DIRC Newsletter

Vol. 18 No. 4 October - December 2016

Newsletter of Drug Information and Research Center, KSPC

Member of International Society of Drug Bulletins (ISDB)

Official Desk

Pharmacy Practice Regulation (PPR), 2015

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President
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Pharmacy is a rapidly changing field. Staying current on new drugs, dosage forms, laws, and regulations is important for a practicing Pharmacist.

As per the Pharmacy Council of India (PCI), the Pharmacists who are practicing either in a hospital or in a community pharmacy are not getting the opportunity to update their knowledge base. As a result, they are not able to cater to the needs of the physician or the patients up to the expected level. Hence, the PCI has proposed to conduct Continuing Pharmacy Education (CPE) by the State Pharmacy Councils. Continuing Pharmacy Education (CPE) may include reading pharmacy journals and newsletters or attending workshops and professional meetings.

The Pharmacy Practice Regulation (PPR), 2015 published by The Government of India Notification No. 14.148/2012PCI, dated: 15.01.2015 published in the Gazette of India and republished in Karnataka State Gazette vide Notification No. HFW 163 PTD 2016, Bengaluru, the 17th June, 2016 also specifies to conduct CPE.

As per the PCI and PPR 2015 for renewal of Registration, the Pharmacist should give evidence of his being practice and shall attend 2 refresher course in Pharmacy or CPE (with a gap of 20 months) of minimum one day duration each in a span of 5 years organized and conducted by Karnataka State Pharmacy Council. The Registered Pharmacists should submit the certificate of participation to retain his / her name in Karnataka State Pharmacy Council Register in accordance with Rule 4.2 of PPR 2015.

In this regard, Karnataka State Pharmacy Council is in the process of starting CPE for the Registered Pharmacist. This program will be done in 5-6 zones depending upon the needs and initiated through selected Pharmacy colleges with in Karnataka. The CPE will have five topics, which will cover pharmacy promotion, pharmaceutical care, patient counselling, health education and regulations.

Hence, Continuing Pharmacy Education (CPE) programme organized by council will be a boon to the practicing pharmacists.

Hence, the pharmacists are requested to gear up to cope with the needs in the best interest of public service.

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Implementation of Pharmacy Practice Regulations, 2015

(The Government of India Notification No. 14.148/2012-PCI, dated: 15.01.2015 published in the Gazette of India dated Friday January 16, 2015)

(Republished in Government of Karnataka Gazette videNotification No. HFW 163 PTD 2016, Bangalore, the 17th June, 2016)

The Pharmacy Council of India has brought out the Pharmacy Practice Regulations, 2015 and published in the Government of India Gazette. The same was republished by Government of Karnataka Gazette in 2016 (refer notification above).

The main objective of framing the Pharmacy Practice Regulations is

- ✓ To improve quality of healthcare
- ✓ To ensure that Pharmacists maintain high standards in their duty.
- ✓ To reduce cost of healthcare
- ✓ To inhibit criminal abuse of medicines

The Pharmacy Practice Regulations, 2015 contains Chapters from 1-9 which covers the following like definitions, code of pharmacy ethics, duties and responsibilities of the registered pharmacist in general, pharmacy inspectors to inspect pharmacies, maintaining good pharmacy practice, application of other laws not barred, duties of registered pharmacists to their patients, duties of registered pharmacist, responsibilities of registered pharmacists to each other, duties of registered pharmacist to the public and to the profession, unethical acts, misconduct, punishment and disciplinary action, appendix, format for prescription record.

More details of the Pharmacy Practice Regulations, 2015 can be viewed on council website under Act and Rules (www.kspcdic.com) ❑

Drug of the Quarter

Drug : **Perampanel**

Class : Anticonvulsant

Dosage Form : Tablet

DCGI Approval : 2nd December 2016

USFDA Approval : 22nd October 2012

Indication : This drug is indicated for adjunctive treatment of partial-onset seizures with or without secondary generalization in patients with epilepsy 12 years of age and above.

Dose Information

Adult Dosing: Partial-Onset seizures & Primary Generalized Tonic-Clonic Seizures: Initially start with 2 mg once daily taken orally at bedtime. Increase dosage by increments of 2 mg once daily no more frequently than at weekly intervals.

Pediatric Dosing: (12 years or older) Same as Adult dose.

Pharmacokinetics

Absorption

- Tmax, Oral: 0.5 to 2.5 hours
- Bioavailability, Oral: Rapid and complete
- Effects of food: Food does not affect the extent of absorption (AUC), but slows the rate of absorption.

Distribution

Protein binding, plasma proteins mainly albumin and alpha 1-acid glycoprotein: 95% to 96%.

Metabolism

- Liver: Extensively metabolized by liver via primary oxidation and sequential glucuronidation.

Excretion

- Fecal: 48%
- Renal: 22%
- Total body clearance: 12 mL/min

Elimination Half Life: 105 hours

Caution

- Psychiatric and behavioral reactions, including severe and life-threatening reactions and hostility-and aggression-related reactions, have been reported. Monitoring is necessary and dose should be reduced if the patient exhibits symptoms and discontinued for persistent severe or worsening psychiatric behaviors or symptoms.
- Avoid concomitant use with alcohol. It may significantly worsen mood and increase anger.
- Increased risks in the elderly have occurred due to falls, occasionally leading to serious injuries including head injuries and bone fracture.
- Use in severe hepatic impairment not recommended.
- Increased risk in the elderly due to neurologic effects, including dizziness, vertigo, gait disturbance, somnolence, and fatigue-related events, have been reported.
- Increased risk for suicidal behavior and ideation. Monitoring recommended.
- Use in severe renal impairment or undergoing hemodialysis not recommended.
- Increased risk of seizure frequency due to abrupt withdrawal of the treatment.

Mechanism of Action/Pharmacology

Although the exact mechanism of action of perampanel has not been fully determined, it exerts its antiepileptic effects by reducing neuronal excitation via the noncompetitive antagonism of the ionotropic-AMPA-glutamate receptor on postsynaptic neurons.

Adverse Effects

Common

- **Neurologic:** Abnormal gait,dizziness, headache, somnolence
- **Psychiatric:** Irritability, mood disorder
- **Other:** Fatigue

Serious

- **Dermatologic:** Drug reaction with eosinophilia and systemic symptoms
- **Psychiatric:** Aggressive behavior, homicidal thoughts, suicidal thoughts

Drug-Drug interactions

Category	Drug/s (Example)	Interaction Effect	Management
Alcohol & Other CNS Depressants*	Buprenorphine, Codeine Doxylamine, Hydrocodone, Pentazocine, Tramadol	Additive risk of CNS depression (ie, respiratory depression, pro-found sedation, coma)	Avoid concomitant use.
Antifungal Antibiotic*	Fluconazole	Increases Perampanel plasma concentrations.	Avoid concomitant use.
Cytochrome P450 Inducers	Carbamazepine, Phenytoin, Oxcarbazepine, Fentanyl, Orlistat	Decreases Perampanel plasma concentrations.	Use caution if concomitant use is required.
Contraceptives	Levonorgestrel	Decreases contraceptive effec-tiveness.	Use caution if concomitant use is required.

Severity: *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 Perampanel 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 advice patient or caretakers to immediately report worsening of depression, suicidal ideation or psychiatric or behavioral reactions (aggression, hostility, anger).
- Please instruct patient to avoid activities requiring mental alertness or coordination until drug effects are realized, as drug may cause dizziness, somnolence and fatigue.
- Please counsel patient that this drug may cause balance disorder, vertigo, gait problems, ataxia, irritability, nausea, or weight gain.
- Please advice patient patient against sudden discontinuation of drug as this may increase seizure frequency.
- Strictly instruct patient to avoid alcohol with this drug.

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

Meaning: AMPA- AMPA (α-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid) is a compound that is a specific agonist for the AMPA receptor, where it mimics the effects of the neurotransmitter glutamate. ❑

Safety Information

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)	Potential Signal of a Serious Risk / New Safety Information	Additional Information
July - September 2016			
Cardiovascular Agent	Ivabradine	Ventricular arrhythmias	Evaluation is in progress. **(as of 3rd November 2016)**
Anticoagulant	Apixaban, Dabigatran, Rivaroxaban	Vasculitis	Evaluation is in progress. **(as of 3rd November 2016)**
Dermatological Agent	Deoxycholic acid	Injection-site alopecia	Evaluation is in progress. **(as of 3rd November 2016)**
Alpha-Adrenergic Agonist	Midodrine hydrochloride	Interaction with monoamine oxidase inhibitors (MAOIs) may lead to a risk of cerebrovascular accident	Evaluation is in progress. **(as of 3rd November 2016)**
Calcium Regulator	Cinacalcet	Gastrointestinal bleeding	Evaluation is in progress. **(as of 3rd November 2016)**

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

Meanings : Thrombotic Thrombocytopenic Purpura : A rare blood disorder characterized by clotting in small blood vessels of the body, **Vasculitis :** An inflammation of the blood vessels that causes changes in the blood vessel walls. ❑

Continuing Pharmacy Education (CPE)

Dispensing Instructions to the Pharmacists

Depression-Drug Therapy

Depression is a disorder of the brain. According to the World Health Organization (WHO) globally, an estimated 350 million people of all ages suffer from depression.

In India, around 10.6 lakh more prescriptions for anti-depressants were written in 2016 in comparison to 2015, shows data collated by health information agencies. While 3.35 crore prescriptions (for newly diagnosed patients) were written in 2015, doctors wrote 3.46 crore new prescriptions in 2016.

There are a variety of causes, including genetic, biological, environmental and psychological factors for depression.

It causes severe symptoms that affect how a person feels, think and handle daily activities, such as sleeping, eating or working.

Anti-depressants are drugs that treat depression and improve the symptoms. They correct chemical imbalances of neurotransmitters in the brain which probably cause changes in mood and behavior.

Antidepressants were initially developed in the 1950s. Their use has become progressively more common over the last twenty years.

The most popular types of antidepressants are,

- Selective serotonin reuptake inhibitors (SSRIs)- egs: Fluoxetine, Citalopram, Sertraline, Paroxetine, Escitalopram,

Other types of antidepressants are,

- Serotonin and norepinephrine reuptake inhibitors (SNRIs) - egs: Venlafaxine, Duloxetine. SNRIs are similar to SSRIs.

Another antidepressant that is commonly used is Bupropion which works differently than either SSRIs or SNRIs. Bupropion is also used to treat seasonal affective disorder and to help people stop smoking.

SSRIs, SNRIs, and Bupropion are popular because they do not cause as many side effects as older classes of antidepressants and seem to help a broader group of depressive and anxiety disorders.

Older antidepressant medications include tricyclics, tetracyclics and monoamine oxidase inhibitors (MAOIs).

Below is a brief overview of few drugs.

Drugs	Use	Warnings*	Less serious side effects	Advice
Fluoxetine Drugs Contraindicated: MAO inhibitors or thioridazine	Treatment of depression, obsessive-compulsive disorder, panic disorder, premenstrual dysphoric disorder.	Prescription to be reconfirmed in case of patients with a history of liver disease, kidney disease, diabetes or pancreas problems.	Abnormal ejaculation or impotence, nausea, dry mouth, dyspepsia, diarrhea, anxiety, insomnia, nervousness, somnolence, tremor, asthenia, rash, sweating, weight loss.	Do not discontinue this drug without the advice of the doctor. This medicine may affect mental alertness and or co-ordination. Advice the patient to avoid driving vehicle or operate machinery while taking this medicine. Advise to avoid alcohol.
Citalopram Drugs Contraindicated: MAO inhibitors	Treatment of depression.	Prescription to be reconfirmed in case of patients with a history of liver disease, kidney disease, diabetes or pancreas problems.	Ejaculation disorder, fatigue, impotence, nausea, somnolence, dizziness, diarrhea, lightheadedness/ fainting, confusion, hallucinations dry mouth, rhinitis, sweating, tremor.	Do not discontinue this drug without the advice of the doctor. Advise to take with or without food. This medicine may affect mental alertness and or co-ordination. Advice the patient to avoid driving vehicle or operate machinery while taking this medicine. Advise to avoid alcohol.
Sertraline Drugs Contraindicated: Pimozide MAOI drugs	Treatment of depression, obsessive compulsive disorder, panic disorder, post-traumatic stress disorder, premenstrual dysphoric disorder, social anxiety disorder.	Prescription to be reconfirmed in case of patients with a history of seizures, diabetes, liver disease or kidney disease.	Abnormal ejaculation, nausea, decreased libido, diarrhea, agitation, insomnia, fatigue, somnolence, tremor, tremor, anorexia, dry mouth, visual abnormalities, dyspepsia, constipation, vomiting, dizziness, headache, sweating, yawning.	Advise to take with food to avoid stomach upset. Advise the patient not to stop taking this medicine abruptly unless otherwise advised by doctor. This medicine may affect mental alertness and or co-ordination. Advice the patient to avoid driving vehicle or operate machinery while taking this medicine.
Paroxetine Drugs Contraindicated: Monoamine oxidase inhibitor, thioridazine.	Treatment of depression, social anxiety disorder, obsessive, panic disorder, generalized anxiety compulsive disorder, post-traumatic stress disorder, premenstrual dysphoric disorder.	Prescription to be reconfirmed in case of patients with a history of liver disease, epilepsy or a history of mania or bipolar disorder.	Anorexia, constipation, diarrhea, dry mouth, tremor, flatulence, nausea, anxiety, anorgasmia, abnormal ejaculation, erectile difficulties, dizziness, insomnia, nervousness, somnolence, asthenia, sweating, yawning, blurred vision.	This medicine is usually taken in the morning. Advise to take with or without food. Advise not to stop taking this medicine abruptly unless otherwise advised by doctor. This medicine may affect mental alertness and/or co-ordination. If affected, advise not to drive a motor vehicle or operate machinery. Advise to avoid alcohol.
Escitalopram Drugs Contraindicated: MAO inhibitors, pimozide	Treatment of depression, generalized anxiety disorder.	Prescription to be reconfirmed in case of patients with a history of kidney disease, liver disease, heart disease, a seizure disorder such as epilepsy, or a history of mania or bipolar disorder.	Diarrhea, nausea, sleeps disorders (somnolence or insomnia), ejaculation disorder, impotence, diaphoresis, fatigue.	Advise to take with or without food. Advise the patient not to drive a motor vehicle or operate machinery. Advise to avoid alcohol.

Drugs	Use	Warnings*	Less serious side effects	Advice
Venlafaxine Drugs Contraindicated: MAOIs.	Treatment of depression, generalized anxiety disorder (extended-release), social anxiety disorder (extended-release).	Prescription to be reconfirmed in case of patients with a history of liver disease, kidney disease or seizures.	Abnormal ejaculation, anorgasmia, impotence, anorexia, constipation, weight loss diarrhea, dyspepsia, anxiety, dizziness, insomnia, nervousness, somnolence, tremor, asthenia, dry mouth, nausea, vomiting, sweating, rash, blurred vision, mydriasis.	Advise to take with food and a full glass of liquid. Advice the patient to avoid driving vehicle or operate machinery while taking this medicine. Advise to avoid alcohol.
Duloxetine Drugs Contraindicated: MAOIs.	Treatment of depression, anxiety disorder, diabetic peripheral neuropathy, musculoskeletal pain.	Prescription to be reconfirmed in case of patients with a history of kidney disease, liver disease, heart disease, high or low blood pressure or problems with urination.	Insomnia, somnolence, headache, nausea, diarrhea, and dry mouth, fatigue, constipation, decreased appetite, gastritis (frequent) dizziness, dysuria (frequent), increased sweating, blurred vision.	Advise the patient not to chew, crush or sprinkle the contents on food or mix with liquids before swallowing. Advice the patient to avoid driving vehicle or operate machinery while taking this medicine. Advise to avoid alcohol.
Bupropion Drugs Contraindicated: MAO inhibitor including linezolid or IV methylene blue.	Treatment of Depression. (smoking cessation).	Prescription to be reconfirmed in case of patients with a history of liver disease, kidney disease, heart disease, high blood pressure, diabetes or mental problems such as bipolar (manic-depressive) disorder.	Agitation, anxiety, confusion, auditory disturbance, blurred vision, constipation, dry mouth, gustatory disturbance, nausea / vomiting, dizziness, headache, hostility, impaired sleep quality, insomnia, menstrual complaints, pruritus, rash, sweating, weight changes, tremor.	Advise to take with or without food. Advice the patient to avoid driving vehicle or operate machinery while taking this medicine Advise to avoid alcohol.

References:

1. Handbook of Pharma SOS, Educational Series-III, 6th Edition 2014, published by Karnataka State Pharmacy Council, Bangalore.
2. www.micromedexsolutions.com, Micromedex (R) 2.0, 2002-2017, Truven Health Analytics Inc.
3. http://emedicine.medscape.com/
4. http://www.drugs.com

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

Store the medicine in a closed container at room temperature, away from heat, moisture and direct light. ❑

Drug Usage in Special Population - Pediatrics and Geriatrics

(From our publications)

Diuretics

Drug (Oral)	Use in Children (Paediatrics)	Use in Elderly (Geriatric)
Amiloride	Safety and effectiveness have been established.	No dosage adjustment required.
Acetazolamide	Safety and effectiveness in children have not been established.	No dosage adjustment required.
Bisoprolol+ Hydrochlorothiazide	Safety and effectiveness in children have not been established.	No dosage adjustment required.
Bumetanide	Safety and effectiveness in children have not been established.	No dosage adjustment required.

Reference: Drug Usage in special Population-Pediatrics and Geriatrics, Educational Series-II, 6thEdition 2016, published by Karnataka State Pharmacy Council, Bangalore.

Drug Usage in Special Population - Pregnancy and Lactation

(From our publications)

Diuretics

Drug (Oral)	Use in Pregnancy (Teratogenicity)	Use in Breastfeeding (Lactation)
Amiloride	USFDA Category B. Limited data on Hydrochlorothiazide during pregnancy. To be used when benefit outweighs risk.	Data not available. Medical advice is necessary.
Acetazolamide	USFDA Category C. Insufficient data to confirm its safety in pregnancy.Use only if the potential benefit outweighs the potential risk to the fetus.	Data not available. Medical advice is necessary.
Bisoprolol+ Hydrochlorothiazide	USFDA Category C. Insufficient data to confirm its safety in pregnancy. Use only if the potential benefit outweighs the potential risk to the fetus.	Data not available. Medical advice is necessary.
Bumetanide	USFDA Category C. Contraindicated in pregnancy because it reduces the uteroplacental perfusion (eg, preeclampsia and intrauterine growth retardation) or cause severe hemo-concentration. Use only if the potential benefit outweighs the potential risk to the fetus.	Data not available. Medical advice is necessary.

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-I, 6th Edition 2016, published by Karnataka State Pharmacy Council, Bangalore.

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Drug News – Around the Globe

1. Drug: Deflazacort** **Country: USA**

Deflazacort is a corticosteroid.

Approved Indications: Deflazacort tablet and oral suspension is approved to treat patient's aged 5 years and above with Duchenne muscular dystrophy (DMD). This works by decreasing inflammation and reducing the activity of the immune system.

Side-effects: Facial puffiness (Cushingoid appearance), weight gain, increased appetite, upper respiratory tract infection, cough, extraordinary daytime urinary frequency (pollakiuria), unwanted hair growth (hirsutism) and excessive fat around the stomach (central obesity)[1].

2. Drug: Plecanatide* **Country: USA**

Plecanatide is a gastrointestinal agent.

Approved Indications: Plecanatide is used for the treatment of Chronic Idiopathic Constipation (CIC) in adult patients.Safety and effectiveness of Plecanatide have not been established in patients less than 18 years of age due to deaths due to dehydration. Plecanatide should not be used in patients with known or suspected mechanical gastrointestinal obstruction.

Side-effects: Diarrhea[1].

3. Drug: Sodium Oxybate* **Country: USA**

Sodium Oxybate is an anesthetic-hypnotic agent used in general anesthesia.

Approved Indications: Sodium oxybate oral solution is used to treat cataplexy and excessive daytime sleepiness in patients with narcolepsy, which is a potentially debilitating disease. Sodium oxybate is the only medication approved to treat cataplexy in patients with narcolepsy.

Side-effects: Seizures, trouble breathing, changes in alertness, coma and death[1].

4. Drug: Nusinersen* **Country: USA**

Nusinersen is an anesthetic-hypnotic agent used in general anesthesia.

Approved Indications: Nusinersen injection is the first drug approved to treat children and adults with spinal muscular atrophy (SMA).

Side-effects: Upper respiratory infection, lower respiratory infection and constipation[1].

5. Drug: Brodalumab* **Country: USA**

Brodalumab is an immunosuppressant.

Approved Indications: Injection Brodalumab is used to treat adults with moderate-to-severe plaque psoriasis.Brodalumab is intended for patients who are candidates for systemic therapy (treatment using substances that travel through the bloodstream, after being taken by mouth or injected) or phototherapy (ultraviolet light treatment) and have failed to respond, or have stopped responding to other systemic therapies.

Side-effects: Joint pain (arthralgia), headache, fatigue, diarrhea, throat pain (oropharyngeal pain), nausea, muscle pain (myalgia), injection site reactions, influenza, low white blood cell count (neutropenia) and fungal (tinea) infections[1].

6. Drug: Desmopressin** **Country: USA**

Desmopressinis a synthetic vasopressin analogue.

Approved Indications: Desmopressinnasal spray is approved for adults who awaken at least two times per night to urinate due to a

condition known as nocturnal polyuria (overproduction of urine during the night). Desmopressin is the first FDA-approved treatment for this condition.

Desmopressin is being approved with a special warning because it can cause low sodium levels in the blood (hyponatremia). Severe hyponatremia can be life-threatening if it is not promptly diagnosed and treated, leading to seizures, coma, respiratory arrest or death. Health care professionals should make sure the patient's sodium level is normal before starting Desmopressin and should check sodium levels within one week and approximately one month after starting treatment and periodically thereafter.Desmopressin is also not recommended for the treatment of nocturia in pregnant women. Desmopressinshould not be used in children.

Side-effects: Nasal discomfort, cold symptoms (nasopharyngitis), nasal congestion, sneezing, high or increased blood pressure, back pain, nose bleeds, bronchitis and dizziness[1].

7. Drug: Telotristat* **Country: USA**

Telotristat is a gastrointestinal agent.

Approved Indications: Telotristat tablet is approved in combination with somatostatin analog (SSA) therapy for the treatment of adults with carcinoid syndrome diarrhea that SSA therapy alone has inadequately controlled.

Telotristat in combination with SSA therapy, is approved in tablet form to be taken orally three times daily with food. Telotristat inhibits the production of serotonin by carcinoid tumors and reduces the frequency of carcinoid syndrome diarrhea.

Side-effects: Nausea, headache, increased levels of the liver enzyme gamma-glutamyl transferase, depression, accumulation of fluid causing swelling (peripheral edema), flatulence, decreased appetite and fever 1.

Reference: ww.fda.gov

Note - *Not available in India ****Available in India**

Meanings: Carcinoid syndrome- A chronic condition caused by neuroendocrine tumors that usually originate from the gastrointestinal tract and is characterized by severe diarrhea and flushing episodes with long-term consequences that may include cardiac valve disease. **Duchenne muscular dystrophy (DMD)-** A rare genetic disorder that causes progressive muscle deterioration and weakness, **Spinal muscular atrophy (SMA)-** A rare and often fatal genetic disease affecting muscle strength and movement.

Safety Alerts

1. Drugs: Chlorhexidine Gluconate** **Country: USA**

- May cause serious allergic reactions

Chlorhexidine gluconate is an antibacterial agent.

Alert: The USFDA warns that rare but serious allergic reactions have been reported with the widely used skin antiseptic products containing chlorhexidine gluconate. These reactions can occur within minutes of exposure. Symptoms include wheezing or difficulty breathing, swelling of the face, hives that can quickly progress to more serious symptoms, severe rash or shock, which is a life-threatening condition that occurs when the body is not getting enough blood flow.

Hence, KSPC-DIRC alerts the healthcare professionals to confirm from patients, if they ever had an allergic reaction to any antiseptics before recommending or prescribing a Chlorhexidine Gluconate product or watchout for the said symptoms if inevitable[1].

Reference: ww.fda.gov

Note - **Available in India

KSPC News

68th Indian Pharmaceutical Congress (IPC), Visakhapatnam

The President, Vice-President, Registrar, Dy.Registrar & DIRC Pharmacist and the members of Karnataka State Pharmacy Council, Bengaluru attended the three days Indian Pharmaceutical Congress (IPC) conference held during at Visakhapatnam,Hyderabad during 16th -18th December 2016. The theme of 68th IPC was "Quality Pharmaceuticals and Patient Welfare".

Visitors of Honour

1. Delhi Pharmacy Council

Sri. S.L. Nasa, Registrar, Delhi Pharmacy Council, Delhi visited the council to study and discuss the functional methods of this council and Drug Information and Research Center.

Sri. D.A. Gundu Rao, Vice-President, Karnataka State Pharmacy Council, Prof. B.G.Shivananda, Registrar, Karnataka State Pharmacy Council welcomed and presented a set of KSPC publications and DIRC Newsletter to Sri. S.L. Nasa.

He appreciated the activity and had wide range of discussion on the professional status and development of Pharmacy.

2. Tripura State Pharmacy Council

Sri. Anirban Kar, Member of Tripura State Pharmacy Council, Tripura visited the council to study and discuss the functional methods of this council and Drug Information and Research Center.

Prof. B. G. Shivananda, Registrar, Karnataka State Pharmacy Council, Sri.M.S.Nagaraj, Member, Karnataka State Pharmacy Council along with Dr. R.S.Thakurwelcomed and presented a set of KSPC publications and DIRC Newsletter to Sri. AnirbanKar.

He appreciated the activity and development of Karnataka State Pharmacy Council and Drug Information and Research Center.

ಅಧಿಸೂಚನೆ (Notification)

ಕರ್ನಾಟಕ ಸರ್ಕಾರವು ಫಾರ್ಮಸಿ ಪ್ರಾಕ್ಟೀಸ್‌ರೆಗ್ಯುಲೇಶನ್ 2015 (ಪಿಪಿಆರ್, 2015), ಅನ್ನು ಕರ್ನಾಟಕ ಗೆಜೆಟ್, ಸಂಪುಟ 151, ನವೆಂಬರ್ 24, 2015 ರ ಸಂಚಿಕೆಯಲ್ಲಿ ಅಧಿಸೂಚನೆ ಸಂಖ್ಯೆ ಎಚ್‌ಎಫ್‌ಡಬ್ಲ್ಯು 163 ಪಿಟಿಡಿ 2016, ದಿನಾಂಕ ಜೂನ್ 17, 2016 ರಂತೆ ಪುನಃ ಪ್ರಕಟಿಸಿರುತ್ತದೆ.

ಎಲ್ಲಾ ನೋಂದಾಯಿತ ಫಾರ್ಮಾಸಿಸ್ಟ್‌ರು (ಅಜೀವ ಸದಸ್ಯರು (Life Member), ಎಲ್‌ಟಿಆರ್ ಶುಲ್ಕ ಹಣ ಪಾವತಿಸಿದವರು (LTR Fees), ಕಾಯಂ ಶುಲ್ಕ ಹಣ ಪಾವತಿಸಿದವರು (fees permanently paid)) ತಮ್ಮ ನೋಂದಣಿಯನ್ನು ಫಾರ್ಮಸಿ ಕಾಯಿದೆ 1948, ಸೆಕ್ಷನ್. 34ರ ವಿಧಿಯಅನ್ವಯ ನವೀಕರಿಸುವುದುಅಗತ್ಯ.

ಕಾಯಿದೆಅನ್ವಯ, ನೊಂದಣಿಯಾದ ವರ್ಷ ದ ನಂತರ, ಅಂದರೆ ಡಿಸೆಂಬರ್ 31ರ ನಂತರ ಫಾರ್ಮಾಸಿಸ್ಟ್‌ರು ತಮ್ಮ ಹೆಸರನ್ನು ರಿಜಿಸ್ಟರಿನಲ್ಲಿ ಜೀವಂತ ಇರಿಸಿಕೊಳ್ಳಲು, ನಿಗದಿತ ವಾರ್ಷಿಕ ಶುಲ್ಕವನ್ನು ಪ್ರತೀ ವರ್ಷ ಪಾವತಿಸುವ ಮೂಲಕ ನವೀಕರಿಸಿಕೊಳ್ಳಬೇಕು. ನವೀಕರಣದ ಶುಲ್ಕಗಳನ್ನು ಸಂಬಂಧಿಸಿದ ವರ್ಷದ ಮಾರ್ಚ್ 31ನೇ ದಿನಾಂಕಕ್ಕಿಂತ ಮೊದಲೇ ಪಾವತಿಸಬೇಕು.

ಫಾರ್ಮಸಿ ಪ್ರಾಕ್ಟೀಸ್‌ರೆಗ್ಯುಲೇಶನ್ 2015ರ (Pharmacy Practice Regulation, 2015), ಪ್ರಕಾರ ನೋಂದಣಿಯ ನವೀಕರಣಕ್ಕೆ ಫಾರ್ಮಾಸಿಸ್ಟ್‌ರು 5 ವರ್ಷಗಳ ಕಾಲಾವಧಿಯಲ್ಲಿ ರಾಜ್ಯದ ಫಾರ್ಮಸಿ ಕೌನ್ಸಿಲ್‌ನಿಂದ ಸಂಘಟಿಸಲಾಗುವ ಒಂದು ದಿನದ ಅವಧಿಯ ಕನಿಷ್ಠ 2 ಫಾರ್ಮಸಿ ರಿಫ್ರೆಶರ್ ಕೋರ್ಸುಗಳಿಗೆ ಹಾಜರಾಗತಕ್ಕದ್ದು. (ನಿಯಮ. 4.2, ಪಿಪಿಆರ್, 2015) ಈ ವಿಚಾರವಾಗಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಫಾರ್ಮಸಿ ಪರಿಷತ್ತನ್ನು ಸಂಪರ್ಕಿಸತಕ್ಕದ್ದು.

ಕೌನ್ಸಿಲ್‌ಎಲ್ಲ ನೋಂದಾಯಿತ ಫಾರ್ಮಾಸಿಸ್ಟ್‌ರ ವಾಸದ ಖಾಯಂ ಹಾಗೂ ವೃತ್ತಿಪರ ವಿಳಾಸ, ಆಧಾರ್ ಸಂಖ್ಯೆ, ಮೊಬೈಲ್ ಸಂಖ್ಯೆ ಮತ್ತು ಇಮೇಲ್ ಅನ್ನು ಅಪ್‌ಡೇಟ್ ಮಾಡುವ ಪ್ರಕ್ರಿಯೆಯನ್ನು ನಡೆಸುತ್ತಿದೆ.

ಆದ್ದರಿಂದ ಎಲ್ಲ ನೋಂದಾಯಿತ ಫಾರ್ಮಾಸಿಸ್ಟ್‌ರು ತಮ್ಮದೇ ಲಾಗ್‌ಇನ್ ಖಾತೆಯನ್ನು www.kspcdic.com ವೆಬ್‌ಸೈಟಿನಲ್ಲಿ ರಚಿಸಿ ಮಾರ್ಚ್ 31, 2017ರ ಒಳಗೆ ತಮ್ಮ ಪ್ರೊಫೈಲ್ ಅಪ್‌ಡೇಟ್ ಮಾಡಲು ಸೂಚಿಸಲಾಗಿದೆ. ಎಲ್ಲಾ ಅರ್ಹ ಫಾರ್ಮಸಿಸ್ಟರು ನೋಂದಣಿಗಾಗಿ ಅರ್ಜಿಯನ್ನು ಆನ್‌ಲೈನ್ ಮೂಲಕವಾಗಿ ಮಾತ್ರ ಸಲ್ಲಿಸಲು ಸೂಚಿಸಲಾಗಿದೆ.

ಅಧ್ಯಕ್ಷರು
ಗಂಗಾಧರ್ ವಿ. ಯಾವಗಲ್

ರಿಜಿಸ್ಟ್ರಾರ್
ಪ್ರೊ. ಶಿವಾನಂದ ಬಿ.ಜಿ.

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Printed & published by: Registrar on behalf of Drug Information and Research Center (DIRC), Karnataka State Pharmacy Council