical industry and to provide quality products in the society.

We wish to raise the flag of Micro Labs globally.

Mission

Our mission is to contribute towards the treatment of BPH and to create Customer value and satisfaction.

OBJECTIVE

Short term objective

To achieve maximum market share in the year of product launch.

Long term objective

To be in Top brands 5 brands of Silodosin market by 2022.

COMPETITORS

Top brands of silodosin

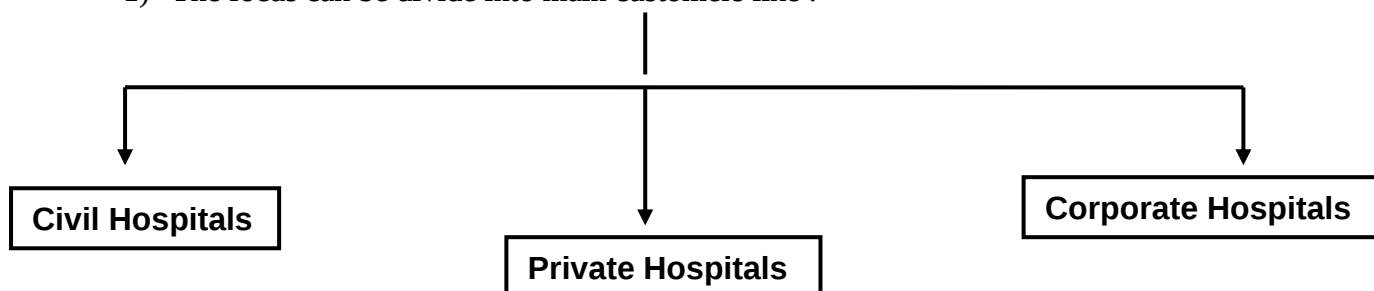
Brand Name	Company	Price/ 10 CAPS (8mg)
RAPILIF (8MG)	IPCA laboratories .	Rs185
SILOFAST (8 MG)	Cipla Ltd.	Rs.190
SILODAL	Sun Pharmaceutical Industries Ltd	₹213
SILDOO	Dr Reddy's Laboratories Ltd	₹276
GERIPOD	Alembic Pharmaceuticals Ltd	₹241
SILOTIME	Intas Pharmaceuticals Ltd	₹246
MAXVOID	Alkem Laboratories Ltd	₹347
ALPHACEPT	Lupin Ltd	₹220
FLOSPURT	Zydus Cadila	₹185
SILURI	Emcure Pharmaceuticals Ltd	₹195

SWOT

STRENGTHS Uriflo is the most efficacious with rapid onset of actions. US FDA approved drug. Manufactured at GMP certified plant.	WEAKNESS Uriflo has more adverse events when compared to tamsulosin and alfuzosin.
OPPORTUNITIES Increasing Prevalence of disease globally. Increasing Demand in the market due to its efficacy. Does not fall under DPCO	THREATS Growing competition from MNC's is high . High number of researches are going on for the treatment of BPH

Marketing Segmentation

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



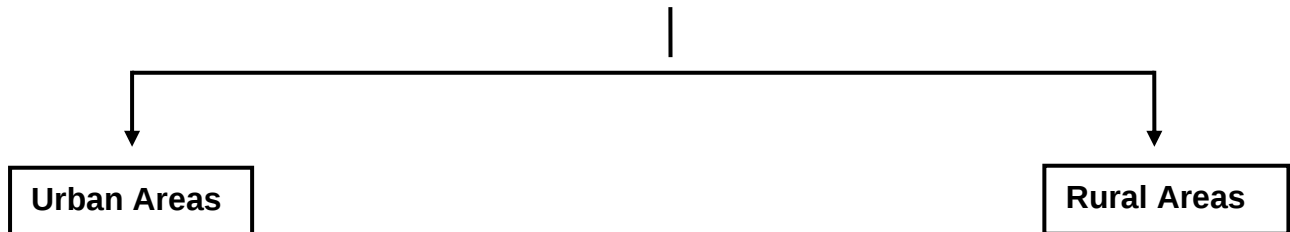
- 2) Awareness and value can be created in the doctor's mind by telling the benefits of the molecule.

3) Something related to the molecule can be given to the doctor as a reminder.

4) CSR activities can also be performed.

Action Plan

The customers will be targeted geographically.



TARGETED CUSTOMERS

- ☐ Urologist
- ☐ General Physician
- ☐ Neurologist
- ☐ Nephrologists

PROMOTIONAL STRATEGIES

- **Consumer level (patient)**

- 1.Free Medical Camps with diagnostic and analysis programmes
- 2.Patient education programs

- **Costumer level (doctors)**

- 1.Samples to detect chemical efficacy on patients
- 2.Seminars , symposia and CME's
- 3.Hospital/ward improvement programs
4. E-Marketing and mobile apps as per MCI guidelines

- **Chemist/pharmacy level**

1. Availablity at key pharmacies with nearby clinics and hospitals
2. Display in front rows at viewers eye level
- 3.Bonus offers

PACK SHOT OF COMPETITORS



COMMUNICATION

Communication Message

- Good Morning Doctor, I am (_____) from MICRO LABS Ltd.
- I would like to introduce our new product '**URIFLO-8**' .
- Doctor as we are aware about the global market of BPH which is valued at \$10,689.72 million in 2017, and is projected to reach \$20,097.68 million by 2025 at a CAGR of 8% from 2018 to 2025.
- **Uriflo** contains 'Silodosin' 8 mg which is used to treat Benign Prostatic hyperplasia (BPH) and LUTS associated with BPH .
- **Uriflo** is a new FDA approved α_{1A} -adrenergic receptor antagonist.
- **Uriflo** has excellent early efficacy and more effective than tamsulosin.
- The dose of **URIFLO** is 8 mg is once in a day, it improves both symptoms and urine flow.
- Therefore, Doctor **URIFLO** is the best suitable product for your patients suffering from BPH , seeking your valuable prescription support for **URIFLO**.
- Thank you so much for your valuable time .

Now live a happy and healthy life with

URIFLO-8

Silodosin 8 mg caps.

Silodosin

- ✓ A new α_{1A} -adrenergic receptor antagonist
- ✓ FDA approved to reduce the risk for acute urinary retention.
- ✓ For symptomatic benign prostatic hyperplasia (BPH) in men with enlarged prostate.
- ✓ Lower urinary tract symptoms due to BPH.

Dosage

Once daily is safe, improves both symptoms and urine flow.

Uriflo.... Gives a better life to BPH patients



Now live a happy life with.....

URIFLO-8 Silodosin 8 mg caps

Silodosin

- For symptomatic BPH in men with enlarged prostate.
- Lower urinary tract symptoms due to BPH.
- Once in a day .

Now Get relieve from BPH faster.....



Inputs Planning

- 1) Visual Aid
- 2) Literature
- 3) Scientific Gifts
- 4) CME

PRICING

Basic cost /strip (including all manufacturing and packaging cost)		Rs.30
Company Margin	80 %	Rs. 24
Total Price		= Rs.54
Discount to Stockist	10 %	Rs. 5.4
Price to stockist		Rs.59.4
Discount to Retailers	22 %	Rs 13
Price to Retailer		Rs.72
Taxes	12 %	Rs 8.64
Total Price		Rs.80.64
Other charges	35 %	Rs 28
Total Cost		108.50
MRP		Rs.130

Promotional Expense

Promotional Inputs	Amount (for one quarter)
Samples	30,000
Leave Behind Literatures & Visual Aids	50,000
Gifts	40,000
Activities(CMEs, Health Campaigns)	55,000
Incentives	45,000
Other discounts and offers	20,000
Total	2,40,000

RCPA Report

Name	Contact Person	Phone	Brand	Company	Pack	Price (Rs)	Stps/Month	Scheme
Sethi Medicals	Mr.Vinod Sethi	9829651070	Sildoo	Dr.Reddy	10's	276	35-40 stps	No
			Silofast	Cipla	15's	429	30 stps	No
Ridhi Sidhi Medicals	Mr.G .L Sharma	9351623062	Silofast	Cipla	15's	426	20-25 approx	No
			Silodal	Sun Pharma	10's	213	25-30 Stps	No
Alankar Medicals	Mr Arun Jain	9414539575	Sildoo	Dr.Reddy	10's	275	10-15 stps	No
			Silofast	Cipla	15's	430	10-15 stps	No
Medicine Centre	Mr.Anil Sharma	9950411805	Sildoo	Dr.Reddy	10's	275	10-20 stps	No
Ananya Medical	Mr.Pradeep Kumar	8562000792	Silofast	Cipla	15's	420	10 stps	No
			Silotime	Intas	10's	245	10-15 stps	No
Rohit Medical	Mr.Vinod Jhamtani	9983404546	Silodal	Sun Pharma	10's	220	Non- Moving	No
			Alphacept	Lupin	10's	215	10-20 total	No
Vijayvargiya Medicals	Mr. Pravag Raj	9829789461	Silodoo	Dr.Reddy	10's	240	25-30 stps	No
			Silotime	Intas	10's	270	25-30 stps	No
Rakshit	Mr Mukesh	9887015542	Silofast	Cipla	15's	430	10-15 stps	No

Medicose								
			Geripod	Alembic	10's	245	20 stps	No
Appraisal								
Pharma	Mr.Ashish Pandey	8385907007	Sildoo	Dr.Reddy	10's	280	10-20 stps	No
			Silofast	Cipla	15's	430	10-20 stps	No
Kailash								
Medical	Mr. Vasudev							
Store	sharma	9414209252	Sildoo	Dr.Reddy	10's	272	10-15 stps	No
			Geripod	Alembic	10's	240	10-15 stps	No

Brand Name: Solichem

Disease Information and Brand Plan

Disease:- Overactive bladder

Molecule Name: Solifenacin



OVER ACTIVE BLADDER

Overactive bladder (OAB) is a condition in which there is sudden, involuntary smooth muscle contraction in the wall of urinary bladder.

Thus even when a small amount of urine is present in the bladder , there is sudden compelling need to urinate which is difficult to suppress.

The main symptom of OAB is sudden urge to void with or without urgency urinary incontinence, associated with frequent urination and nocturia

Liquids, such as coffee, tea, spicy foods, and alcohol can increase the symptoms.

A typical person with over active bladder syndrome may urinate 12 times a day.

Medication may reduce this by 2-3 and urinary incontinence events by 1-2 per day.

SYMPTOMS

- Feeling of sudden urge to urinate which is difficult to suppress.
- Experiencing urge incontinence (involuntary urine loss immediately following an urgent micturition).
- Frequency of urination is increased, usually eight or more times in a day.

CAUSES

- Drinking a lot of liquid.
- Taking those medications that increase production of urine.
- Urinary tract infections.
- Consumption of alcohol, caffeine (Tea/coffee) or other bladder irritants.
- Unable to completely empty the bladder.
- Bladder abnormalities such as stones .

Treatment

- **Medications**

Medications are used for relieving symptoms of over active bladder syndrome by relaxing the bladder and also in reducing episodes of “urge incontinence”. Below are the examples of these drugs.

- Tolterodine (BRAND - Detrol, Detrol LA)
- Oxybutynin (BRAND - Ditropan XL)

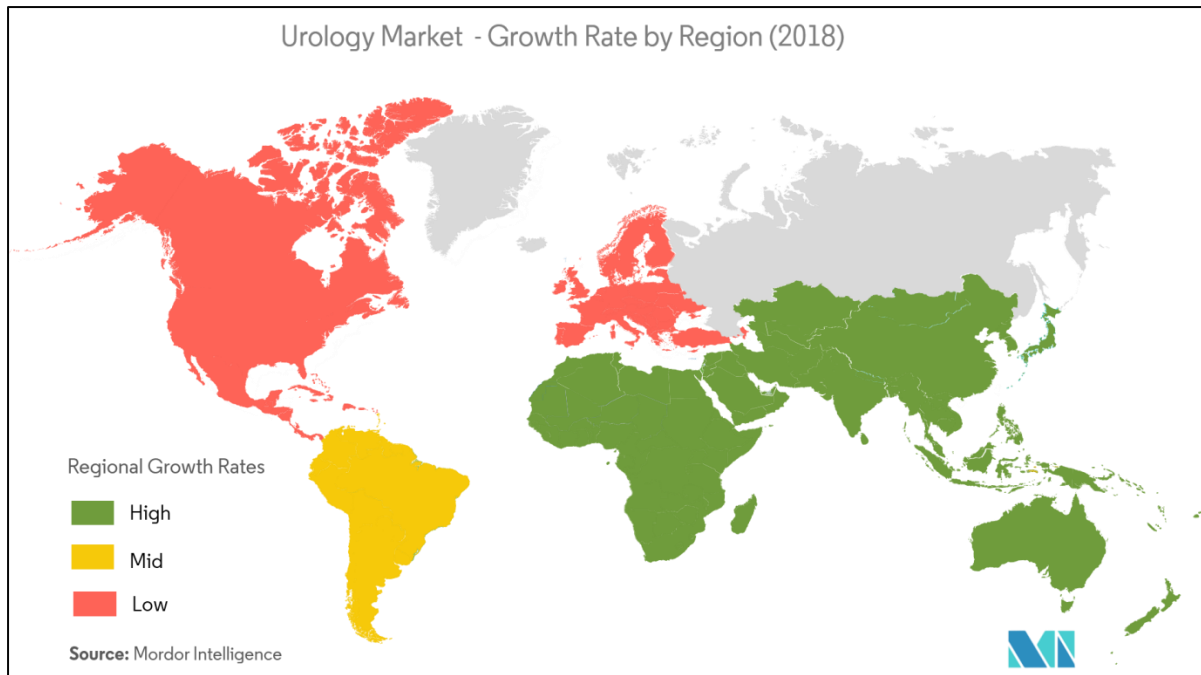
- **Bladder injections**

- **Nerve stimulation**

- **Surgery**

Prevalence of OAB syndrome

- Overactive bladder syndrome is highly prevalent, and increasingly so with aging.
- The global market is projected to be valued at USD 3.63 Billion in 2017 and expected to grow at CAGR of 2.9% during the forecast period to reach to USD 4.19 Billion by 2022.
- In Asia, the prevalence of OAB is reported at 53.1%.
- The overall prevalence of overactive bladder syndrome is approximately 12%.
- In women the prevalence of OAB with incontinence ranges from 2.0% (aged 18-24 years) to 19.0% (aged 65-74 years) which is increasing markedly after age 45 years.
- According to reports , “ most OAB affected region is asia other than Europe followed by Africa, North and South America”.
- From year 2008 to 2018, the OAB patients will going to be increased in Asia, South America and Africa as 22 %, 22.5% and 31% respectively.
- According to some studies conducted in 2008, “456 million people experienced OAB worldwide and there will be an anticipated increase to 545 million (20%) till 2018”.
- In year 2008, the global prevalence of OAB in women 11.5% which was more than men 9.7% .



Name: Solichem

Description - Solichem , a urinary antispasmodic belongs from class anticholinergics.

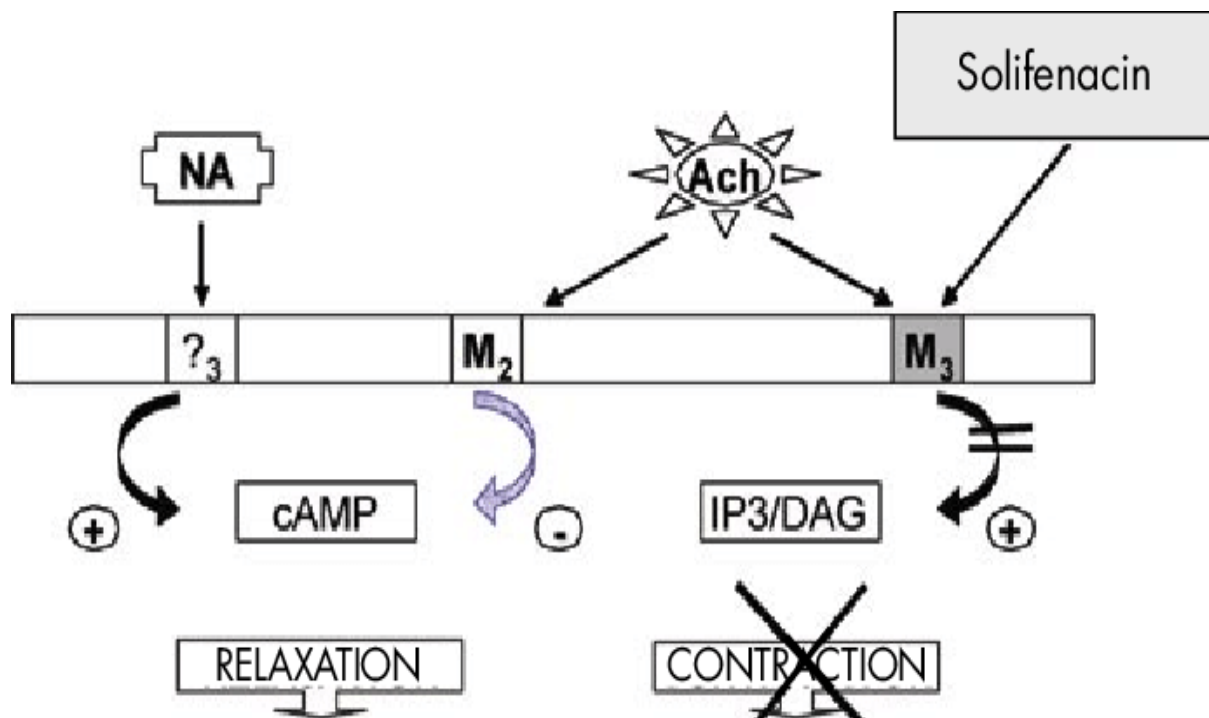
This drug is used in the treatment of over active bladder with urge incontinence.

Pharmacodynamics

Solichem is a **competitive muscarinic receptor antagonist**. These receptors play a very important role in several major cholinergically mediated functions which includes smooth muscles contraction of urinary bladder and stimulation of salivary secretions.

Mechanism of action

Solichem is a competitive muscarinic acetylcholine receptor antagonist with highest activity at the M3 receptor. Inhibition of this receptor lowers smooth muscle tone in the bladder, and prevent contractions and reducing incontinence.



Absorption

The bioavailability of drug Solifenacin is approximately 90%, and plasma

Concentrations is proportional to the dose administered.

Volume of distribution - 600 L

Protein binding

Solifenacin drug is approximately 98% (in vivo) bound to human plasma proteins.

Half life

The elimination half-life of Solifenacin drug is approximately 45- 66 hours.

Side effects

Side effects of drug are constipation, drymouth, hoarse voice, slightly blurred vision, nausea, loss of appetite, stomach upset.

DIRECT COMPETITORS

BRAND NAME	COMPANY	Price / 10 tabs
BISPEC (5mg /10mg)	Dr. Reddy 's lab.	Rs.190 /275
SOLICEPT (5 MG)	Lupin Laboratories	Rs.190
SOLITEN (5 MG/ 10 MG)	Ranbaxy lab.	Rs.192/274
VESIACT (5MG)	Fourrts (India) Laboratories Pvt. Ltd.	Rs. 165

INDIRECT COMPETITORS (molecules)

Molecules	Brand Name	Company	Price /10 stps
Tolterodine (2 mg)	Urotel - XL	Sun Pharma	Rs 84
Oxybutynin (5 mg)	Oxypas	Cipla	Rs. 80.52
Trospium (60 mg)	Flotros SR	IPCA labs.	Rs.209
Darifenacin 7.5mg	Xelena	Dr.Reddy labs.	Rs.220
Darifenacin 7.5mg	Vesigard	Cipla	Rs.154
Oxybutynin (5 mg)	Tropan	Sun Pharma	Rs 90

SWOT

STRENGTH • Solichem has 98% plasma protein binding and is highly distributed to peripheral tissues. • US FDA approved Drug • More effective than other class of drugs.	WEAKNESS • The drug may show some adverse effects.
OPPORTUNITIES • Increasing Prevalence of disease globally. • Increasing Demand in the market due to its efficacy. • Does not fall under DPCO	THREATS • Growing competition from MNC's is high . • Possiblity of coming new molecule. • New Regulations

Pack Shot of Competitors



buy-pharma.md





Market Segmentation

1. Geographic :-

Most OAB affected region is asia other than Europe followed by Africa,
North and South America.

2. Demographic:-

Gender – Males and females

3. Behavioural :-

Patient suffering from Overactive bladder
(urgent urination and urine leakage).

TARGETED CUSTOMERS

Primary

- ☐ Urologist

Secondary

- ☐ General Physician
- ☐ Neurologist
- ☐ Nephrologists

Communication Message (Initial Comm.)

"Good morning Dr. , Thank you for allowing me to see you today.

My name is Bhumika from micro labs ltd.

Sir, As you know Asia is the most OAB affected region , the prevalence of OAB is reported at 53.1%. The global market is projected to be valued at USD 3.63 Billion in 2017 and expected to reach 4.19 billion by 2022.

SOLICHEM is our new product which contain Solifenacin 5 mg .

SOLICHEM is used to treat condition of Over active bladder.

SILOCHEM blocks the muscarinic receptors and reduces symptoms of urge urinary incontinence , urgency and urinary frequency .

Recommended dose of **Silochem** is 5 mg once daily .

Therefore doctor , **SILOCHEM** is the best choice for your patients suffering from OAB.

I am giving you some **samples** of **SILOCHEM** So that you can see the response and efficacy of our product on your patient.

Again, thank you for your time."

Communication Message (later comm.)

Good morning Dr. , I am Bhumika from micro labs ltd.

As I had discussed earlier about my product **SILOCHEM** which contain Solifenacin 5 mg **used in the treatment of over active bladder** and also with that I had given some samples too.

So Sir , what is your opinion about our product ?

Doctor –

Thank you Dr . for showing your confidence in our brand .

SILOCHEM is the best choice for your patients suffering from OAB.

Sir give a chance to our product , I request you to prescribe **Silochem** to your patients .

Looking forward for your support.

Thank You so much .

VISUAL AID

In the condition of over active bladder

Now choose ..

SOLICHEM *solifenacin 5 mg tabs.*

- Solichem blocks the muscarinic receptors.
- It has 98% plasma protein binding.
- Has 90% bioavailability.
- More Effective Than Tolterodine ER in Reducing Incontinence
- High efficacy in reducing incontinence
- High efficacy in reducing micturition



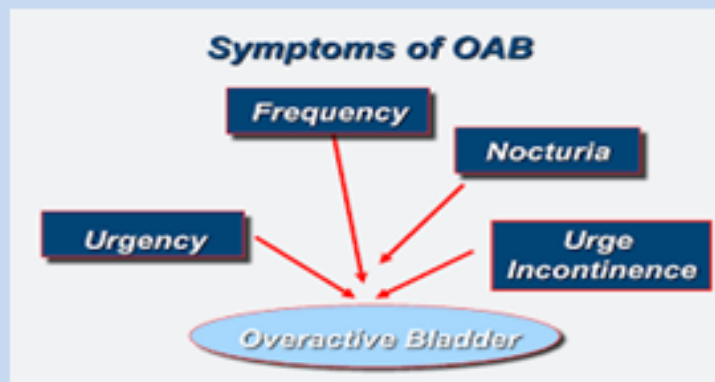
Pack shot

DOSE – 5 mg once in a day

*Ensures healthy life with
SOLICHEM*

BRAND RECALL

What are the symptoms of overactive bladder?



Now fight against OAB with

SOLICHEM *solifenacin 5 mg tabs.*

- Efficient in reducing incontinence.
- Efficient in reducing micturition.
- More effective than other class of drugs.
- Dose – 5 mg once in a day.



Promotional Strategies

- **CONSUMER LEVEL (PATIENT)**

1. Medical Camps with diagnostic and analysis programmes
2. Patient education programmes

- **COSTUMER LEVEL (DOCTORS)**

1. Samples to detect clinical efficacy on patients
2. Seminars , symposia and CME's
3. Hospital/ward improvement programmes
4. E-Marketing and mobile apps as per MCI guidelines

- **CHEMIST/PHARMACY LEVEL**

1. Availability at key pharmacies with nearby clinics and hospitals
2. Display in front rows at viewers eye level
3. Bonus offers

PROMOTIONAL INPUTS

Scientific input

- Visual aid
- Product reminder card / lbl's
- Product Monograph / Posters
- Reference folder etc

Brand reminder input

- Today's request card
- Rx Pad/Slip pads
- Pen/ Paper weight
- Key chains etc

GIFTS





Promotional Expense

Promotional Inputs	Amount (for one quarter)
Samples	50,000
Leave Behind Literatures & Visual Aids	30,000
Gifts	60,000
Activities(CMEs, Health Campaigns)	50,000
Incentives	45,000
Other discounts and offers	10,000
Total	2,45,000

Sales forecasting

Quarter (3 months)	No of Dr	No.of visits	Total Visits	Success Rate	Sucessful visits	Rx/dr/ month	No.of Rx	No of Mr's	Total Rx
1 st qtr.	100	2	200	15%	30	2	60	100	6000
2 nd qtr.	100	2	200	20%	40	2	80	100	8000
3 rd qtr	100	2	200	25%	50	2	100	100	10,000
4 th qtr	100	2	200	30%	60	2	120	100	12,000

1 prescription – 100 Rs

Total Rx	Total sales in 1 month	Total sales in 1quarter
6000	$6000 \times 100 = 600,000$	$600,000 \times 3 = \mathbf{18,00,000}$
8000	$8000 \times 100 = 800,000$	$800000 \times 3 = \mathbf{24,00,000}$
10,000	$10,000 \times 100 = 10,00,000$	$10,00,000 \times 3 = \mathbf{30,00,000}$
12,000	$12,000 \times 100 = 12,00,000$	$12,00,000 \times 3 = \mathbf{36,00,000}$

References

1. www.ncbi.nlm.nih.gov/pmc/articles/PMC2990389
2. www.accessdata.fda.gov/drugsatfda_docs/label/2013/022206s012lbl.pdf
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