DIRC Newsletter

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Official Desk

Pharmacy Education Scholarship

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President
Karnataka State
Pharmacy Council

Karnataka State Pharmacy Council (KSPC) was established in the year 1963 as per the Pharmacy act 1948. KSPC right from its inception started to function and serve the profession of Pharmacy with utmost dedication and sincerity. KSPC pioneered in adopting innovative methods for serving the profession and became a model Pharmacy Council for other states of the country. KSPC in its pursuit to serve and extend the helping hand to practicing pharmacists, set up a Drug Information Center, published many books to educate pharmacists. In addition, a Social Welfare Scheme named as Karnataka Pharmacy Council Registered Pharmacist Welfare Trust (KPCRPWT) has been introduced by the Council in the year 1999 with the intent of providing financial stability for nominees of Registered Pharmacist.

It is my pleasure to share with you all, the new scheme called 'Pharmacy Education Scholarship Scheme' introduced by this Council to encourage and financially support the legal heirs of Registered Pharmacists to pursue Pharmacy education and continue to practice this profession and thereby develop an outstanding professionals and experts to meet the needs of the global society.

The legal heirs of the Registered Pharmacist who gets admission to D.Pharm/B.Pharm/M.Pharm/PharmD courses can appy for this scholarship, provided such Registered Pharmacist renewal status must be up-to-date/current. Other eligibility, criteria and conditions for the scholarship scheme are available on our website www.kspcdic.com.

The evaluation, selection or any other matter for the scholarship will be finally decided by the committee of this council. ❑

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Dear 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. Hence, I request the Registered Pharmacists to withdraw their Certificate lent without the physical presence to avoid legal action under intimation to this office.

President

Doctorate Award

Sri. Gangadhar V. Yavagal, President along with Vice-President, Registrar and all the members of the Council congratulated Sri. Y. Veeranarayana Gowda, Executive Council Member, Karnataka State Pharmacy Council for being awarded an **"Honorary Doctorate"** in "PHARMACEUTICALS" specialization in "LEGAL STUDIES" by the Indian Virtual Academy for Peace and Education 2018-19 held in Pune.

Importance of taking care of Kidneys

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Introduction

Chronic diseases are now considered a major threat to human health worldwide. These diseases were earlier considered to be a health concern only for the developed nations. With the significant rise in number of chronic disease deaths in developing countries, it has now become a global health problem. It is projected that the chronic disease deaths will show a staggering rise to 7.63 million by 2020 accounting for 66.7% of total deaths. The increase in chronic kidney disease (CKD) prevalence progressing up to end-stage renal disease (ESRD) and the resulting high expenditure associated with renal replacement therapy (RRT) brings to light the utmost necessity to be informed about the importance and tips on how to take care of kidneys.

Incidence of chronic kidney disease in India

The rise in incidence of CKD will cause negative implications for healthcare and economy in India. The age-adjusted incidence rate of ESRD is estimated to be 229 per million population with more than 100,000 new patients opting for renal replacement per year in India. However, due to scarcity of resources only 10% of the Indian ESRD patients could be benefited from renal replacement therapy. Owing to lack of community-based screening programs, the CKD patients are identified at advanced stages of the disease which adds to the complications. Figure 1 depicts a breakdown of the causes for CKD as mentioned in Indian CKD registry.

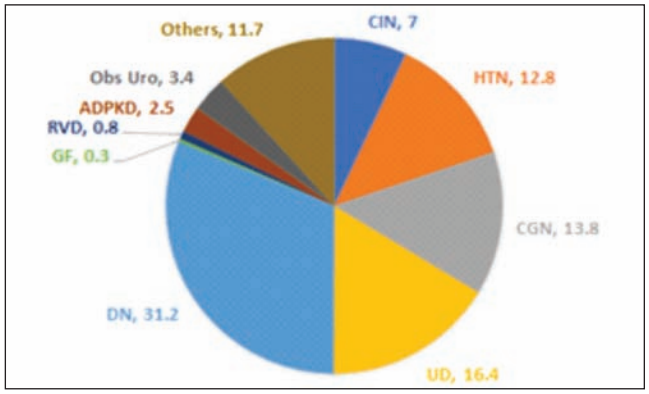

Figure 1. Causes of CKD in India

CIN = chronic interstitial nephritis; HTN = Hypertension; CGN = chronic glomerulonephritis, UD = Undetermined; DN = Diabetic nephropathy; GF = Graft failure; RVD = Renovascular disease; ADPKD = Autosomal dominant polycystic kidney disease

Quality-of-life in CKD patients

CKD patients suffer from a range of medical conditions such as pain, fatigue, muscle cramps, sleep disorders, sexual dysfunction and depression associated with a high death risk. These multitude of physical and emotional symptoms result in significantly impairing the quality-of-life (QoL) of the patients. Apart from this, a range of sociodemographic, clinical and laboratory risk factors as educational level, gender, individual income, professional activity, age, hemoglobin levels, serum phosphorus level, diabetes and comorbidities contribute to worsening of the QoL in CKD patients. To improve the QoL of the patients, efforts are required to decrease the effects of factors that can be changed.

Cost of treatment of CKD in India and its implications

The management of CKD in India is mainly guided by economic considerations owing to high expenses associated with RRT. The absence of health insurance as well as financially weak public hospitals results in less than 10% CKD patients receive RRT. The total expense incurred in India on HD (Hemodialysis) session, arterio venous fistula surgery and erythropoietin is $20-$40, $150 and $400/month respectively. The renal transplant which is the best treatment option costs $8900 in the first year, which later decreases to $3000 per year. India with a per capita income of $460/yr leads to only 30% of patients being treated with erythropoietin therapy. Cyclosporine, azathioprine and prednisolone are still used for immunosuppression in India despite availability of new drugs in the market. To cut down costs, low cyclosporine doses with ketoconazole or discontinuing use of cyclosporine after one year is followed. Thus, financial considerations hamper appropriate treatment of CKD resulting in high morbidity and mortality.

How the current lifestyle leads to kidney diseases?

Lifestyle factors as physical inactivity, smoking, morbid obesity contributes to CKD. The physical inactivity among diabetic adults results in early renal function decline. Smoking results in an increase in microalbuminuria, proteinuria and serum creatinine; decreases the rate of glomerular filtration as well as repeated increase in blood pressure resulting in renal hemodynamic dysfunction and small vessel damage. An overlapping trend of obesity and increased incidence of CKD is quite evident. Obesity is related to hypertension and glomerulosclerosis and thus renal failure.

Dos and Don'ts for maintaining healthy kidneys

- Avoid Smoking
- Obese people should be encouraged to reduce BMI. Maintenance of a health body weight (BMI 18.5–24.9 kg/m2; waist circumference <102 cm for men, <88 cm for women) is recommended
- Protein-controlled diet (0.80–1.0 g/kg/d) is recommended for adult CKD patients
- Limit alcohol consumption (Limit to 2 drinks or less per day, weekly consumption not to exceed 14 standard drinks per week for men and 9 standard drinks per week for women
- Moderate-intensity dynamic exercise recommended: Perform 30–60 minutes of moderate-intensity dynamic exercise (walking, jogging, cycling or swimming) for 4–7 days per week
- Reduce dietary salt intake: Limit to <100 mmol/day, Limit to 65–100 mmol/day (for hypertension patients)

References:

1. Agarwal SK, Srivastava RK. Chronic kidney disease in India: challenges and solutions. *Nephron Clin Pract.* 2009;111(3):197-03.
2. Singh AK, Farag YM, Mittal BV, et al. Epidemiology and risk factors of chronic kidney disease in India–results from the SEEK (Screening and Early Evaluation of Kidney Disease) study. *BMC Nephrol.* 2013;14(1):114.
3. Cohen SD, Patel SS, Khetpal P, et al. Pain, sleep disturbance, and

quality of life in patients with chronic kidney disease. *Clin J Am Soc Nephrol.* 2007;2(5):919-25.

4. Cruz MC, Andrade C, Urrutia M, et al. Quality of life in patients with chronic kidney disease. *Clinics.* 2011; 66(6):991-95.
5. Murugesan RP, Venkataram C, Periasamy S. Epidemic of Chronic Kidney Disease in India -What Can Be Done?. *Saudi J Kidney Dis Transpl.* 2008; 19(5):847-53.
6. Levin A, Hemmelgarn B, Culleton B, Tobe S, et al. Guidelines for the management of chronic kidney disease. *Can Med Assoc J.* 2008;179(11):1154-162.

Drug of the Quarter

Drug : **Macitentan**
Class : Anti-Hypertensive
Dosage For : Tablet
Strength : 10 mg
DCGI Approval : 31-12-2017
USFDA Approval : 18-10-2013

Indication: Treatment of pulmonary arterial hypertension.

Dose Information

Adult Dosing

Pulmonary hypertension: 10 mg orally once a day to delay progression of pulmonary arterial hypertension. Doses greater than 10 mg daily have not been evaluated under clinical trials.

Pediatric Dosing: Safety and efficacy have not been established in pediatric patients.

Pharmacokinetics

Absorption

- Tmax, Oral: 8 to 9 hours
- Effect of food: No effect on exposure

Distribution

- Protein binding, albumin and alpha-1-glycoprotein: Greater than 99%
- Vd: 50 L

Metabolism

- Liver: Extensive via CYP3A4, CYP2C19, CYP2C8 and CYP2C9
- ACT-132577: Major, active
- Substrate of CYP3A4

Excretion

- Renal: 50%
- Fecal: 24%

Elimination Half Life

- Macitentan: 14.1 to 18.5 hours
- ACT-132577: 46.7 to 55.8 hours

Contraindication: Contraindicated in pregnancy.

Cautions:

- **Cardiovascular:** Peripheral edema, fluid retention and worsening of heart failure have been reported, increased risk in patients with underlying left ventricular dysfunction. monitoring recommended and discontinuation may be warranted.
- **Concomitant use:** Avoid strong CYP3A4 inducers such as rifampin or CYP3A4 inhibitors such as ketoconazole or ritonavir.
- **Hematologic:** Monitoring recommended due to reports of decrease in hemoglobin concentration and hematocrit value.
- **Hematologic:** Use not recommended in patients with severe anemia.
- **Hepatic:** Hepatotoxicity, elevated aminotransferases and liver failure have occurred with other endothelin receptor antagonists. Monitoring recommended and discontinuation may be necessary.
- **Reproductive:** Adverse effects on spermatogenesis have occurred with other endothelin receptor antagonists.
- **Respiratory:** Pulmonary edema with pulmonary venoocclusive disease may occur; discontinue if confirmed.

Storage: Protect from moisture.

Mechanism of Action/Pharmacology: Macitentan is a dual endothelin ET(A) and ET(B) receptor antagonist with a high affinity for and long occupancy period of ET receptors in pulmonary arterial smooth muscle cells. Endothelin-1 (ET) can cause inflammation, hypertrophy, vasoconstriction, fibrosis and proliferation when it binds to ET-A and ET-B receptors.

Adverse Effects

Common

- Hematologic: Anemia
- Immunologic: Influenza
- Neurologic: Headache
- Renal: Urinary tract infectious disease
- Respiratory: Bronchitis, Nasopharyngitis, Pharyngitis

Serious

- Hepatic: Increased liver aminotransferase level

Drug-Drug Interactions

Category	Drug/s (Example)	Interaction Effect	Management
Strong CYP3A4 inhibitors*	Ketoconazole	May result in increased macitentan exposure.	Avoid concomitant use.
Strong CYP3A4 inducers*	Rifampin	May result in reduced macitentan exposure.	Avoid concomitant use.
Antifungal drug	Fluconazole	May result in increased macitentan exposure and risk for toxicity.	Use with caution.

Severity: *The interaction may be life-threatening and/or require medical intervention to minimize or prevent serious adverse effects.

Effects in Pregnancy

Severity	Management
Contraindicated	Macitentan is rated as USFDA Category X. Adequate well-controlled or observational studies in animals or pregnant women have demonstrated positive evidence of fetal abnormalities. The use of Macitentan is contraindicated in women who are or may become pregnant.

Effects in Lactation:

Severity	Management
Major	Infant risk cannot be ruled out. Available evidence and/or expert consensus is inconclusive or is inadequate for determining infant risk when Macitentan is used during breast-feeding. Weigh the potential benefits of treatment against potential risks before prescribing Macitentan during breast-feeding.

Patient Education

1. Please advise women of child bearing potential to avoid pregnancy and breastfeeding during therapy.
2. Please counsel the patient regarding side effects which may include headache, stuffy or runny nose, sore throat, itching or hives, swelling in your face or hands, swelling or tingling in your mouth or throat, chest tightness, trouble breathing, dark urine or pale stools, nausea, vomiting, loss of appetite, stomach pain, yellow skin or eyes, rapid weight gain, swelling in your hands, ankles, or feet, trouble breathing, unusual bleeding, bruising or weakness.
3. Please advise 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
December 2017				
1.	Fluoxetine	Antidepressant	Psychological disorders and also in premature ejaculation.	Urinary Incontinence
November 2017				
2.	Quetiapine	Antipsychotic	Schizophrenia and bipolar disorders.	Gynaecomastia
3.	Ceftriaxone	Antibiotic - 3rd generation Cephalosporin	Serious infections like septicaemia, pneumonia and meningitis; surgical prophylaxis; prophylaxis of meningococcal meningitis; gonorrhoea; bone and joint infection	Palpitations

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: **Urinary incontinence-** the loss of urinary bladder control, **Gynaecomastia-** Swollen male breast tissue caused by a hormone imbalance.

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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
July - September 2017					
Antirheumatic / Immunological Agent	Tocilizumab	Intravenous & Subcutaneous	Injection	Pancreatitis and hepatotoxicity	Evaluation is in progress.
Antihyperlipidemics	Fenofibrate, Fenofibric acid,	Oral	Tablet, Capsule	Serious skin reactions	Evaluation is in progress.

Therapeutic Class / Category	Drug (Examples)	Route of Administration	Dosage Form	Potential Signal of a Serious Risk / New Safety Information	Additional Information
Antidepressant Drugs	Amitriptyline Bupropion Citalopram Duloxetine Escitalopram Fluoxetine Paroxetine Sertraline Venlafaxine	-	-	Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)	Evaluation is in progress.
Antibiotic/ Antibacterial drugs	Moxifloxacin, Ciprofloxacin, Gemifloxacin, Levofloxacin,	Oral, Intravenous & Subcutaneous	Tablet, Injection	Hypoglycemic coma	Evaluation is in progress.
Anti-histamines	Cetirizine, Levocetirizine, Pseudoephedrine	Oral	Tablet	Rebound Pruritis	Evaluation is in progress.
Decongestant	Pseudoephedrine	Oral	Tablet	Acute generalized exanthematous pustulosis	Evaluation is in progress.
Antineoplastic drug	Ibrutinib	Oral	Capsule	Hepatotoxicity	Evaluation is in progress.
Antineoplastic drug	Ibrutinib	Oral	Capsule	Ventricular arrhythmia	The labeling section of the product was updated to include ventricular arrhythmia.
Antineoplastic drug	Methotrexate	Oral & Intravenous	Oral Solution	Drug interaction with nitrous oxide - potentiated effect of methotrexate on folate metabolism, resulting in increased toxicity (severe myelosuppression, stomatitis, and neurotoxicity)	Evaluation is in progress.
Antibiotic/ Antibacterial drug	Nafcillin	Intravenous	Injection	Acute renal failure	Evaluation is in progress.
Gastrointestinal Agent	Obeticholic acid	Oral	Tablet	Liver injury	Evaluation is in progress.
Antineoplastic drug	Eculizumab	Intravenous	Injection	Nongroupable meningitis infections and Neisseria (other than N. meningitides) infections	Evaluation is in progress.
Blood Modifier Agent/Cardiovascular agent	Selexipag	Oral	Tablet	Hypotension	The labeling section of the product was updated to include hypotension.
Antipsychotic drug	Cariprazine	Oral	Capsule	Stevens-Johnson syndrome (SJS)	Evaluation is in progress.
Anticoagulant	Rivaroxaban	Oral	Tablet	Liver injury	FDA decided that no action is necessary at this time.

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

Drug News – Around the Globe

1. Drug: Brentuximab Vedotin* **Country: USA**

Brentuximab Vedotin is an antineoplastic drug.

Approved Indications: Brentuximab Vedotin is approved to treat adult patients with previously untreated stage III or IV classical Hodgkin lymphoma (cHL) in combination with chemotherapy.

Approved Dosage Form: Injection

Side-effects: Low levels of certain blood cells (neutropenia, anemia), nerve damage causing numbness or weakness in the hands and feet (peripheral neuropathy), nausea, fatigue, constipation, diarrhea, vomiting and fever (pyrexia)[1].

2. Drug: Durvalumab* **Country: USA**

Durvalumab is an antineoplastic drug.

Approved Indications: Durvalumab is approved for the treatment of patients with stage III non-small cell lung cancer (NSCLC) whose tumors are not able to be surgically removed (unresectable) and whose cancer has not progressed after treatment with chemotherapy and radiation (chemoradiation).

Approved Dosage Form: Intravenous

Side-effects: Cough, fatigue, inflammation in the lungs (pneumonitis/radiation pneumonitis), upper respiratory tract infections, difficulty breathing (dyspnea) and rash[1].

3. Drug: Olaparib* **Country: USA**

Olaparib is an antineoplastic agent.

Approved Indications: Olaparib tablet is approved for the treatment of patients with certain types of breast cancer that have spread (metastasized) and whose tumors have a specific inherited (germline) genetic mutation, making it the first drug in its class (PARP inhibitor) approved to treat breast cancer and it is the first time any drug has been approved to treat certain patients with metastatic breast cancer who have a "BRCA" gene mutation.

Approved Dosage Form: Oral

Side-effects: Low levels of red blood cells (anemia), low levels of certain white blood cells (neutropenia, leukopenia), nausea, fatigue, vomiting, common cold (nasopharyngitis), respiratory tract infection, influenza, diarrhea, joint pain (arthralgia/myalgia), unusual taste sensation (dysgeusia), headache, indigestion (dyspepsia), decreased appetite, constipation and inflammation and sores in the mouth (stomatitis)[1].

4. Drug: Apalutamide* **Country: USA**

Apalutamide is an antineoplastic agent.

Approved Indications: Apalutamide tablet is approved for the treatment of patients with prostate cancer that has not spread (non-metastatic) but that continues to grow despite treatment with hormone therapy (castration-resistant). This is the first FDA-approved treatment for non-metastatic, castration-resistant prostate cancer.

Approved Route of Administration: Oral

Side-effects: Fatigue, high blood pressure (hypertension), rash, diarrhea, nausea, weight loss, joint pain (arthralgia), falls, hot flush, decreased appetite, fractures and swelling in the limbs (peripheral edema)[1].

Reference: www.fda.gov

Note - *Not available in India

Safety Alerts – Around the Globe

1. Drug: Daclizumab* **Country: UK**

May increase the risk of serious inflammatory brain disorders

Daclizumab is an immune suppressant and indicated for the treatment of relapsing multiple sclerosis.

Alert: The European Medicines Agency (EMA) warns that Daclizumab injection can cause serious inflammatory brain disorders, including encephalitis and meningoencephalitis, in patients with multiple sclerosis. Symptoms include severe headache or any symptoms of liver injury such as prolonged fever, abdominal pain, jaundice, dark urine or unexplained nausea or vomiting or serious immune-mediated hepatic injury can occur up to 6 months after the final dose.

Hence, KSPC-DIRC alerts the healthcare professionals about the new safety changes for Daclizumab[1].

2. Drug: Recombinant Human Erythropoietin* **Country: UK**

May increase the risk of severe cutaneous adverse reactions (SCARs)

Recombinant Human Erythropoietin (r-HuEPOs) is a glycoprotein hormone that promotes differentiation of erythroid progenitor cells in bone marrow.

Alert: The European Medicines Agency (EMA) warns that human erythropoietin injection can cause life-threatening severe cutaneous adverse reactions (SCARs), including Stevens Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN). Withdraw r-HuEPOs permanently in patients who develop severe skin reactions such as SJS or TEN1.

Hence, KSPC-DIRC alerts the healthcare professionals about the new safety changes for human erythropoietin[1].

3. Drug: Chlorhexidine* **Country: Singapore**

May increase the risk of serious allergic reactions

Chlorhexidine is a broad spectrum antiseptic which is effective against gram-positive and gram-negative bacteria on the skin and is widely used to reduce the risk of bacterial infection.

Alert: The Health Sciences Authority (HSA) informed that chlorhexidine containing products may cause increase the known risk of allergic reactions, including anaphylactic reactions.

Hence, KSPC-DIRC alerts the healthcare professionals about the new safety changes for chlorhexidine containing products[2].

4. Drug: Clozapine* **Country: UK**

May increase the fatal risk of intestinal obstruction, faecal impaction and paralytic ileus

Clozapine is an atypical antipsychotic drug.

Alert: The Medicines and Healthcare Products Regulatory Agency (MHRA) has alerted that clozapine is contraindicated in patients with paralytic ileus and when prescribing clozapine, particular care should be taken in patients at risk of constipation.

Hence, KSPC-DIRC alerts the healthcare professionals to be cautious while prescribing Clozapine[1].

5. Drug: Febuxostat* **Country: USA**

May increase the risk of heart-related death

Febuxostat is a xanthine oxidase inhibitor which acts by decreasing serum uric acid.

Alert: The US Food and Drug Administration (FDA) alerts that the febuxostat may increase the risk of heart-related death.

Hence, KSPC-DIRC alerts the healthcare professionals about the new safety changes for Febuxostat[4].

6. Drug: Finasteride* **Country: France**

May increase the risk of depression and suicidal thoughts

Finasteride is used for the treatment of androgenic alopecia and control benign prostatic hyperplasia.

Alert: The French National Agency for Medicines and Health Products Safety has informed patients and health-care professionals of the risk of depression and suicidal thoughts with the use of finasteride.

Hence, KSPC-DIRC alerts the healthcare professionals to be cautious while prescribing Finasteride[4].

7. Drug: Gabapentin* **Country: UK**

May increase the risk of severe respiratory depression

Gabapentin is an anti-epileptic drug.

Alert: The Medicines and Healthcare Products Regulatory Agency (MHRA) has alerted that gabapentin may cause rare risk of central nervous system depression, severe respiratory depression including in elderly people, patients with compromised respiratory function, respiratory or neurological disease or renal impairment and patients taking other CNS depressants.

Hence, KSPC-DIRC alerts the healthcare professionals to be cautious while prescribing Gabapentin[1].

8. Drug: Isotretinoin* **Country: UK**

May cause rare sexual adverse effects Rare reports of erectile dysfunction and decreased libido

Isotretinoin is classified as a retinoid and used as antiacne medication.

Alert: The MHRA has alerted that Isotretinoin may cause rare adverse effects of sexual dysfunction, like erectile dysfunction and decreased libido in patients taking oral isotretinoin for severe acne.

Hence, KSPC-DIRC alerts the healthcare professionals to be cautious while prescribing Isotretinoin[1].

9. Drug: Clarithromycin * **Country: USA**

May increase the risk of heart problems or death

Alert: The USFDA caution that prescribing the antibiotic clarithromycin to patients with heart disease may increase the risk of heart problems or death that can occur years later.

Hence, KSPC-DIRC alerts the healthcare professionals to be cautious while prescribing Clarithromycin[3].

References:

1. www.gov.uk/
2. www.hsa.gov.sg
3. www.fda.gov
4. www.ansm.sante.fr

Note - *Available in India

Continuing Pharmacy Education (CPE)

Dispensing Instructions to the Pharmacists

Psoriasis

Psoriasis is a chronic autoimmune condition in which skin cells build up and form scales and itchy, dry patches. Inflammation and redness around the scales are fairly common.

The exact cause remains unknown. A combination of elements, including genetic predisposition and environmental factors are involved. It is common for psoriasis to be found in members of the same family. Defects in immune regulation and the control of inflammation are thought to play major roles. Certain medications like beta-blockers have been linked to psoriasis.

The signs and symptoms are different for everyone. Common signs and symptoms include:

- Red patches of skin covered with thick, silvery scales
- Small scaling spots (commonly seen in children)
- Dry, cracked skin that may bleed
- Itching, burning or soreness
- Thickened, pitted or ridged nails
- Swollen and stiff joints

The risk factors include the family history of psoriasis, viral and bacterial infections, stress, obesity, smoking etc.

There are several types of psoriasis like plaque psoriasis, nail psoriasis, guttate psoriasis, inverse psoriasis, pustular psoriasis, erythrodermic psoriasis, psoriatic arthritis.

Self-care

Patients with psoriasis should receive education regarding self-management of other systemic inflammatory diseases, as there are interrelationships between psoriasis and other comorbid diseases such as obesity, metabolic syndrome, and cardiovascular disorders. It is of particular importance to provide appropriate education and supervision for cardiovascular disease risk factors including smoking, hypertension, alcohol abuse, dyslipidemia, and a sedentary lifestyle. Sun exposure may be beneficial in patients with psoriasis

Treatment

Psoriasis treatments reduce inflammation and clear the skin. Treatments can be divided into three main types: topical treatments, systemic medications and light therapy. Minimizing the side effects of psoriasis treatment is an ongoing concern.

I. **Topical treatments includes creams and ointments**
   a. Topical corticosteroids: e.g.'s: Betamethasone, Clobetasol, Halobetasol, Mometasone
   b. Topical retinoids: e.g.: Vitamin A derivative
   c. Vitamin D analogues: e.g.'s: Calcipotriene, Calcitriol
   d. Topical Keratolytics: e.g.: Salicylic acid
   e. Calcineurin Inhibitors: e.g.'s: Pimecrolimus, Tacrolimus
   f. Photosensitizing Agents: e.g.: Psoralen (chemical name Methoxypsoralen)
   g. Antipsoriatics: e.g.'s: Coal tar preparations, Anthralin

II. **Systemic Antipsoriatic Agents:** e.g.'s: Sulfasalazine, Methotrexate, Cyclosporine, Azathioprine, Hydroxyurea, Leflunomide, Mycophenolate

III. **Light therapy:** Use of ultraviolet (UV) or natural light

Drugs / Category	Use	Warnings	Less serious side effects	Advice
Betamethasone, Halobetasol **Route:** Topical	Treats to relieve pain, swelling and itching of the skin.	Prescription to be reconfirmed in case of patients using steroid medicine such as hydrocortisone, methylprednisolone or prednisone.	Local irritation burning sensation, itching, stinging of skin.	Advice patient to report symptoms of Cushing syndrome like moon facies, facial edema, easy bruising, muscle weakness to their doctor or pharmacist. Advice the patient to report any visual symptoms and to avoid contact with eyes. Advice to avoid any occlusive dressings over treated areas unless instructed to do so by physician. Wash hands with soap and water before and after applying this medicine.
Clobetasol **Route:** Topical	Treats psoriasis and irritation from skin diseases.	Prescription to be reconfirmed in case of patient is pregnant or breastfeeding or liver disease or adrenal problem (including Cushing disease), diabetes or a skin infection.	Application site discoloration, application site atrophy, telangiectasia or rash.	Avoid contact with face, scalp, groin or axillae. Report symptoms of local or systemic reactions to their doctor or pharmacist. Avoid using bandages, wraps or other occlusive dressings over the treatment area or where the medicine is applied. Advise the patient to use this medicine for the full time of treatment to clear up the skin or scalp problem completely or as prescribed by the doctor. Discontinue use of this medicine once psoriasis is controlled. Use beyond 2 weeks is not recommended. Wash hands with soap and water before and after applying this medicine.
Calcipotriene **Route:** Topical	Treats plaque psoriasis in adults.	Prescription to be reconfirmed in case of patient is pregnant or breastfeeding or have any other medical problems.	Rash, dermatitis, or skin irritation or burning sensation, dry skin.	Advise the patient to avoid excessive exposure of treated areas to natural or artificial sunlight, including sun lamps. Advise the patient that this medicine is for external use only, not for ophthalmic, oral or intravaginal use.
Calcitriol **Route:** Topical	Treats psoriasis. This medicine is a form of vitamin D.	Prescription to be reconfirmed in case of patient is pregnant or breastfeeding or have any other medical problems. Use is not recommended, if allergic to calcitriol or to vitamin D.	Itching or hives, blistering, peeling, red skin rash, hypercalciuria, and pruritus.	Advise to use this medicine only as topical. Advise not to use this medicine in eyes, nose, or mouth. Advise patient using topical form to avoid excessive exposure to natural or artificial sunlight for treated areas. Do not use more calcitriol than prescribed by the doctor. Too much use of this medicine may cause a dangerous amount of calcium to build up in the body.

Drugs / Category	Use	Warnings	Less serious side effects	Advice
Salicylic acid **Route:** Topical/ Transdermal	Treats skin problems, including acne, psoriasis, and warts.	Prescription to be reconfirmed in case of patient is pregnant or breastfeeding or have blood circulation problems, liver problems or kidney problems.	Skin erythema, irritation, scaling, or dryness.	Advise patient to avoid contact with eyes and mucous membranes. Advise patient to use a test dose for over-the-counter (OTC) products due to potential hypersensitivity reactions. Apply small amount of the topical preparation to skin for 3 days and if no discomfort occurs, use product as directed. Advise patient that prolonged use over large skin areas may cause salicylate toxicity.

(to be continued.....)

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-I, 7th Edition 2018, published by Karnataka State Pharmacy Council, Bangalore.
2. www.micromedexsolutions.com, Micromedex (R) 2.0, 2002-2018, Truven Health Analytics Inc.
3. https://www.webmd.com/
4. http://emedicine.medscape.com/
5. https://www.mayoclinic.org/
6. https://www.healthline.com/

Drug Usage in Special Population - Pediatrics and Geriatrics

(From KSPCDIRC publication)

Antiemetic & Antispasmodic Drugs (oral)

Drug	Usage in Children (Pediatrics)	Usage in Elderly (Geriatrics)
Antiemetic Drugs		
Domperidone	Safety and efficacy have not been established in paediatric patients.	Contraindicated in moderate to severe hepatic impairment. Dose reduction is may be necessary in renal impairments.
Metoclopramide	Safety and efficacy not established in children except to facilitate small bowel intubation.	Dosage adjustments required in renal failure and not required in hepatic insufficiency.
Prochloperazine	Safety and efficacy not established in children below 2 years of age.	Dosage reduction is required in geriatric patients.
Promethazine	Contraindicated in children below 2 years of age.	No dosage adjustment required in renal impairment. But start treatment with low dose in geriatric patients.
Palonosetron	Safety and efficacy have not been established in paediatric patients.	No dosage adjustment required.
Antispasmodic Drugs		
Dicyclomine	Safety and efficacy not established in pediatric patients.	Age based recommendations are not available.
Hyoscine (Scopolamine)	Safety and efficacy have not been established in pediatric patients less than 6 months.	Contraindicated in myasthenia gravis, narrow- angle glaucoma, obstructive gastrointestinal disease obstructive uropathy paralytic ileus or intestinal atony, reflux esophagitis, ulcerative colitis or toxic megacolon, unstable cardiovascular status and in acute hemorrhage.

Reference: Drug Usage in special Population-Pediatrics and Geriatrics, Educational Series-III, 7th Edition 2018, published by Karnataka State Pharmacy Council, Bengaluru.

Drug Usage in Special Population - Pregnancy and Lactation

(From KSPCDIRC publication)

Antiemetic & Antispasmodic Drugs (oral)

Drug	Usage in Pregnancy (Teratogenicity)	Usage in Breastfeeding (Lactation)
Antiemetic Drugs		
Domperidone	ADEC Category B2. Limited human data, no fetal adverse effects reported but should be avoided in first trimester unless potential benefits outweigh risks.	Excreted into milk in very small amounts. Medical advice is necessary.
Metoclopramide	USFDA Category B. No adverse effects on the mother or fetus have been reported when administered during the first trimester of pregnancy. Caution.	Controversial data available. Medical advice is necessary.
Prochloperazine	Fetal risk cannot be ruled out. Use only if the potential benefit outweighs the potential risk to the fetus.	Data not available. Medical advice is necessary.
Promethazine	USFDA Category C. Reported to cause neonatal respiratory depression and neonatal platelet dysfunction. Use only if the potential benefit outweighs the potential risk to the fetus.	Safe in usual dosage; monitor infant for drowsiness.
Palonosetron	USFDA Category B. Limited data available. Use only if the potential benefit outweighs the potential risk to the fetus.	Data not available. Medical advice is necessary.
Antispasmodic Drugs		
Dicyclomine	USFDA Category B. There are no adequate and well-controlled studies. But few reports on congenital malformations have been reported. Use only if the potential benefit outweighs the potential risk to the fetus.	Controversial data. Medical advice is necessary.
Hyoscine (Scopolamine)	USFDA Category C. This drug may cause fetal tachycardia, decreased heart rate variability. Caution advised.	Safe to use.

ADEC Category B2: Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed. Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of fetal damage.

USFDA Category B: Either animal-reproduction studies have not demonstrated a fetal risk but there are no controlled studies in pregnant women or animal-reproduction studies have shown adverse effect (other than a decrease in fertility) that was not confirmed in controlled studies in women in the first trimester (and there is no evidence of a risk in later trimesters).

USFDA Category C: Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans. Drug should be given only if the potential benefit justifies the potential risk to the fetus.

Reference: Drug Usage in special Population-Pregnancy and Lactation, Educational Series-II, 7th Edition 2018, published by Karnataka State Pharmacy Council, Bangalore.

Guest Column

Nagarjuna Reddy, M. Pharm
Patient safety Pharmacovigilance
Associate, NCC-PvPI, IPC
Adverse drug reaction monitoring center:
Indira Gandhi Institute of Child Health, Bengaluru

Pharmacovigilance Programme of India (PvPI)
National Coordination Centre (NCC)
Indian Pharmacopoeia Commission (IPC)
Ministry of Health & Family welfare Government of India

Dear Healthcare professionals/Consumers,

The Pharmacovigilance Program of India (PvPI) was launched with a broad objective to safe guard the health of 1.27 billion people of India. Adverse drug Reactions (ADRs) are reported from all over the country to NCC-PvPI, which also work in collaboration with the global ADR monitoring centre (WHO-UMC), Sweden to contribute in the global ADRs data base. NCC-PvPI monitors the ADRs among Indian population and helps the regulatory authority of India (CDSCO) in taking decision for safe use of medicines. I invite all the health care professionals and patients/consumers to join us in our mission to promote patient safety.

The NCC-PvPI provides scientific support for vital functions of CDSCO in the regulation of drug safety. The Individual Case Safety Reports (ICSRs) are collected/collated in a scientific way and analysed to facilitate appropriate decisions at CDSCO.

Who can report?

- All healthcare professionals (clinicians, dentists, pharmacists, NURSES etc.,)
- Non-healthcare professionals including Consumers/patients
- Pharmaceutical industries

Why to report?

- All healthcare professional, it is a moral responsibility to report ADR associated with use of medicines and safeguard the health of public
- India has a vast genetic and ethnic variability with different disease prevalence
- Use of multi-modal practices
- Poor patient compliance

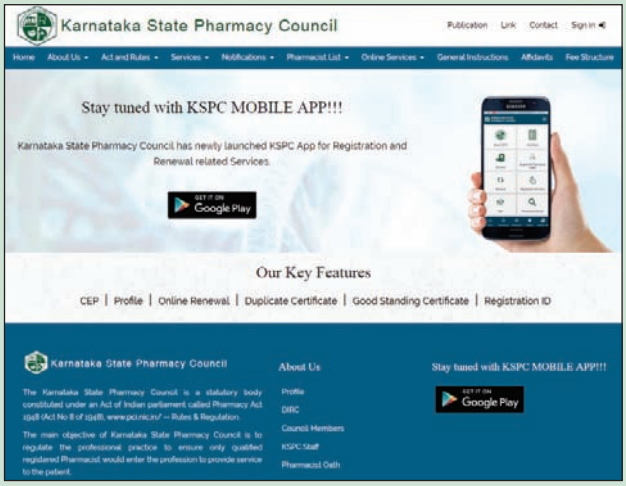
What to report?

- In order to foster the culture of reporting, PvPI encourages reporting of all types of suspected ADRs- irrespective of whether they were known or unknown, serious or non-serious, frequent or rare and regardless of an established casual relationship
- Pharmacovigilance is primarily concerned with medicines, vaccines, traditional medicines, medical devices, contrast media and other pharmaceuticals.

How and whom to report?

- Use the "suspected adverse drug reaction form" which is available on the official website of IPC www.ipc.gov.in and www.cdsco.nic.in
- Toll free number: **1800-180-3024**
- Patient safety Pharmacovigilance associate from **AMC** centers across the country.
- Mail to pvpi.ipcindia@gmail.com
- Android app: PvPI ADR app in Google play store https://play.google.com/store/apps/details?id=com.vinfotech.suspectedadversedrugreaction&hl=en

'KSPCDIC' Mobile App



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

KSPC News

1. Rajiv Memorial Education Society's College of Pharmacy, Kalaburagi

Sri. Gangadhar V.Yavagal, President, Karnataka State Pharmacy Council was the guest of honour for the Silver Jubilee Celebration and Alumini Meet of Rajiv Memorial Education Society's College of Pharmacy, Kalaburagi held on 23-01-2018 at S.M.Pandit Rangamandir, Kalaburagi. During this celebration Dr.B.Suresh, President, Pharmacy Council of India, New Delhi was honored with **'Prestigious Pharma Ratna Award 2018'** by Hyderabad Karnataka Pharmacy Excellence Academy. A 'Pharma Future' news bulletin was released during this event.

2. Continuing Pharmacy Education (CPE) programme, Bengaluru

The demo of Continuing Pharmacy Education (CPE) programme was conducted for the Pharmacy Principals of the selected centers on 06/01/2018 at the seminar room of Karnataka State Pharmacy Council,

Bengaluru. The program included the various steps involved like Registration for CPE by the Registered Pharmacist, the role of Center Co-ordinators-Principals in respective centers, pre and post evaluation forms, feedback form by the registered participants before and after the CPE programme and its verification etc. was demonstrated. 30 Principals from various centers participated in the program.

KPCRPWT Compensation

The death compensation of Rs.1,00,000/- was handed over to the nominee Sri. K.R. Rangereji son of Sri. Ravindra Sa Ramakrishnasarangre, Reg.No.3990 by Sri. Gangadhar V Yavagal, President and Prof.B.G.Shivananda, Registrar, Karnataka State Pharmacy Council, Bengaluru at Council office on 05-01-2018.

Pharmacy Practice Regulations, 2015

Displaying name of owner and registered pharmacist:

3 (3.3) a) Name of the owner of pharmacy business shall be displayed at or near the main entrance of each premises in which the business is carried on.

b) Name of the registered pharmacist along with his registration number and qualification along with his/her photograph shall be displayed adjacent to the area where dispensing is carried on in the pharmacy. Registered pharmacist shall also comply with a dress code of, being dressed formally and wearing clean white overall (coat/apron) with a badge displaying the name and registration number.

c) Registered pharmacists shall display as suffix to their names only recognized pharmacy qualification / degrees or such certificates / diplomas and memberships / honours which confer professional knowledge or recognizes any exemplary qualification / achievements.

ಭೇಷಜೀ ಪರಿಕರ್ಮ ನಿಬಂಧನೆಗಳು, 2015

ಮಾಲೀಕರ ಮತ್ತು ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರ ಹೆಸರು ಪ್ರದರ್ಶಿಸುವುದು:

(ಎ) ಭೇಷಜೀ ವ್ಯವಹಾರ ಸಂಸ್ಥೆಯ ಮಾಲೀಕರ ಹೆಸರು, ಆ ಸಂಸ್ಥೆಯ ವ್ಯವಹಾರ ನಡೆಯುತ್ತಿರುವ ಪ್ರತಿಯೊಂದು ಆವರಣದಲ್ಲೂ, ಹೆಬ್ಬಾಗಿಲಿನಲ್ಲಿ ಅಥವಾ ಅದರ ಸಮೀಪದಲ್ಲೇ ಪ್ರದರ್ಶಿಸಲ್ಪಡತಕ್ಕದ್ದು.

(ಬಿ) ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರ ಹೆಸರು, ಆತನ ನೋಂದಣಿ ಸಂಖ್ಯೆ ಮತ್ತು ವಿದ್ಯಾರ್ಹತೆಗಳು ಅತನ/ಅವಳ ಭಾವಚಿತ್ರದೊಂದಿಗೆ, ಭೇಷಜೀಯಲ್ಲಿ ಎಲ್ಲಿ ವಿನಿಯೋಗ ಕ್ರಿಯೆ ನಡೆಸಲಾಗುತ್ತದೆಯೋ ಆ ಸ್ಥಳದ ಪಕ್ಕದಲ್ಲೇ ಪ್ರದರ್ಶಿಸಲ್ಪಡತಕ್ಕದ್ದು. ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರು, ಒಂದು ವಸ್ತ್ರ ಸಂಹಿತೆಗೆ ಬದ್ದರಾಗಿ, ಔಪಚಾರಿಕ ಉಡುಪು ಧರಿಸಿದ್ದು, ಮತ್ತು ಶುಚಿಯಾದ ಬಳಿ ಮೇಲು ವಸ್ತ್ರ (ಕೋಟು/ಏಪ್ರಾನ್) ಧರಿಸಿಕೊಂಡು ಅದರ ಮೇಲೆ ಹೆಸರು ಮತ್ತು ನೋಂದಣಿ ಸಂಖ್ಯೆ ಪ್ರದರ್ಶಿಸುತ್ತಿರುವ ಒಂದು ಬಿಲ್ಲೆಯನ್ನು ಧರಿಸಿರತಕ್ಕದ್ದು.

(ಸಿ) ಯಾವ ಅನುಮೋದಿತ ಭೇಷಜೀ ವಿದ್ಯಾರ್ಹತೆ/ಪದವಿಗಳು ಅಥವಾ ಅಂತಹ ಪ್ರಮಾಣ ಪತ್ರಗಳು / ಡಿಪ್ಲೊಮಾಗಳು ಮತ್ತು ಸದಸ್ಯತ್ವಗಳು /ಗೌರವ ಪದವಿಗಳು ವೃತ್ತಿಪರ ಜ್ಞಾನ ನೀಡುವಂತಹುಗಳಾಗಿವೆ ಅಥವಾ ಯಾವುದೇ ಅನುಪವ ಅರ್ಹತೆ / ಸಾಧನೆಗಳನ್ನು ಪ್ರಧಾನ ಮಾಡುವಂತಹುದಾಗಿವೆಯೋ ಅಂತಹುಗಳನ್ನು ಮಾತ್ರ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರು ತಮ್ಮ ಹೆಸರುಗಳಿಗೆ ಹಿಂಬರೆಹಗಳನ್ನಾಗಿ ಪ್ರದರ್ಶಿಸಿಕೊಳ್ಳತಕ್ಕದ್ದು.

Additional Information on any article is available on request
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