



"Vidhya Rathna"  
**Prof. Dr. M. KARUNANITHI,**  
 B.Pharm., M.S., Ph.D., D.Litt.,  
 Chairman & Secretary

A News letter on

# CLINICAL PHARMA PRACTICE

An update of Clinical research  
 and Drug information



Vol. No. 1

Issue No. 2

January - April 2015

An official Publication from

**Department of Pharmacy Practice,  
 Swamy Vivekanandha College of Pharmacy,**

Elayamapalayam, Tiruchengode - 637 205,  
 Namakkal (Dt.), Tamilnadu, Phone : 04288 - 234417  
 E-mail : svcdpic2012@gmail.com

Patron : Prof. Dr. M. Karunanithi  
 Advisory Board : Dr. S. Arthanareeswaran  
 Dr. K. Sreeraaghanidhi Arthanareeswaran  
 Dr. S. Ananda Thangadurai  
 Chief Editor : Dr. A. Palanisamy  
 Editorial Board : Mr. S. Anandkumar, Dr. T. Suthanth &  
 Ms. D. Saranya Shanmugapriya



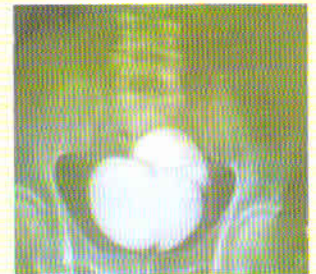
**Dr. T. POOVENDRAN, M.S., DNB (Urology),**  
 Consultant Urologist & Andrologist,  
 Vivekanandha Medical Care Hospital

## PHYSICIAN DESK

**Case Study :** 60 years old female patient with severe burning micturition for the past 6 years. Her ultrasound / X ray KUB revealed very large three multiple urinary bladder calculi (Each 6 to 7cm in size). Size of the stone was very uncommon among the calculi patients. All three stones are removed by open cystolithotomy. (Surgical removal of bladder stones).

## BLADDER CALCULI

Bladder calculi are stone-like masses (composed of mineral salts) that form in the bladder. Normal urine contains predictable amounts of calcium, magnesium, uric acid, and other by-products of metabolism, which have passed into the bladder in solution form. However, under certain conditions the chemicals may crystallize and form stone-like particles. Once formed, continued crystallization is stimulated. Most bladder stones are struvite stones (infection stones) or composed of uric acid.



- Risk factors** : Decrease flow of urine from the bladder, Urinary tract infection, Neurogenic bladder, Bladder diverticulum, Enlarged prostate, Radiation cystitis, and Bladder neck obstruction.
- Symptoms** : Difficulty during urination (Dysuria), Increased frequency and urgency of urination, Incontinence, Lower abdominal pain (Flank pain), Blood in urine (Hematuria), Abnormally colored or dark colour urine.
- Physical examination** : Palpation indicates enlarged and tender bladder, Examination to check the prostate enlargement, Urologic examination, Rectal examination.
- Test** : Urinalysis, Excretory urogram, CT scan, Cystoscopy, MRI, Ultrasound and X-ray unit.
- Management** : Non pharmacological management: Drink 6 to 8 glass of water, Urinate completely.
- Pharmacological Management** : Analgesic, Antimicrobials, IV fluids, Cystoscopy, Cystourethroscopy, Laser lithotripsy, Extracorporeal shock wave lithotripsy, Surgical removal of stones, Cystolithotomy.

## CLINICAL RESEARCH

### **POLYSACCHARIDE CONJUGATE VACCINE AGAINST PNEUMOCOCCAL PNEUMONIA IN ADULTS**

Pneumococcal polysaccharide conjugate vaccines prevent pneumococcal disease in infants, but their efficacy against pneumococcal community-acquired pneumonia in adults 65 years of age or older is unknown. Recent findings indicate among the older adults, polysaccharide conjugate vaccine (PCV13) was effective in preventing vaccine-type pneumococcal, bacteremic, and non bacteremic community-acquired pneumonia and vaccine-type invasive pneumococcal disease but not in preventing community acquired pneumonia from any cause.

N Engl J Med; March 19, 2015

### **NEW TREATMENT FOR DIABETIC RETINOPATHY IN PATIENTS WITH DIABETIC MACULAR EDEMA**

The U.S. Food and Drug Administration today expanded the approved use for aflibercept injection to treat diabetic retinopathy in patients with diabetic macular edema. Aflibercept is administered by a physician as an injection into the eye once a month for the first five injections and then once in every two months. It is intended to be used along with appropriate interventions to control blood sugar, blood pressure and cholesterol.

<http://www.fda.gov>; March 25, 2015

### **CRYOABLATION TREATMENT FOR PRIMARY BREAST CANCER**

Cryoablation is a technique which uses extreme cold to kill (ablate) cancer cells. In this technique, a probe filled with liquid nitrogen, able to reach -40 Celsius degrees, is placed into the tumor using ultrasound to guide the cryoprobe and avoid damage to healthy tissue. The tumor is then exposed to cycles of freeze and thaw from inside-out causing cancer cells to die. Cellular debris is naturally absorbed by the immune system over time. This technique takes around 30 minutes and has been used in cancers like liver, lung and prostate in the past.

[www.fcrindia.org](http://www.fcrindia.org); March 26, 2015

### **EBOLA VIRUS EVOLVING, BUT ISN'T GETTING DEADLIER, STUDY SAYS**

The Ebola virus has evolved but hasn't become more lethal since the first outbreak 40 years ago, a new study suggests. British researchers conducted a computer analysis of data from every outbreak since 1976 and found that a number of genetic changes have occurred in the Ebola virus, but those changes haven't made it more or less deadly. The findings suggest that the high death toll in the current outbreak in West Africa -- the largest to date at about 10,500 fatalities -- is not due to mutations or evolution making the virus more deadly or infectious, according to the investigators.

Drugs.com, April 14, 2015

### **TAKE ACTION TO PROMOTE BRAIN HEALTH: IOM REPORT**

Older adults can take action to combat the gradual decline in cognitive function that occurs naturally with age, the Institute of Medicine (IOM) says in a new report released today. In the report, "Cognitive Aging: Progress in Understanding and Opportunities for Action," The IOM Committee on the Public Health Dimensions of Cognitive Aging advises that outside of the effects of neurologic disease, such as Alzheimer's disease, individuals of all ages should take three steps to help promote cognitive health:

- Be physically active.
- Reduce and manage cardiovascular disease risk factors, including high blood pressure, diabetes, and smoking.
- Regularly discuss and review with a healthcare professional health conditions and medications that might have a negative effect on cognitive function.

Medscape Medical News, April 14, 2015

### **IBRUTINIB IN PREVIOUSLY TREATED WALDENSTROM'S MACROGLOBULINEMIA**

MYD88L265P and CXCR4WHIM mutations are highly prevalent in Waldenstrom's macroglobulinemia. MYD88L265P triggers tumor-cell growth through Burton's tyrosine kinase, a target of ibrutinib. CXCR4WHIM mutations confer in vitro resistance to ibrutinib. Ibrutinib was highly active, associated with durable responses, and safe in pretreated patients with Waldenstrom's macroglobulinemia. MYD88 and CXCR4 mutation status affected responses to this drug.

N Engl J Med, April 9, 2015

## RECENTLY APPROVED DRUGS BY FDA

S. No.	BRAND NAME / COMPANY	MOLECULE NAME	INDICATIONS	APPROVED MONTH AND YEAR
1	Unituxin / United Therapeutics	Dinutuximab	Pediatrics with high-risk neuroblastoma	March 2015
2	Opdivo / Bristol-Myers Squibb	Nivolumab	Metastatic lung cancer	March 2015
3	Ibrance / Pfizer	Palbociclib	ER-positive	February 2015
4	Avycaz / Actavis	Ceftazidime-Avibactam	Urinary tract infections	February 2015
5	Farydak / Novartis	Panobinostat	Multiple myeloma	February 2015
6	Evotaz / Bristol-Myers Squibb	Atazanavir and Cobicistat	HIV-1 infection	January 2015
7	Prezcobix / Janssen	Darunavir and Cobicistat	HIV-1 infection	January 2015
8	Prestalia / Symplmed Pharmaceuticals	Perindopril arginine and amlodipine besylate	Hypertension	January 2015
9	Cosentyx / Novartis	Secukinumab	Plaque psoriasis	January 2015
10	Savaysa / Daiichi Sankyo	Edoxaban	DVT/pulmonary embolism	January 2015

## NEW DRUG PROFILE

### LIXISENATIDE

#### Indication

Treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with oral glucose lowering medicinal products.

#### Dosage and administration

- Starting dose : dosing is initiated at 10 mcg once daily for 14 days
- Maintenance dose: a fixed maintenance dose of 20 mcg once daily is started on Day 15

#### Dosage forms and strengths

- 10 micrograms solution for injection: Each dose (0.2 ml) contains 10 micrograms (mcg) of lixisenatide (50 mcg per ml).
- 20 micrograms solution for injection: Each dose (0.2 ml) contains 20 micrograms (mcg) of lixisenatide (100 mcg per ml).

#### Contraindications

Hypersensitivity to lixisenatide, metacresol, or any component of the product.

#### Precautions

- Diabetes ketoacidosis; avoid use
- Diabetes mellitus type 1; avoid use
- Gastrointestinal disease; use not recommended
- Hypoglycemia; increased risk with concomitant use of basal insulin or sulfonylurea; dose reduction of concomitant medication may be required; monitoring recommended
- Pancreatitis; acute pancreatitis has occurred with use of glucagon-like peptide-1 receptor agonists;

#### Pregnancy category

- Fetal risk cannot be ruled out. (TH)

### BEDAQUILINE

#### Indication

Bedaquiline is a diarylquinoline antimycobacterial drug indicated as part of combination therapy in adults ( $\geq 18$  years) with pulmonary multi-drug resistant tuberculosis (MDR-TB).

#### Dosage and administration

- 400 mg once daily for 2 weeks followed by 200 mg 3 times per week for 22 weeks with food.
- Swallow tablets whole with water.

#### Dosage forms and strengths

- 100 mg tablet

#### Contraindications

Specific contraindications have not been determined

#### Precautions

- Alcohol consumption or concomitant use of other hepatotoxic drugs; avoid use
- Concomitant use of strong CYP3A4 inducers, including rifampin, rifapentine, and rifabutin; avoid use
- Concomitant use of strong CYP3A4 inhibitors systemically for more than 14 consecutive days; avoid use unless benefits outweigh risk; monitoring recommended
- Hepatic-related adverse reactions have been reported; monitoring recommended;
- Relapse or failure to convert; monitoring recommended
- Renal impairment, severe, or end-stage renal disease requiring hemodialysis or peritoneal dialysis

#### Adverse reactions

- Chest pain, Nausea, Increased liver enzyme, Arthralgia, Headache, Hemoptysis

#### Pregnancy category

- Category B

## DEPARTMENT ACTIVITIES (January - April 2015)

Our M.Pharm (Pharmacy Practice) and Pharm.D students are trained by the suitable preceptors in our Vivekanadha Medical Care Hospital in the following areas

### Ward Round Participation

- ◆ General Medicine
- ◆ Cardiology
- ◆ Urology
- ◆ Orthopedics
- ◆ Ophthalmology
- ◆ Gynecology

Drug and Poison information

Patient Counseling

Pharmacovigilance

Dispensing practice



Number of drug information queries answered - 83, **Poison information queries answered - 06**, **Patient counseled - 1272**

Details of guest lecture on various topics organized by "Department of Pharmacy Practice"

Date : 31.01.2015

Topic : "Recent trends in the management of eczema"

Speaker : **Dr. Chakravarthi Mailer Ravindran**, M.B.B.S., M.D., DVL.,  
Consultant Dermatologist, Erode.

Date : 28.02.2015

Topic : "Hospital and Community Pharmacy Management"

Speaker : **Mr. B. Nandhakumar**, M.Pharm.,  
Drugs inspector, Salem.

Date : 27.03.2015

Topic : "Patient counseling and its significance-Physician's perspective"

Speaker : **Dr. B. Amirtaganesh**, M.B.B.S., M.D., DNB.,  
Interventional Cardiologist, Vivekanandha Medical Care Hospital, Tiruchengode.

### Pharmacovigilance Program

Faculties, Pharm.D and M.Pharm (Pharmacy Practice) students participated in "National level conference on Pharmacovigilance" - Optimizing quantitative escalation of safety signals of drugs and diagnostics" held in Nandha College of Pharmacy, Erode on 5<sup>th</sup> & 6<sup>th</sup> December, 2014. During the session speakers discussed about Various types of ADR and its preventive measures, Animal models used in clinical trials and Phases of clinical trial, etc.



Please send your suggestions to

The Chief Editor

**CLINICAL PHARMA PRACTICE NEWSLETTER**

Department of Pharmacy Practice,

**Swamy Vivekanandha College of Pharmacy,**

Elayamapalayam, Tiruchengode - 637 205,

Namakkal (Dt.), Tamilnadu, Phone : 04288 - 234417

Email : svcpdpic2012@gmail.com

To

Book Post