



**Prof. Dr. M. KARUNANITHI**  
B.Pharm., M.S., Ph.D., D.Litt.,  
CHAIRMAN & SECRETARY

A Newsletter on

# CLINICAL PHARMA PRACTICE

An Update on Clinical Research and Drug Information



Volume : 2

Issue : 3

September - December 2016

An Official Publication from

Department of Pharmacy Practice,

**Swamy Vivekanandha College of Pharmacy,**

Elayampalayam, Tiruchengode - 637 205,

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

E-mail : svcdpic@gmail.com

Patron : Prof. Dr. M. Karunanithi  
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Dr. M. Selvabalambigai

## PHYSICIAN DESK



**Dr. P. KALAISELVI, M.S (Gen. Surgery), DGO.,**  
Obstetrician & Gynaecologist / Consultant,  
Vivekanandha Medical Care Hospital

## POLYCYSTIC OVARIAN SYNDROME (PCOS)

PCOS is a set of symptoms due to elevated androgens in women. It is the common endocrine disorder among women between the ages of 20-30yrs.

### SIGNS & SYMPTOMS

Menstrual disorders, infertility, acne, hirsutism, metabolic syndrome, difficulty getting pregnant

### CAUSE

PCOS is due to a combination of genetic & environmental factors. Risk factors include obesity, not enough physical exercise, and a family history of someone with the condition.

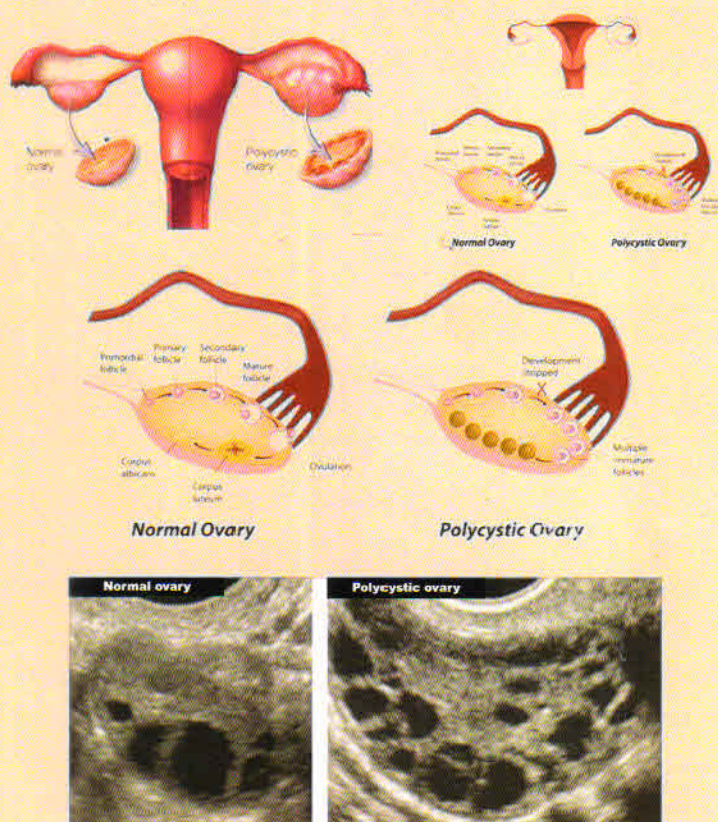
A patient to be labelled as PCOS only if she meets at least 2 of the 3 following criteria,

- 1) Oligo ovulation
- 2) Clinical or biochemical evidence of hyperandrogenism
- 3) Sonographic evidence of polycystic ovaries

Normally ovaries produce a small amount of androgens but in PCOS there are excessive androgens. The excess androgens suppress ovulation, cause acne and hirsutism. The excess androgens are converted to oestrogens in the ovary and adipose tissue. The high oestrogen inhibits FSH and stimulates LH. The elevated LH causes theca cell hyperplasia and androgen excess. PCOS patients have LH 3-4 times the FSH on day 2 of the menstrual cycle. The high oestrogen causes endometrial hyperplasia, later on atypical hyperplasia and endometrial carcinoma.

## DIAGNOSIS OF PCOS

In an ultra sound, ovaries of PCOS patient appear enlarged in size with multiple tiny cysts.



## MANAGEMENT OF PCOS

It is not a curable disease. It can only be controlled. The objectives of treatment are to reduce endometrial hyperplasia, to control hirsutism and to induce ovulation if fertility is required.

Patients should be educated about their future risk of diabetes. Adopting a healthy eating habit with lots of fresh vegetables, fruits avoiding fried foods and carbonated drinks.



**FDA GRANTS ACCELERATED APPROVAL TO RUBRACA (RUCAPARIB) FOR ADVANCED OVARIAN CANCER.**

The U.S. Food and Drug Administration granted accelerated approval to Rubraca (rucaparib) to treat women with a certain type of ovarian cancer. Rubraca is approved for women with advanced ovarian cancer who have been treated with two or more chemotherapies and whose tumours have a specific gene mutation (deleterious BRCA) as identified by an FDA-approved companion diagnostic test. The safety and efficacy of Rubraca were studied in two, single-arm clinical trials involving 106 participants with BRCA-mutated advanced ovarian cancer who had been treated with two or more chemotherapy regimens. BRCA gene mutations were confirmed in 96 percent of tested trial participants with available tumour tissue using the Foundation Focus CDxBRCA companion diagnostic.

**Dr. T. TAMILSELVAN,**  
Head, Department of Pharmacy Practice

Ref : <https://www.drugs.com/newdrugs/fda-grants-accelerated-approval-rubraca-rucaparib-advanced-ovarian-cancer>.

**IRON THERAPY IN PATIENTS WITH HEART FAILURE AND IRON DEFICIENCY : REVIEW OF IRON PREPARATIONS FOR PRACTITIONERS**

In patients with heart failure (HF), iron deficiency (ID) correlates with decreased exercise capacity and poor health-related quality of life, and predicts worse outcomes. Iron deficiency, regardless of haemoglobin level, is an indication for supplementation in symptomatic patients with heart failure with reduced ejection fraction. Only intravenous carboxymaltose has been demonstrated to be safe and effective for iron repletion in these patients. ID in HF was managed with iron preparation and the information about the treatment was provided to the clinicians.

**Mr. Josephstalin D, Assistant Professor**  
Absela kabeer, Absey Varghese, Amrita Lekshmi, Anju Sukumaran, Pharm.D (Interns)

Ref: <http://link.springer.com/article/10.1007/s40256-016-0211-2>

**DRUGS FOR DIABETES AND HYPERTENSION MAY COMBINE TO TREAT CANCER**

A combination of a diabetes medication and an antihypertensive drug can effectively combat cancer cells. Metformin is the most widely prescribed drug for the treatment of type 2 diabetes. Besides its blood sugar lowering effect, it also displays anti-cancer properties. The usual therapeutic dose, is too low to effectively fight cancer. The antihypertensive drug syrosingopine potentiates the anti-cancer efficacy of metformin. Apparently, this drug combination drives cancer cells to programmed "suicide." These two drugs are effective in a wide range of cancers. "For example, in samples from leukaemia patients." The data from this study support the development of combination approaches for the treatment of cancer patients."

**Sandra Wilson, Sherin Johny, Silpa Sunny, Soni Rose Mathew, Pharm.D (Interns)**

Ref : <https://www.sciencedaily.com/releases/2016/12/161227083500.htm>

**PREVENTION OF BLEEDING IN PATIENTS WITH ATRIAL FIBRILLATION UNDERGOING PCI**

In patients with atrial fibrillation undergoing percutaneous coronary intervention (PCI) with placement of stents, The administration of either low-dose rivaroxaban plus a P2Y<sub>12</sub> inhibitor for 12 months or very-low-dose rivaroxaban plus DAPT for 1, 6, or 12 months was associated with a lower rate of clinically significant bleeding than was standard therapy with a vitamin K antagonist plus DAPT for 1, 6, or 12 months. The three groups had similar efficacy rates, although the observed broad confidence intervals diminish the surety of any conclusions regarding efficacy.

**Nicky Kuriakose, Nissy Varghrse, Reshma Jose, Rinkle Priya C, Pharm.D (Interns)**

Ref : <http://www.nejm.org/doi/full/10.1056/NEJMoa1611594>



## RECENTLY APPROVED DRUGS BY CDSCO

S. No.	DRUG NAME	DOSE	DOSAGE	INDICATIONS	APPROVED MONTH AND YEAR
1.	Palbociclib	75mg/100mg/125 mg	Capsules	Breast cancer	11.08.2016
2.	Midodrine. Hcl	2.5 mg	Tablet	Orthostatic hypotension	02.09.2016
3.	Dolutegravir	50 mg	Tablet	HIV-1 infection	07.11.2016
4.	Alcaftadine	0.25% w/v	Eye Drops	Allergic Conjunctivitis	21.11.2016
5.	Azilsartan Medoxomil	40mg/80mg	Tablets	Hypertension	09.12.2016
6.	Lenvatinib	4mg/10mg	Tablets	Thyroid Cancer	02.12.2016
7.	Perampanel	2mg/4mg/6mg/8mg/ 10mg/12mg	Tablets	Epilepsy	02.12.2016

Mr.S.Anandkumar, Assistant Professor

Ref: <http://www.cdscn.in/forms/list.aspx?lid=2034&ld=11>

### NEW DRUG PROFILE

#### PERAMPANEL

##### CATEGORY

Anticonvulsants, CNS Depressants

##### MECHANISM OF ACTION

A non-competitive antagonist of the ionotropic  $\alpha$ -amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid (AMPA) glutamate receptor on post-synaptic neurons.

##### INDICATION

Adjunctive therapy for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy aged 12 years and older.

##### DOSE AND DOSAGE

- ★ 2 mg once daily at bedtime in patients not on enzyme-inducing anti-epileptic drugs
- ★ Maximum recommended daily dose is 12 mg once daily at bedtime.
- ★ Tablets: 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg

##### INTERACTION

Contraceptives, Cytochrome P450 Inducers, Strong CYP3A Inducers Other than AEDs

##### PRECAUTION

Suicidal Behavior and Ideation, Neurologic Effects, Falls, Withdrawal of Antiepileptic Drugs.

##### ADVERSE REACTION

Dizziness, somnolence, fatigue, irritability, falls, nausea, weight gain, vertigo, ataxia, gait disturbance, and balance disorder

##### PREGNANCY CATEGORY

Based on animal data, may cause fetal harm.

##### BRAND NAME - Fycompa

#### BEZLOTOXUMAB

##### CATEGORY

Human Monoclonal Antibody

##### MECHANISM OF ACTION

Bezlotoxumab is a human monoclonal antibody that binds C. difficile toxin B. It inhibits the binding of toxin B and prevents its effects on mammalian cells.

##### INDICATION

Reduce recurrence of Clostridium difficile infection (CDI) in patients 18 years of age or older who are receiving antibacterial drug treatment of CDI and are at a high risk for CDI recurrence

##### DOSE AND DOSAGE

- ★ Single dose of 10 mg/kg administered as an intravenous infusion over 60 minutes.
- ★ Injection: 1,000 mg/40 mL (25 mg/mL) clear to moderately opalescent, colorless to pale yellow solution in a single-dose vial.

##### DRUG INTERACTION

Monoclonal Antibodies may enhance the adverse/toxic effect of Belimumab.

##### PRECAUTION

In patients with a history of CHF

##### ADVERSE REACTION

Nausea, Pyrexia, and Headache

##### PREGNANCY CATEGORY

Bezlotoxumab is monoclonal antibody; monoclonal antibodies are known to cross the placenta.

##### BRAND NAME - Zinplava

Mrs.T.Kumutha, Lecturer

Ref: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2012/202834lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202834lbl.pdf)

<http://www.zinplava.com/>



## DEPARTMENT ACTIVITIES

### AWARDS / ACHIEVEMENTS

★ "A retrospective study of prescription pattern and cost analysis of selected drugs used in coronary artery disease and angioplasty in cardiac patients" of Hesly Rajan guided by Dr. T. Tamilselvan has awarded "G. Rangachari Memorial Award" with Scholarships of Rs. 8000/- by Tamilnadu Pharmaceutical Sciences Welfare Trust, Chennai.

★ "Drug related problems in Intensive Care Unit" received 1<sup>st</sup> price for best oral presentation in National Level Seminar on "Recent innovations in pharmaceutical sciences" held on November 28<sup>th</sup>, 2016 at JKK. Nattaraj College of Pharmacy, Kumarapalayam by Sree Laxshmi. ER (Pharm. D Intern)

★ "Prescription Pattern and cost analysis of antiepileptic Drugs" received 3<sup>rd</sup> price for best oral presentation in National level seminar on "Recent innovations in pharmaceutical sciences" held on November 28<sup>th</sup>, 2016 at JKK. Nattaraj College of Pharmacy, Kumarapalayam by Leena Priya (Pharm. D Intern)

### 68<sup>th</sup> IPC, DECEMBER 16<sup>th</sup> - 18<sup>th</sup> 2016, Vizag

★ "Assessment of long term antiepileptic drug monotherapy in the alteration of folic acid and lipid profile level on cardiovascular risk and atherosclerosis" presented by H Kalaivani.

★ "A prospective study on comparative efficacy and potentiality of antidiabetic drug therapy among uncontrolled type II diabetes mellitus population" presented by Nithya R, S.Anandkumar, Dr. T. Tamilselvan.

★ "Assessment and management of menopause and cardiovascular risk in hypertensive woman" presented by E Jennifar, Dr. T. Tamilselvan.

### OUTREACH ACTIVITIES

★ World Diabetes Day was observed by staff and final Pharm.D interns in association with Vivekanandha Medical Care Hospital on 19<sup>th</sup> November, 2016. In Continuation, free medical camp was conducted in six rural areas around Tiruchengode. The public were screened BP and Random Blood Sugar at free of cost.

★ Dr. T. Tamilselvan, S. Anandkumar, Joseph Stalin. D participated in "Dengue Awareness Programme" conducted by Primary Health Center, Manikampalayam at Swamy Vivekanandha College Pharmacy on 23<sup>rd</sup> November, 2016.

★ On the occasion of Pharmacy week celebration we have organized Health awareness rally on the theme of "Pharmacists for Healthy India; Role in prevention and management of diabetes on 23<sup>rd</sup> December 2016 from GH to Old Busstand, Tiruchengode.



### RESEARCH PUBLICATIONS

★ Tamilselvan T, Hesly Rajan, Sabith T, Anandkumar S, Kumutha T, A Retrospective Study Of Prescription Pattern And Cost Analysis Of Selected Drugs Used In Coronary Artery Disease And Angioplasty Patients, International Journal of Recent Trends in Science And Technology, 2016; 21(1): 09-12.

★ Tamilselvan T, Kumutha T, Lekshmi VA, James AC, Reji JS and Cheriyan N: Pharmacoeconomical evaluation of oral hypoglycemic agents for type-2 diabetes mellitus in a multispeciality hospital. Int J Pharm Sci Res 2017; 8(5):1000-06.

### DIC ACTIVITIES

### NUMBER

No. of Patients Counseling  
Drug Information Queries Answered

675  
25

Book Post



Please send your suggestions to  
The Chief Editor

### CLINICAL PHARMA PRACTICE NEWSLETTER

Drug & Poison Information center,  
Department of Pharmacy Practice,

Swamy Vivekanandha College of Pharmacy,

Elayampalayam, Tiruchengode - 637 205, Namakkal (Dt.), Tamilnadu.

To



Drug and Poison Information Queries Please Contact : Email - [svcpdpic@gmail.com](mailto:svcpdpic@gmail.com), Phone : 04288 - 234417.