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Official Desk

Wish you all a Happy and Prosperous New Year 2018

Sri. Gangadhar V. Yavagal
President
Karnataka State
Pharmacy Council

Launch of KSPCDIC Mobile Application

It is my pleasure to announce the launch of mobile application by Karnataka State Pharmacy Council.

The Registered Pharmacist can install '**KSPCDIC**' application from Google Play Store or from https://app.kspcdic.com

Once the application is installed, Registered Pharmacist has to login with their Registered mobile number OR Registered E-Mail ID and enter the OTP or One time password received to their mobile or email to avail various services.

The services for Registered Pharmacist include Renewal of Registration, applying for Identity Card, Good Standing Certificate, Registration for Continuing Pharmacy Education programme, verification of the authenticity of Registration certificate etc., They can also view their profile, status of their application, fee receipts etc.,

Candidates applying for fresh registration (KSPC-A), transfer of registration from other states (KSPC-B), Registered Pharmacist applying for Duplicate Certificate (KSPC-C) and Additional Qualification (KSPC-D) has to apply only through the KSPC website- https://www.kspdic.com.

First time users who are renewing their regisration has to avail the service through our website https://kspcdic.com and also refer General Instructions before applying.

I request all the Registered Pharmacists to take the best advantage of this service by installing the '**KSPCDIC**' App for quick renewal of registration and other services through this mobile app. ❑

CONTENTS

Know about your medicines: Ask your Pharmacist

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56th National Pharmacy Week theme is "**Know about your medicines: Ask your Pharmacist**" signifies importance of pharmacist in ensuring safe and effective therapy by avoiding irrational use of medicines. Modern allopathic medicines are very potent and toxic too. Research findings on side-effects, untoward effects and dose dependent toxicities emanating from modern allopathic medicines are voluminous. The darker sides of medicines necessitate that every patient must know everything about her/his medicines.

Introduction

According to Dr. Mercola's Natural Health Newsletter April 12, 2008 the side effects of prescription medication can be horrific. It asserts, is it really worth taking medication if the cure is worse than the disease? This reminds the famous observation of Oliver Wendell Holmes Sr. an American physician of 19th century "If we doctors threw all our medicines into the sea, it would be that much better for our patients and that much worse for the fishes."

The common side effects with many prescription drugs on the market are drainage, crusting, or oozing of your eyes or eyelids; swollen, black, or "hairy" tongue; changes in the shape or location of body fat; decrease in testicle size; sores or swelling in rectal or genital area; blue lips or fingernails; purple spots on skin; white patches or sores inside mouth or on lips; irregular back-and- forth movements of eyes; enlarged

breasts in males; unusual risk-taking behavior, no fear of danger; extreme fear; hallucinations, fainting, coma; fussiness, irritability, crying for an hour or longer; paralysis; bleeding in chest; blood clot in lung; liver damage, kidney damage; lump in breast; decreased bone marrow function; congestive heart failure; nerve pain lasting for several weeks or months; bleeding that will not stop; coughing up blood or vomit that looks like coffee grounds, etc.

Study Reports

Every year, more than 2 million Americans suffer from serious adverse drug reactions. According to the U.S. Food and Drug Administration (FDA), these reactions cause about 100,000 deaths per year, making prescription drugs the fourth-leading cause of death in that country. As compared to the death toll from illegal drugs in USA, irrational use of prescription medicines is ten times more troublesome. Since 2001, a recorded 490,000 people have died from properly prescribed drugs in the United States.This reflection from the most advanced nation substantiates the importance of "Know about your medicines". Every patient must be aware of the potential side effects of the medicines, read the package insert, and remember that even if it lists a side effect as rare, it can still happen to her/him.

Many drugs are often over-prescribed and unnecessarily prescribed as greed for commercial gains overpowers professional judgment of prescribers. Marketing overture undoubtedly influences prescribing habit and kills professionalism. This again strengthens the case of "Know about your medicines".

According to Prof Libby Roug, Head of University of South Australia, 10 % of Australians are suffering from an adverse medication reaction at any given time. He emphasizes "We live in a society where multiple chronic illnesses are common – 40 % of Australians report three or more chronic conditions.An increasing number of people are being treated with more medicines and they are using those medicines for longer. In addition, most people with multiple health conditions see multiple health care providers, many of whom prescribe additional medicines. We need to move from systems that are disease focused and the appropriate use of treatments for that disease, to a system that focuses on the appropriate use of medicines for the person given all their conditions and the outcomes the person wants to achieve."

Reports estimated that around 230,000 Australians are admitted to hospital every year because of problems associated with the use of medicines, including side effects.Consuming alcohol with some medicines cause unwanted and sometimes dangerous side effects.

Guidelines

To reduce the risk of side-effects:

- Patient should take all medicines strictly as prescribed. (Taking medication incorrectly can cause side effects.)
- Patient should not take any other medicine.
- Patient should learn about medication. All prescription medicines have an information leaflet that includes detailed information on the medicine in plain English, like use, side effects and precautions. Must read the leaflet and consult the pharmacist for any clarification on your medicine.
- Patient should ask the pharmacist for advice while buying over-the-counter medicines. He can advise about side effects and interactions with other medicines likely to be taken together.
- Patient should tell the doctor about all the medicines being taken, including prescription, over-the-counter and complementary medicines.
- Patient should ask doctor/pharmacist if improving your lifestyle could reduce the need for medication. Some conditions can be better managed with changes in diet and regular exercise.
- Patients on long term therapy must have an annual review of all the medicines they take. This is particularly important for older people because, as people age, they are more likely to have side effects from medicines. Any medicines considered no longer necessary should be stopped. A pharmacist will help review all the medicines one takes.
- Safely dispose of all unwanted and date expired medicines.
- Patient should ask doctor or pharmacist questions so as to clearly understand the benefits and risks of medicines prescribed. ❑

World Heart Day

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It is a privilege to write this article on eve of the World Heart Day on 29th September. As fellow pharmacists, it is crucial to support the "I am a Pharmacist' campaign promoted by the International Federation of Pharmacists, as we take pride in the service we could enhance for the patient and the local population we serve in our individual and communal capacities. We are 'healthcare' professionals and our crucial role in putting 'health' back into the equation that has consistently progressed towards 'disease management', will be our defining moment. Though the dominant Biomedical model trains us to focus on 'Disease- Drug- Dispense', we have the excellent potential to adopt a game changer that focuses on a holistic 'prevention and empowered self-management of health by individuals' aspect, which emphasizes public health.

As part of understanding our local health challenges, it is important that we are well aware of our Burden of Diseases, so that we respond in a strategic manner. Our growing population with 1.3 billion people, are facing the expanding epidemic of PREVENTABLE Non Communicable Diseases (NCDs) which accounts for almost 53% of the annual deaths in our country. Communicable diseases, maternal and perinatal as well as nutritional conditions contribute to 37% of annual deaths in our country while 53% from NCDs are made up of 24% Cardiovascular Diseases (CVDs), 11% from respiratory diseases, 10% from other NCDs, 6% from cancers and 2% from diabetes.

This write-up focuses on the role of pharmacists in responding to our biggest challenge- Cardiovascular Diseases. The World Heart Federation(WHF) is highlighting one of the Global Action Plan which is: Striving for a 25% reduction by 2025 in premature deaths from cardiovascular disease around the worldas a response to CVDs being the biggest killer in the world with 31% (17.5 million) of all global deaths, resulting in massive health and development repercussions with 1 in 10 aged 30-70 years dying from CVDs.

As a response to reversing the impact of the major preventable high morbidity and mortality, WHF's 2017's advocacy activity focuses on

Share the Power, and highlights the WHD Policy Call while promoting activities globally. This call to healthcare professionals and all key stake holders alike is to raise awareness on the dangers of the epidemic increase in CVD from the current 17.3 million deaths a year to a projected 23 million by 2030 and the key role of its prevention. It is clearly documented that four key trigger factors fuelling CVDs (and NCDs) are: processed food /diet high in salt, fat and sugar; decreased physical inactivity and increased use of tobacco and alcohol. If these behavioral responses are managed better with more mindful lifestyle choices, and by enjoying the 'good things' more moderately, it can form the first step in empowering patients and population towards healthier living and more fuller, productive lives. In addition program such as the WHO Programme on Cardiovascular Diseases works on prevention, management and monitoring of cardiovascular diseaseare focusing on several strategies from policies to practices such as salt reduction programs.

Overall on eve of the World Heart Day, it is time we align to the bigger picture of global actions that are aligned to the holistic prevention, treatment and rehabilitative aspects which promotes public health.

References:

1. https://www.who.int/

2. https://www.world-heart-federation.org/

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Drug of the Quarter

Drug : **Delamanid**

Class : Antimycobacterial/Antitubercular Antibiotic

Dosage Form : Tablet

Strength : 50 mg

DCGI Approval : 02.08.2017

EMA Approval : 2014

Indication: Treatment of for pulmonary multi-drug resistant tuberculosis (MDR-TB) which is used along with other anti-tuberculosis medications.

Dose Information

Adult Dosing:

Multidrug resistant tuberculosis: 100 mg orally twice daily for 24 weeks in combination with an optimized multidrug-resistant TB regimen; continue optimized regimen after the 24-week delamanid treatment period.

Pediatric Dosing: Safety and efficacy not established in patients younger than 18 years.

Pharmacokinetics

Absorption:

2.7-fold increased exposure with standard meal.

Distribution:

1) Protein binding, 99.5% or greater. (2) Vd, approximately 2100 L

Metabolism

1) Plasma: Primarily by albumin and to a lesser extent via CYP3A4.

2) Metabolites: DM-6705, inactive.

Excretion

Renal: Less than 5% unchanged.

Dialyzable

Unknown (hemodialysis and peritoneal dialysis)

Elimination Half Life

30 to 38 hours

Contraindications

a) Concomitant use of strong CYP3A4 inducers (eg, carbamazepine)

b) Hypersensitivity to delamanid or any component of the product.

c) Serum albumin less than 2.8 g/dL

Cautions:

- **Cardiovascular:** Monitor frequently if used in patients with congenital QT prolongation, history of cardiac arrhythmia, clinically relevant bradycardia or cardiac conditions that predispose arrhythmia.
- **Endocrine and Metabolic:** Avoid use in patients with electrolyte disturbances, especially hypokalemia, hypocalcemia or hypomagnesemia.
- **Hepatic:** Not recommended to use in patients with moderate to severe hepatic impairment.
- **Renal:** Not recommended to use in patients with severe renal impairment.
- **Reproductive:** Not recommended to use during pregnancy.
- **Concomitant use:** Avoid concomitant use with antiarrhythmics; neuroleptics (eg., phenothiazines, sertindole, sultopride, chlorpromazine, haloperidol, mesoridazine, pimozide, thioridazine); antidepressives; strong inhibitors of CYP3A (eg, lopinavir/ritonavir), certain antimicrobial agents (including macrolides, fluoroquinolones, triazole antifungal agents, pentamidine, saquinavir); certain nonsedating antihistamines (eg, terfenadine, astemizole, mizolastine); and other certainQT prolonging drugs (ie, cisapride, droperidol, domperidone, bepridil, diphemanil, probucol, levomethadyl, methadone, vinca alkaloids).

Storage

Protect from moisture.

Mechanism of Action/Pharmacology: Delamanid is an anti-mycobacterial antibiotic that exerts its cytotoxic activity by inhibiting methoxy-mycolic and keto-mycolic acid synthesis. These are necessary components of the mycobacterial cell wall.

Adverse Effects

Common

- Cardiovascular: Palpitations
- Endocrine metabolic: Hyperuricemia, hypokalemia
- Gastrointestinal: Decrease in appetite, diarrhea, nausea, upper abdominal pain, vomiting
- Hematologic: Reticulocytosis
- Musculoskeletal: Arthralgia, myalgia
- Neurologic: Asthenia, dizziness, headache, insomnia, paresthesia, tremor
- Otic: Tinnitus
- Respiratory: Hemoptysis

Serious

- Cardiovascular: Prolonged QT interval
- Other: Drug resistance

Drug-Drug Interactions

Category	Drug/s (Example)	Interaction Effect	Management
Strong CYP3A4 inducers*	Phenytoin, carbamazepine, primidone, rifampin, Mitotane, St John's Wort, Enzalutamide	Decreased exposure of delamanid when used concomitantly.	Contraindicated for concurrent use.
CYP3A strong inhibitors	Lopinavir/ritonavir, nefazodone, indinavir, delavirdine	Concurrent use may result in increased risk of QT prolongation due to inhibition of CYP3A-mediated metabolism of delamanid.	Use caution if concomitant use is required.
Antineoplastic drug**	Nilotinib	Concurrent use may result in increased risk of QT-interval prolongation and increased exposure of delamanid.	Avoid concomitant use.
QT prolonging drugs (major)*	Cisapride, droperidol, domperidone, bepridil, methadone, vinca alkaloids	Concurrent use may result in increased risk of QT-interval prolongation.	Contraindicated for concurrent use.
Anti-tubercular drug	Ethambutol	Increased exposure of ethambutol when used concomitantly.	Use caution if concomitant use is required.

Drug-Food Interactions

Category	Interaction Effect	Management
Grapefruit Juice	Concurrent use may result in increased risk of QT prolongation due to inhibition of CYP3A4-mediated delamanid metabolism by grapefruit juice.	Use caution if concomitant use is required.

Severity: * The drugs are contraindicated for concurrent use. ** The interaction may be life-threatening and/or require medical intervention to minimize or prevent serious adverse effects.

Effects in Pregnancy and Lactation

Pregnancy: Study report or Clinical data during pregnancy are not available. Weigh the potential benefits of Delamanid against potential risks before prescribing this drug during pregnancy.

Breast-feeding: Study report or clinical data on weaning children are not available.

Patient Education

- Please advise women of child bearing potential to avoid pregnancy and breastfeeding during therapy.
- Please counsel the patient regarding side effects which may include dizziness, headache, paresthesia, tremor, anorexia, insomnia, tinnitus, arthralgia or myalgia.
- Please advise patient to take this drug with food.
- Please advise patient of the importance for completing the entire course of therapy as prescribed by the physician.
- Advise patient that there are multiple significant drug-drug interactions for this drug. Hence, educate the patient to consult a healthcare professional prior to the use of new drugs, including over-the-counter and herbal drugs.

References:

1. http://www.micromedexsolutions.com/
2. http://www.cdsco.nic.in/
3. http://www.rxlist.com/

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Drug Safety Alerts – National

Pharmacovigilance Programme of India (PvPI)

The preliminary analysis of Serious Unexpected Serious Adverse Reaction (SUSARs) from the PvPI database reveals that the following drugs are associated with the risks as given below.

Sl. No.	Suspected Drug/s	Category	Indication/Use	Adverse Reaction/s Reported
October 2017				
1.	Amikacin	Aminoglycoside Antibiotics	Treatment of serious infections due to susceptible strains of Gram-negative bacteria, including Pseudomonas species, Escherichia coli, species of indole-positive and indole-negative proteus, providencia species, Klebsiella, Enterobacter, Serratia species and Acinetobacter species.	Stevens Johnson Syndrome

Sl. No.	Suspected Drug/s	Category	Indication/Use	Adverse Reaction/s Reported
2.	Allopurinol	Antigout	Prophylaxis of gout; prophylaxis of hyperuricaemia associated with cancer chemotherapy.	Uveitis
September 2017				
3.	Acetazolamide	Antiglaucoma Anticonvulsant	Adjunct in treatment of chronic open-angle glaucoma; secondary glaucoma; as a part of pre-operative treatment of acute angle-closure glaucoma.	Drug Hypersensitivity Syndrome
4.	Linagliptin	Antidiabetic	Type 2 Diabetes Mellitus	Acute Generalised Exanthematous Pustulosis (AGEP)
5.	Diloxanide	Antiprotozoal	Amoebiasis	Glossitis
August 2017				
6.	Terbinafine	Antifungal	Treatment of fungal infections	Acute Generalised Exanthematous Pustulosis (AGEP)
7.	Nitrofurantoin	Antibacterial	Urinary tract infections; cystitis.	Vasculitis
July 2017				
8.	Clindamycin	Antibiotic	Respiratory tract infections, penicillin resistant staphylococcal infections and many anaerobes such as bacteroides, skin, soft tissue and dental infections.	Acute Generalised Exanthematous Pustulosis
9.	Triamcinolone	Anti-inflammatory and antipruritic agents	Corticosteroid	Skin Peeling
10.	Polymyxin B	Antibiotic	Treatment of serious infections due to susceptible strains of Gram-negative bacteria.	Mottled Skin
11.	Diclofenac	Nonsteroidal Anti-inflammatory drug (NSAID)	Acute musculo-skeletal pain; arthritis; gout; spondylitis; migraine; post-operative pain	Nicolau Syndrome

Healthcare professionals, Patients/Consumers are advised to closely monitor the possibility of the above adverse events associated with the use of above drugs.

If such events are encountered please report to the NCC-PvPI either by filling of Suspected Adverse Drug Reactions Reporting Form/Medicines Side Effect Reporting Form for Consumer(http://www.ipc.gov.in) or by PvPI Helpline No. 1800-180-3024.

Reference: www.ipc.gov.in

Meanings: Glossitis- Inflammation of the tongue, **Acute generalized exanthematouspustulosis (AGEP) -** (also known as "pustular drug eruption" and "toxic pustuloderma") - A rare skin reaction that in 90% of cases is related to medication administration. AGEP is characterized by a sudden skin eruption that appears on average five days after the medication is started. **Nicolau syndrome-** A rare iatrogenic cutaneous reaction that occurs immediately after a drug injection.

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Serious Risks/Safety Information – USFDA

Potential Signals of Serious Risks/New Safety Information Identified by the Adverse Event Reporting System (AERS)-USFDA

The USFDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's post-marketing safety surveillance program for drug and therapeutic biologic products.

The appearance of a drug on this list does not mean that conclusive of the risk. It means that FDA has identified a ***potential safety issue***, but does not mean that FDA has identified a causal relationship between the drug and the listed risk. If after further evaluation the FDA determines whether the drug is associated with the risk or not and it may take a variety of actions including requiring changes to the labeling of the drug, requiring development of a Risk Evaluation and Mitigation Strategy (REMS) or gathering additional data to better characterize the risk.

Therapeutic Class / Category	Drug (Examples)	Route of Administration	Dosage Form	Potential Signal of a Serious Risk / New Safety Information	Additional Information
April - June 2017					
Immune response modifier	Imiquimod	Topical use	Cream	Drug induced vitiligo-like depigmentation	Evaluation is in progress.
Antineoplastic Agent	Aminolevulinic acid hydrochloride	Topical use	Gel	Transient global amnesia	The labeling section of the product was updated to include transient amnestic episodes.

Therapeutic Class / Category	Drug (Examples)	Route of Administration	Dosage Form	Potential Signal of a Serious Risk / New Safety Information	Additional Information
Antineoplastic Agent	Alemtuzumab	Intravenous	Injection	Acute acalculous cholecystitis	Evaluation is in progress.
Antimalarial	Artemether / Lumefantrine	Oral	Tablet	Hemolytic anemia	Evaluation is in progress.
Dipeptidyl peptidase-4 inhibitors	Empagliflozin, Linagliptin, Saxagliptin, Sitagliptin and Metformin Hcl, Linagliptin and Metformin Hcl, Saxagliptin + Metformin.	Oral	Tablet	Rhabdomyolysis	Evaluation is in progress.
Immune Modulator	Fingolimod	Oral	Capsule	Rebound multiple sclerosis upon discontinuation of fingolimod	Evaluation is in progress.
Antineoplastic Agent	Imatinib mesylate	Oral	Tablet	Decline in renal function	The labeling section of the product was updated to include renal toxicity.
Beta-Adrenergic Blocker Antagonist	Glucagon	Subcutaneous, Intramuscular, or Intravenous	Injection	Necrolytic migratory erythema	Evaluation is in progress.
Antineoplastic Agent	Pembrolizumab, Nivolumab	Intravenous	Injection	Complications of allogeneic hematopoietic stem cell transplantation	Evaluation is in progress.
Antineoplastic Agent	Pembrolizumab	Intravenous	Injection	Stevens-Johnson syndrome and toxic epidermal necrolysis	The labeling section of the product was updated to include Stevens-Johnson syndrome and toxic epidermal necrolysis.
Antineoplastic Agent	Pomalidomide	Oral	Capsule	Ischemic colitis	FDA decided that no action is necessary at this time.
Proton Pump Inhibitors	Rabeprazole, Esomeprazole, Lansoprazole, Omeprazole, Pantoprazole	Oral, Intravenous	Tablet, Capsule, Injection	Polyps of stomach and duodenum	Evaluation is in progress.
Proton Pump Inhibitors	Rabeprazole, Esomeprazole, Lansoprazole, Omeprazole, Pantoprazole	Oral, Intravenous	Tablet, Capsule, Injection	Chronic kidney disease/ acute kidney injury	FDA decided that no action is necessary at this time.
Antihyperlipidemic	Evolocumab	Subcutaneous	Injection	Skin and subcutaneous tissue bacterial infections	Evaluation is in progress.
Antineoplastic Agent	Docetaxel	Intravenous Infusion	Injection	Docetaxel and neutropenic enterocolitis	Evaluation is in progress.
Antipsoriatic/ Dermatological Agent	Methoxsalen	Solution	Injection	Embolism and thrombosis	Evaluation is in progress.

Reference: http://www.fda.gov/

Meanings: **Acalculous cholecystitis-** An inflammatory disease of the gallbladder, **Transient global amnesia-** A sudden, temporary episode of memory loss that can't be attributed to a more common neurological condition, such as epilepsy or stroke, **Rhabdomyolysis-** A serious syndrome due to a direct or indirect muscle injury, **Ischemic colitis-** A medical condition in which inflammation and injury of the large intestine result from inadequate blood supply.

Drug News – Around the Globe

1. Drug: Benralizumab* **Country: USA**

Benralizumab is an antiasthmatic or antiinflammatory drug.

Approved Indications: Benralizumab is approved for the treatment of patients with severe eosinophilic asthma. This drug is not indicated for treatment of other eosinophilic conditions or for the relief of acute bronchospasm or status asthmaticus.

Approved Dosage Form: Subcutaneous Solution

Side-effects: Headache, pyrexia, pharyngitis[1].

2. Drug: Glecaprevir&Pibrentasvir* **Country: USA**

Glecaprevir and Pibrentasvir are antiviral drugs.

Approved Indications: Glecaprevir and Pibrentasvir combination were approved to treat adults with chronic hepatitis C virus (HCV) genotypes 1-6 without cirrhosis (liver disease) or with mild cirrhosis, including patients with moderate to severe kidney disease and those who are on dialysis.

This combination is not recommended in patients with moderate cirrhosis and contraindicated in patients with severe cirrhosis. It is also contraindicated in patients taking the drugs Atazanavirand Rifampin.

Approved Dosage Form: Oral

Side-effects: Headache, fatigue and nausea[1].

3. Drug: Enasidenib* **Country: USA**

Enasidenib is an antineoplastic agent.

Approved Indications: Enasidenib is approved for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) who have a specific genetic mutation.

Approved Dosage Form: Oral

Side-effects: Nausea, vomiting, diarrhea, increased levels of bilirubin (substance found in bile) and decreased appetite[1].

4. Drug: Letermovir* **Country: USA**

Letermoviris an antiviral drug.

Approved Indications: Letermovir is approved to prevent Cytomegalovirus (CMV) infection who have been exposed to CMV and have received an allogeneic hematopoietic stem cell (bone marrow) transplant (HSCT).

Letermovir is contraindicated in patients receiving pimozide and ergot alkaloids and in patients receiving Pitavastatin or Simvastatin when co-administered with cyclosporine.

Approved Route of Administration: Oral, Injection

Side-effects: Nausea, diarrhea, vomiting, swelling in the arms and legs, cough, headache, tiredness and stomach (abdominal) pain[1].

5. Drug: Acalabrutinib* **Country: USA**

Acalabrutinib is a kinase inhibitor that works by blocking an enzyme needed by the cancer to multiply and spread.

Approved Indications: Acalabrutinibis approved for the treatment of adults with mantle cell lymphoma who have received at least one prior therapy.a kinase inhibitor that works by blocking an enzyme needed by the cancer to multiply and spread..

Approved Route of Administration: Oral

Side-effects: Headache; diarrhea; bruising; fatigue and muscle pain (myalgia); and reduced levels of red blood cells (anemia), platelets (thrombocytopenia) and neutrophils (neutropenia) in the blood[1].

6. Drug: Benznidazole* **Country: USA**

Benznidazoleis an antiparasiticmedicine used in the treatment of Chagas disease.

Approved Indications: Benznidazole was granted accelerated approval by USFDA for use in children between 2 to 12 years old with Chagas disease. It is the first treatment approved in the United States for the treatment of Chagas disease.

Approved Route of Administration: Oral

Side-effects: Stomach pain, rash, decreased weight, headache, nausea, vomiting, abnormal white blood cell count, urticaria (hives), pruritus (itching) and decreased appetite[1].

7. Drug: Meropenem + Vaborbactam* **Country: USA**

Meropenem is an antibacterial drug and Vaborbactam is not an antibacterial which inhibits certain types of resistance mechanisms used by bacteria.

Approved Indications: Meropenem + Vaborbactam injection is approved for adults with complicated urinary tract infections, including a type of kidney infection, pyelonephritis, caused by specific bacteria. This combination should not be used in patients with a history of anaphylaxis, a type of severe allergic reaction to products in the class of drugs called beta-lactams.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of antibacterial drugs, this drug should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

Approved Route of Administration: Intravenous

Side-effects: Headache, infusion site reactions and diarrhea[1].

8. Drug: Synthetic Human Angiotensin-II* **Country: USA**

Synthetic human angiotensin II peptide hormone vasoconstrictor.

Approved Indications: Synthetic Human Angiotensin IIinjection is approved to increase blood pressure in adults with septic or other distributive shock.

Synthetic Human Angiotensin-II can cause dangerous blood clots with serious consequences (clots in arteries and veins, including deep venous thrombosis); prophylactic treatment for blood clots should be used.

Approved Route of Administration: Intravenous infusion

Side-effects: Deep vein thrombosis, thrombocytopenia, tachycardia, and fungal infection[1,2].

9. Drug: Macimorelin* **Country: USA**

Macimorelin is a growth hormone (GH) secretagogue receptor agonist.

Approved Indications: Macimorelinoral granules areapproved for the diagnosis of adult growth hormone deficiency (AGHD).Macimorelin

prompts growth hormone secretion from the pituitary gland into the circulatory system which is then measured in 4 blood samples over 90 minutes following administration.

Approved Route of Administration: Oral

Side-effects: Deep vein thrombosis, thrombocytopenia, tachycardia, and fungal infection[1,2].

10. Drug: Ertugliflozin* **Country: USA**

Ertugliflozinisasodium-glucose cotransporter 2 (SGLT2) inhibitor.

Approved Indications: Ertugliflozin oral dosage form is approved as an adjunct to diet and exerciseinorder to improve glycemic control in adults with type 2 diabetes mellitus.

Ertugliflozinis not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis and is contraindicated in patients with severe renal impairment, end-stage renal disease or on dialysis or with a history of a serious hypersensitivity reaction to ertugliflozin.

Approved Route of Administration: Oral

Side-effects: Intravascular volume contraction, symptomatic hypotension[1,2].

References:

1. www.fda.gov 2. www.drugs.com

Note - * Not available in India

Meaning: Chagas disease- A parasitic infection caused by Trypanosoma cruzi (a protozoan parasite) which gets transmitted through different routes, including contact with the feces of a certain insect, blood transfusions, or from a mother to her child during pregnancy.

Safety Alert – Around the Globe

1. Drug: Obeticholic Acid* **Country: USA**

May increase the risk of serious liver injury

Obeticholic acid is a gastrointestinal agent used to treat a rare, chronic liver disease known as primary biliary cholangitis (PBC). PBC causes the bile ducts in the liver to become inflamed, damaged and destroyed.

Alert: The USFDA warns that Obeticholic Acid tablet is being incorrectly dosed in some patients with moderate to severe decreases in liver function, resulting in an increased risk of serious liver injury and death. These patients are receiving excessive dosing, particularly a higher frequency of dosing than is recommended in the drug label for them. Obeticholic acid may also be associated with liver injury in some patients with mild disease who are receiving the correct dose.

Hence, KSPC-DIRC alerts the healthcare professionals about the new safety changes for ObeticholicAcid.

2. Drug: Sodium Polystyrene Sulfonate* **Country: USA**

- May bind to many commonly prescribed oral medicines, decreasing the absorption and effectiveness of those oral medicines.

Sodium Polystyrene Sulfonate is used to treat hyperkalemia, a serious condition in which the amount of potassium in the blood is too high. It works by binding with potassium in the intestines so it can be removed from the body.

Alert: The USFDA warns that patients should avoid taking the potassium-lowering drug Sodium polystyrene sulfonate at the same time as any other medicines taken by mouth. A study found that sodium polystyrene sulfonate binds to many commonly prescribed oral medicines, decreasing the absorption and therefore effectiveness of those oral medicines.

Patients should take orally administered prescription and over-the-counter (OTC) medicines at least 3 hours before or 3 hours after sodium polystyrene sulfonate.

Hence, KSPC-DIRC alerts the healthcare professionals about the new safety changes for Sodium Polystyrene Sulfonate.

Reference:

www.fda.gov

Note - * Not available in India

Alert

Aripiprazole tablet with sensor a Digital ingestion tracking system

Aripiprazole is an atypical antipsychotic drug.

Approved: The U.S. Food and Drug administration approved the first drug Aripiprazole tablets with sensor in the United States with a digital ingestion tracking system. This drug has an ingestible sensor embedded in the pill that records that the medication was taken.

It is used for thetreatment of schizophrenia, acute treatment of manic and mixed episodes associated with bipolar disorder and for use as an add-on treatment for depression in adults.

Safety and effectiveness have not been established in pediatric patients

How it works: This ingestion tracking system works by sending a message from the pill's sensor to a wearable patch. The patch transmits the information to a mobile application so that patients can track the ingestion of the medication on their smart phone. Patients can also permit their caregivers and physician to access the information through a web-based portal.

Caution:

- Increased risk of death in elderly patients with dementia-related psychosis treated with antipsychotic drugs.
- Not approved to treat patients with dementia-related psychosis.
- Increases the risk of suicidal thinking and behavior in children, adolescents and young adults taking antidepressants.

Monitor the patients for worsening and emergence of suicidal thoughts and behaviors.

Reference: www.fda.gov

Continuing Pharmacy Education (CPE)

Dispensing Instructions to the Pharmacists

Schizophrenia-Drug Therapy (oral)

A psychotic disorder is usually characterized by thoughts or experiences that seem out of touch with reality, disorganized speech or behavior and decreased participation in daily activities. Difficulty with concentration and memory may also be present.

The exact cause of schizophrenia isn't known, but a combination of genetics, environment and altered brain chemistry and structure may play a role.

Treatment can help relieve many of the symptoms of schizophrenia and requires a combination of psychopharmacological therapy and psychosocial interventions. Specific strategies may vary depending on the illness phase.

Antipsychotic drugs: Antipsychotic drugs are first-line therapy for the treatment of schizophrenia and reduce psychotic symptoms, help prevent relapse, and improve overall long-term functioning.

❖ **First-generation antipsychotics**

These first-generation antipsychotics have frequent and potentially significant neurological side effects, including the possibility of developing a movement disorder (tardive dyskinesia) that may or may not be reversible. First-generation antipsychotics include Chlorpromazine, Fluphenazine, Haloperidol, Perphenazine

❖ **Second-generation antipsychotics**

Newer, atypical antipsychotic drugs or Second-generation antipsychotics are similarly effective and somewhat better tolerated when compared to classical antipsychotics. They have a significantly lower risk of causing extrapyramidal side effects and tardive dyskinesia. Overall tolerability is similar to conventional drugs. They are often used by clinicians as the first drug of choice. Some of the examples of Second-generation antipsychotics are Aripiprazole, Quetiapine, Remoxipride, Sertinodole, Ziprasidone, Clozapine.

Other classes of drugs are as following:

❖ **Benzodiazepines**: Short-acting benzodiazepines are useful in the acute management of the agitated patient, particularly in combination with an antipsychotic agent (eg, haloperidol combined with lorazepam)

❖ **Antidepressants:** Antidepressants may be used as adjunctive agents in schizophrenia for treatment of both depression and negative symptoms.

Below is a brief overview of some drugs under Second-generation antipsychotics.

Drugs/ Category	Use	Warnings*	Less serious side effects	Advice
Aripiprazole **Oral forms available:** Tablet	Treats schizophrenia, and agitation caused by schizophrenia or bipolar disorder.	Prescription to be reconfirmed in case of patients with diabetes, heart failure, heart or blood vessel disease, heart rhythm problems, high or low blood pressure, high cholesterolor a history of seizures, heart attack, or stroke. Caution in case of children, teenagers, and young adults as this medicine may increase mental or emotional problems.	Headache, nausea, vomiting, redness, pain, swelling or itching where the shot was given, unusual weight gain.	Take with or without food. Do not drive a motor vehicle or operate machinery. Avoid alcohol. Do not discontinue this drug without the advice of the doctor.
Clozapine **Oral forms available:** Tablet	Treatment of schizophrenia, treatment-resistant, suicidal behavior, recurrent/chronic (schizophrenic patients).	Prescription to be reconfirmed in case of patients with kidney disease, liver disease, diabetes, digestion problems, glaucoma, heart or blood vessel disease, heart failure, heart rhythm problems, enlarged prostate, or a history of head injury, heart attack, stroke, seizures, or alcohol addiction.	Constipation, stomach upset, excess saliva or drooling, unusual drowsiness or sleepiness, headache, weight gain.	Take with or without food. Avoid driving a motor vehicle or operate machinery while taking this medicine. Do not stop taking this medicine abruptly unless otherwise advised by the doctor. Avoid alcohol.
Olanzapine **Oral forms available:** Capsule	Treats agitation (being overexcited, tense, hostile, or anxious) in patients with schizophrenia or bipolar disorder.	Prescription to be reconfirmed in case of patients with kidney disease, liver disease, diabetes, glaucoma, prostate problems, or a history of breast cancer, neuroleptic malignant syndrome (NMS), seizures, or severe constipation. Tell your doctor if you have any kind of heart or circulation problems, including low blood pressure, heart failure, heart rhythm problems, or a history of a heart attack or stroke.	Constipation, upset stomach, dry mouth, headache, tiredness pain, itching, burning, swelling, or a lump under your skin where the shot was given, sleepiness or unusual drowsiness, weight gain	Take the medicine with food or on an empty stomach. Avoid driving a motor vehicle or operate machinery while taking this medicine. Avoid excessive skin exposure to direct sunlight. Avoid alcohol and smoking tobacco.

Drugs/ Category	Use	Warnings*	Less serious side effects	Advice
Quetiapine **Oral forms available:** Capsule	Treats schizophrenia, bipolar disorder, or depression.	Prescription to be reconfirmed in case of patients with liver disease, breast cancer, diabetes, underactive thyroid, or a history of seizures or neuroleptic malignant syndrome (NMS). Tell your doctor if you have any kind of blood vessel or heart problems, including low or high blood pressure, heart failure, heart rhythm problems (QT prolongation, slow heartbeat), high cholesterol, or a history of heart attack or stroke.	Constipation, vomiting, nausea, dry mouth, headache, tiredness, dizziness, or sleepiness, trouble swallowing, weight gain.	Take with or without food. Avoid driving a motor vehicle or operate machinery while taking this medicine.
Risperidone **Oral forms available:** Tablet	Treats schizophrenia and bipolar disorder.	Prescription to be reconfirmed in case of patients with kidney disease, liver disease, bowel blockage, brain tumor, diabetes, high cholesterol, Parkinson disease, Reye's syndrome, trouble swallowing, or a history of breast cancer or seizures. Tell your doctor if you have heart failure, low blood pressure, or a history of a heart attack or stroke.	Constipation, decreased appetite, vomiting, stomach pain or upset, drowsiness or headache, pain, swelling, or a lump under your skin where the shot is given, weight gain.	Take with or without food. This medicine may affect mental alertness and/or co-ordination. If affected, advise not to drive a motor vehicle or operate machinery. Advice not to discontinue this drug without the advice of the doctor.

Note *Make sure that the patient has informed the doctor the pregnancy and lactating status.

Storage: Advice the patient or caretaker to store the medicine in a closed container at room temperature, away from heat, moisture and direct light. Ensure to keep all medicine out of the reach of children.

References:

1 Handbook of Pharma SOS, Educational Series-III, 6th Edition 2014, published by Karnataka State Pharmacy Council, Bengaluru.

2. www.micromedexsolutions.com, Micromedex (R) 2.0, 2002-2017, Truven Health Analytics Inc.

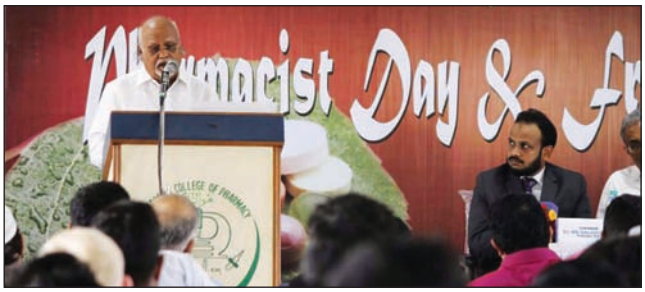
KSPC News

PES College of Pharmacy, Bengaluru

Mr. Samson P. George, Dy. Registrar and DIRC Pharmacist, Karnataka State Pharmacy Council (KSPC) was the chief guests for the **56th National Pharmacist Week** celebration held at PES College of Pharmacy, Bengaluru on 23rd November 2017. He delivered a lecture based on the theme '**From Research to Healthcare-Your Pharmacist is at your Service**'. He highlighted the role of Pharmacist in healthcare, timelines in the field of Pharmacy Practice, reason for professional pharmacy services, Pharmacy Practice Regulations, 2015 etc.

Dr. S. Mohan, Director, PES, Dr.R. Srinivasan, HOD of Pharmacy Practice, PES, Dr. C. S. Satish, Dept. of Pharmaceutics and 60 students with other staffs were present for the celebration.

Farooqia College of Pharmacy, Mysuru



Sri. Gangadhar V Yavagal, President, Karnataka State Pharmacy Council, Bengaluru was the chief guests for the **World Pharmacist Day** celebration held at Farooqia College of Pharmacy (FCP), Mysuru on 25th September 2017. Other guests of honour were Sri. Taj Mohammed Khan, Secretary, FCP, Dr. Md. Salahuddin, Principal, FCP. 250 students along with staff of FCP were present.

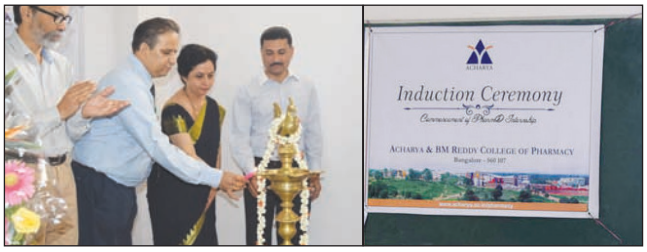
Karnataka College of Pharmacy, Bengaluru

Mr. Samson P. George, Dy. Registrar and DIRC Pharmacist, Karnataka State Pharmacy Council (KSPC) was one of the chief guests for the **World Pharmacist Day** celebration held at Karnataka College of Pharmacy (KCP), Bangalore on 25th September 2017. The World Pharmacist Day theme for 2017 was 'Research to Healthcare, Your Pharmacist is at your Service.'

Mr. Samson gave a presentation on the Pharmacist Day theme. Other guests of honour were Mr.Lokesh Prasad, Senior Scientific Officer & Govt. Analyst, Hi-Tech Lab, Drug Testing Laboratory, Govt. of Karnataka, Dr. K. Ramesh, Director, KCP, Dr. Raju Koneri, Dean, KCP, Dr. T. Prabhakar, Principal, KCP, Dr. R. Balakeshaw, Professor, Dept. of Pharmacy Practice, KCP. 150 students along with staff of KCP were present.

Acharya and BM Reddy College of Pharmacy, Bengaluru

Mr. Samson P. George, Dy. Registrar and DIRC Pharmacist, Karnataka State Pharmacy Council (KSPC) attended an **Induction Ceremony** program organized by Acharya and BM Reddy College of Pharmacy (ABMRCP), Department of Pharmacy Practice, Bengaluru to mark the commencement of Internship of PharmD students on 17th July 2017 at ESIC Medical College – Post Graduate Institute of Medical Sciences & Research and Model Hospital, Rajajinagar, Bengaluru.



Mr. Samson delivered a lecture on '**Drug Information & Clinical Pharmacy Services**' and its importance in in the field of Pharmacy. He discussed about the need of drug information services, commonly used references and briefly discussed the statistics of drug information services provided by the KSPC Drug Information Centre. Other honorable dignitaries were Dr. Jeetendra Kumar, Dean, ESIC MH & PGIMSR, Bengaluru, Dr. Rachita Biswas, Medical Superintendent, ESIC MH, Dr. Divakar Goli, Principal and Campus Director, ABMRCP. 60 students and their staff were present.

Truven Health Analytics - Micromedex Solutions

Mr. Samson P George, Dy. Registrar and DIRC Pharmacist, Karnataka State Pharmacy Council (KSPC) attended a Seminar on **'Role of Evidence based Medicine in Clinical Decision Making'** organized by Truven Health Analytics part of IBM Watson Health business and Vans Scientific Information held on 4-08-2017 at Bengaluru.

Mr. Sandeep Makhijani, Regional Director (Asia Pacific) Valued Based Care, IBM Watson, Micromedex gave a presentation on Practicing Evidence based Medicine with Micromedex and Mr. Ivan Chong, Trainer, Micromedex gave a demo of the Micromedex Product. 35 delegates from various Pharm D colleges attended the seminar.

KPCRPWT Compensation

The death compensation of Sri. Mahantesh Saunshi with registration number 27915 was handed over to his wife Smt. Pushpa M Saunshi by Sri. V.S. Banavi, Member, Karnataka State Pharmacy Council at Hubli.

Left to right: *Sri. Ningaraj Saunshi, President, Kundagol Taluk, Sri. V.V. Kappar Shetter, Secretary, Dharwad District Chemists & Druggists Association, Kum. Soumya Saunshi (Daughter of Mahantesh Saunshi), Ms. Pushpa M Saunshi (Wife), Sri. V.S. Banavi, Member, KSPC, Sri. Chandrakanth Kotagi-Kundgol Chemist, Sri. Jayaprakash Goni, Secretary, Kundagol Chemists and Druggist Association.*

ಭೇಷಜೀ ಪರಿಕರ್ಮ ನಿಬಂಧನೆಗಳು, 2015
(Pharmacy Practice Regulations, 2015)

4.2. ನೋಂದಾವಣೆಯ ನವೀಕರಣ:

ನೋಂದಾವಣಿ ನವೀಕರಿಸಲು ಆ ಭೇಷಜಜ್ಞರು ಐದು ವರ್ಷಗಳ ಅವಧಿಯೊಳಗೆ ಈ ಕೆಳಗೆ ಹೇಳಿದ ಸಂಸ್ಥೆಗಳಲ್ಲಿ ಯಾವುದಾದರೂ ಒಂದು ಸಂಸ್ಥೆಯು, ಭೇಷಜೀ ವಿಷಯದ ಬಗ್ಗೆ ಸಂಘಟಿಸಿದ, ಕನಿಷ್ಠ ಪಕ್ಷ ಒಂದು ದಿನ ಅವಧಿಯ, ಕನಿಷ್ಠ ಪಕ್ಷ ಎರಡು ಪುನ್:ಶ್ಚೇತನ ಪಠ್ಯಕ್ರಮಗಳಲ್ಲಿ ಭಾಗಿಯಾಗಿರತಕ್ಕದ್ದು.

1. ಭಾರತದ ಭೇಷಜೀ ಪರಿಷತ್ತು
2. ರಾಜ್ಯದ ಭೇಷಜೀ ಪರಿಷತ್ತುಗಳು
3. ಕೇಂದ್ರ ಸರಕಾರ / ರಾಜ್ಯ ಸರಕಾರ
4. ಪರಿಷತ್ತಿನಿಂದ ಮಾನ್ಯತೆ ಪಡೆದ ವೃತ್ತಿಪರ ಸಂಸ್ಥೆಗಳು

Attention- Registered Pharmacists

Lending of Registered Pharmacist Certificate to any Chemist and Druggist shop / Hospital / Nursing Home /Wholesale Distributors / Clinics without physical presence will be guilty of such infamous conduct and will be liable to have his/her name removed from the register under u/s 36(1) (ii) of the Pharmacy Act 1948. Such Registered Pharmacists are directed to withdraw their Certificate lent without physical presence to avoid legal action under intimation to this office.

Additional Information on any article is available on request
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514/E, I Main, II Stage, Vijayanagar, Bengaluru-560 104. Ph : 080- 23383142, 23404000, 46729800 (800 to 899 lines)
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