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Official Desk

Sri. Gangadhar V. Yavagal
President
Karnataka State
Pharmacy Council

Dear Pharmacists,

Continuing Pharmacy Education (CPE)

I am happy to share that Karnataka State Pharmacy Council (KSPC) had successfully conducted the first Continuing Pharmacy Education (CPE) programme at BLDEA's SSM College of Pharmacy and Research Centre, Vijayapura on 20th July 2019.

The report of the same in detail is accorded under the CPE, Vijayapura.

The second Continuing Pharmacy Education (CPE) program for Community and Hospital Pharmacist will be conducted at D.R. Karigowda College of Pharmacy, Hassan in association with Karnataka Registered Pharmacists Association, Hassan on 5th October 2019.

Orientation programme

Karnataka State Pharmacy Council (KSPC) is in the process of collaborating with Rajiv Gandhi University of Health Sciences, Bengaluru for organizing an orientation programme for PG students and teachers, training of trainers for teachers, etc. These programs are expected to enhance the quality of practicing pharmacists, academic and research activities at institutional level, so that all the pharmacists are empowered with professional skills to face the challenges of the profession of Pharmacy in their day today practice. More details of this collaborative program will be discussed in the upcoming newsletters.

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Continuing Pharmacy Education (CPE) Programme, Vijayapura

Karnataka State Pharmacy Council (KSPC), Bengaluru in co-ordination with BLDEA's SSM College of Pharmacy and Research Centre, Vijayapura organized a one-day Continuing Pharmacy Education (CPE) Programme for Community and Hospital Pharmacist on 20th July 2019 at BLDEA's SSM College of Pharmacy and Research Centre, Vijayapura.

The CPE was organized with the motto of providing and educating the Community and Hospital Pharmacist to promote the trading of medicine with professional practice and by upgrading their knowledge and skills in health care system.

The programme was inaugurated by lightening the lamp by chief guest Shri Gangadhar V. Yavgal, KSPC President and guest of honors were Shri D S. Guddodagi, Governing Council Chairman,

Inaguaral by lighting the lamp

Audience

BLDEA's SSM College of Pharmacy and Research Centre, Dr. M M. Kapase, District Health Officer, Vijayapura, Shri Annarao Naik, ADC Vijayapura, Dr. N V. Kalyane, Principal, BLDEA's SSM College of Pharmacy, Vijayapura.

Six scientific sessions were conducted by an experienced resource person from different disciplinaries of pharmacy background. The Resource persons were, Dr. M S. Ganachari, Deputy Registrar, KLE University, Dr. Raju Koneri, Research Director for BGS Global Institute of Medical Sciences, Bengaluru, Mr. Manoj Kumar Yadava, M. Pharm, MBA (IT), PhD & Cluster Head, Medical Communications and Digital Technologies, Pharma Pulse, Mr.Srinivas Katta Anand, Founder, Ask your Pharmacist, Bengaluru, Mr. Samson P. George, Dy.Registrar & Drug Information Pharmacist, KSPCDIRC and Shri Bahubali Vandakudari, Retired Chief Pharmacist.

The resource persons gave an excellent and very informative talk which motivated the pharmacist to practice their profession as per the global need. Each session was chaired by chairpersons for making the session more interactive and live.

Scientific session was followed with Valedictory function with Chief Guest as Dr. V.T. Kalyanappagol, Medical Superintendent, Shri B M. Patil Medical College Hospital and Research Centre, Vijayapura and guest of honors were Smt. Swetha Nagathan, ADC Vijayapura, Shri Nagaraj M.S., KSPC & PCI member, Dr. N.V. Kalyane, Principal, BLDEA's SSM College of Pharmacy.

Dignitaries during Valedictory programme

More than 250 delegates from different disciplinaries of pharmacy profession such as, Community Pharmacist, Hospital Pharmacist, Academicians and Quality Control Departments have come from different districts, such as Vijayapura, Belagavi, Bagalkot and Kalaburagi actively participated in the scientific sessions and interacted with resource persons. ❑

Guest Column

Specialty Clinical Pharmacy Practice – A distant dream or a near necessity?

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Clinical Pharmacy was introduced in India in 1998. It was introduced firstly as 2-year post graduation course in Pharmacy Practice by very few pioneering institutes. In 2008 PharmD - a six-year course was introduced on the lines of pharmacy education of western countries especially United States. This resolution attracted many students from across India to get into the PharmD curriculum. As a result, there has been staggering number of available PharmD graduates. Unfortunately, these graduates are still, to be integrated in Indian health care system. The reasons are plenty for this. However, there is tremendous scope of clinical pharmacy services in India. There are multiples areas of pharmacy practice where one can exercise his/her clinical role in different healthcare settings.

Indian Pharmacy education right now does not have curriculum in specialized residencies unlike western world Vis a Vis PGY1 and PGY2 residency. Lack of avenues for Indian Pharmacy Practitioners should not deter from honing the clinical skills as globally majority of countries do not have well-structured curriculum despite, they have very good pharmacy practice/ practitioners. I wanted to enlist very few of the numerous available resources which can be used to attain and update clinical skills of practicing clinical pharmacists in India.

Board of Pharmacy Specialties: It is a premium post – licensure certification agency in US which provide certification in various disciplines like pharmacotherapy, critical care, infectious disease, cardiology, geriatrics to name a few. Getting a certification from BPS is a surest way to update the clinical skills and improve patient care. The exams are conducted twice a year in summer and fall season. The exams are computer based. More information can be obtained from www.bpsweb.org

Certification Courses - ASHP: American Society of Hospital Pharmacists customized program as per requirement of Pharmacists who are practicing outside US namely Clinical Skills for international Pharmacist. Besides, they also have certification courses in various disciplines like Emergency Medicine, Medication Safety, and Pharmacy Informatics to name few. More details can be

obtained from https://www.ashp.org/Professional-Development/Professional-Certificate-Programs.

Medication Safety in Hospitals: Pharmaceutical companies have a robust medication safety curriculum complemented by well-trained medication safety professionals. Unfortunately, medication safety is still untapped territory in many hospitals in India if not all. For Clinical Pharmacist planning a career in medication safety Institute of Safe Medicine Practices (ISMP) can be valuable resource. The resources include right from guidelines, newsletters articles, videos, DVD etc. It also provides robust self-assessments tools to validate the practice within any healthcare setup. It offers fellowship and mentorship certificate programs. Unfortunately, these programs are not offsite. More details can be availed from www.ismp.org

Antibiotic Stewardship: With little research in the area of antibiotics and rampant incidences of resistance for the available antibiotics it is paramount to use them in cautious manner so as have favorable clinical outcome while containing the cost of therapy. Clinical Pharmacists who are interested antibiotic stewardship can develop their skills from Society of Infectious Disease Pharmacists of America and Infectious disease society of America. SIDP offer certification course in antibiotic stewardship. Besides, Sanford antimicrobial guide offers tools to develop own protocols and effectively assist in implementing antibiotic stewardship in the hospital through multidisciplinary approach with ID Physician/ Clinical Pharmacist taking the lead. More details can be availed from www.sidp.org.

Critical Care Pharmacy: Society of Critical Care Medicine is the pioneering organization in the field of critical care medicine. It also has Clinical Pharmacy or Pharmacology section that offers many teaching programs, which are apt for clinical pharmacist interested in Critical care, and some are for multidiscipline. For more details, follow www.sccm.org

In addition to above all mentioned resources, it is strongly recommend going through the resources at American College of Clinical Pharmacy (ACCP) and American Society of Hospital Pharmacists (ASHP) to stay abreast with the current knowledge, practices around the globe, and adapt to it

Pharmacist should not be deterrent in updating their skills as the availability of web-based platform as the specialty clinical pharmacy in around the corner.

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Drug of the Quarter

Drug : **Levomilnacipran**

Class : Antidepressant

Dosage form : Extended Release capsules

Strength : 20mg/40mg/80mg/120mg

DCGI Approval : 13-08-2019

USFDA Approval : July 2013

Indication: For treatment of major depressive disorder. This medicine is a selective serotonin and norepinephrine reuptake inhibitor (SSNRI).

Dosing Information

Adult Dosing

Major depressive disorder: Initiated at 20 mg once daily for 2 days and then increased to 40mg once daily. May increase in 40mg at intervals of 2 or more days. The maximum recommended dose is 120mg once daily.

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

Pharmacokinetics

Absorption

- Tmax: 6 to 8 hours
- Bioavailability of extended-release capsule: 92% (compared with oral solution)
- Effect of food: no effect on levomilnacipran concentration

Distribution

- Protein binding: 22%
- Vd: 387 to 473 L

Metabolism

- Desethylation, mainly by CYP3A4, and hydroxylation with further conjugation
- substrate of CYP3A4

Excretion

- Renal excretion: 58% unchanged, 27% identifiable metabolites
- Total body clearance: 21 to 29 L/hr

Elimination Half Life: 12 hours

Contraindication

- Concomitant use with an MAOI (use within 14 days of discontinuing an MAOI used to treat psychiatric disorders or MAOI use within 7 days after levomilnacipran discontinuation), including linezolid or IV methylene blue; increased risk of serotonin syndrome.
- Hypersensitivity to levomilnacipran, milnacipran hydrochloride or any component of the product.

Cautions

Cardiovascular: Increase in blood pressure and heart rate have been reported; monitoring recommended.

Endocrine and metabolic: Hyponatremia has been reported with other SSRI and SNRI agents; increased risk in elderly, volume-depleted patients, or with concomitant use of diuretics. Caution.

Hematologic: Abnormal bleeding may occur; increased risk with concomitant NSAIDs, aspirin, warfarin and other anticoagulants.

Neurologic: Serotonin syndrome has been reported, often with concurrent use of other serotonergic drugs (eg, triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, St John's wort, amphetamines), and other drugs that impair serotonin metabolism; monitoring recommended and discontinue immediately if reaction is suspected.

Neurologic: Seizures may occur during use; increased risk in patients with a history of seizure.

Ophthalmic: Pupillary dilation that occurs with antidepressants may cause an angle closure attack in patients with anatomically narrow angles who do not have a patent iridectomy.

Psychiatric: Increased risk of suicidal thinking and behavior in children, adolescents and young adults (18 to 24 years); risk may increase during early phase of therapy or with dose changes; monitoring recommended.

Renal: Reduce dose in patients with moderate (CrCl, 30 to 59 mL/min) or severe (CrCl, 15 to 29 mL/min) renal impairment; use not recommended in End Stage renal disease. May cause urinary hesitation, retention, or dysuria, especially in patients prone to obstructive urinary disorders; discontinuation may be necessary.

Withdrawal: Abrupt discontinuation may increase the risk for serious withdrawal symptoms; gradual dose reduction recommended; if symptomatic during taper, resume previous dose and taper more gradually; monitoring recommended.

Storage & Stability: Store the medicine in a closed container at room temperature away from heat, moisture and direct light.

Mechanism of Action: Levomilnacipran is a potent and selective serotonin and norepinephrine reuptake inhibitor (SNRI). The inhibition of reuptake at serotonin and norepinephrine transporters may potentiate serotonin and norepinephrine in the CNS, although the exact antidepressant mechanism of levomilnacipran is unknown.

Adverse Effects

Common

- Cardiovascular: Increased heart rate, Palpitations, Tachycardia
- Dermatologic: Diaphoresis, Hot flash due to medication
- Gastrointestinal: Constipation, Nausea, Vomiting
- Reproductive: Disorder of ejaculation, Erectile dysfunction

Serious

- Cardiovascular: Increased blood pressure, Orthostatic hypotension
- Endocrine metabolic: Hyponatremia
- Hematologic: Abnormal Hemorrhage
- Neurologic: Seizure
- Psychiatric: Mania, Suicidal thoughts, Suicide
- Other: Drug withdrawal, Serotonin syndrome

Drug-Drug Interactions

Category	Drug/s (Examples)	Interaction Effect	Management
Antidote/Anti-Infective Agent*	Methylene blue	Increases the risk of serotonin syndrome.	Contraindicated for concurrent use.
Monoamine Oxidase Inhibitors*	Isocarboxazid, phenelzine, procarbazine, selegiline, furazolidone, rasagiline	Increases the risk of serotonin syndrome.	Contraindicated for concurrent use.
Antiemetic*	Metoclopramide	Increases the risk of extrapyramidal reactions and neuroleptic malignant syndrome.	Contraindicated for concurrent use.
Antiboitic*	Linezolid	Increases the risk of serotonin syndrome.	Contraindicated for concurrent use.
NSAID**	NSAID-Serotonin norepinephrine reuptake inhibitors	Increases the risk of bleeding.	Avoid concomitant use.
Anticonvulsant**	Carbamazepine	Decreases levomilnacipran plasma concentrations thereby increased risk of serotonin syndrome.	Avoid concomitant use.
Strong CYP3A4 Inhibitors**	Ketoconazole, clarithromycin, itraconazole, saquinavir, ritonavir, indinavir, nelfinavir, voriconazole, lopinavir, tipranavir, telithromycin, posaconazole, boceprevir, telaprevir, atazanavir	Increases levomilnacipran plasma concentrations.	Avoid concomitant use.

Category	Drug/s (Examples)	Interaction Effect	Management
Anticoagulants**	Heparin, warfarin, phenindione, enoxaparin, acenocoumarol, dalteparin, parnaparin, danaparoid, nadroparin,	Increases the risk of bleeding.	Avoid concomitant use.
Antifungal**	Fluconazole	Increases the plasma concentrations of serotonin norepinephrine reuptake inhibitor and risk for toxicity, including suicidality or serotonin syndrome.	Avoid concomitant use.
Antiplatelets**	Aspirin, ticlopidine, abciximab, clopidogrel, prasugrel, ticagrelor	Increases the risk of bleeding.	Avoid concomitant use.

**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.

Meaning: Serotonin syndrome-hypertension, hyperthermia, myoclonus, mental status changes.

Drug-Food Interactions

Food	Interaction Effect	Management
Grapefruit Juice**	Increases levomilnacipran plasma concentrations.	Avoid concomitant use.

Drug-Ethanol Interactions

Beverage	Interaction Effect	Management
Ethanol**	May increase the levomilnacipran exposure.	Avoid concomitant use.

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

Effects in Pregnancy

Severity	Management
Moderate	Levomilnacipran is rated as US FDA Category C. Animal studies have shown an adverse effect and there are no adequate and well-controlled studies in pregnant women. (OR) No animal studies have been conducted and there are no adequate and well-controlled studies in pregnant women.

Effect 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 Levomilnacipran is used during breast-feeding. Weigh the potential benefits of treatment against potential risks before prescribing Levomilnacipran during breast-feeding.

Patient Education

1. Counsel female patient to avoid conceiving and to report immediately if become pregnant during therapy.
2. Advice to avoid drinking alcohol.
3. Advice to avoid driving vehicle or operate machinery while taking this medicine.
4. Instruct patient to report symptoms of urinary hesitation, urinary retention, or dysuria.
5. Advice the patient to take capsule at approximately the same time each day.
6. Advise patient against sudden discontinuation of drug.
7. Advise patient to report symptoms of hyponatremia (eg, headache, difficulty concentrating, memory impairment, confusion, weakness, unsteadiness, hallucinations, syncope, or seizures).

Instruct patient to report worsening depression, suicidal ideation, agitation, irritability, or unusual changes in behavior, especially at initiation of therapy or with dose changes.

References:

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

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Drug Safety Alerts - 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
August 2019				
1	Metronidazole	Amebicide	Treatment of amoebiasis, urogenital trichomoniasis and giardiasis.	Vasculitis
2	Risperidone	Antipsychotic	Used as monotherapy or as adjunctive therapy in combination with lithium or valproate for the maintenance treatment of Bipolar-1 disorder.	Rabbit Syndrome
July 2019				
3	Febuxostat	Antigout/ Musculoskeletal agent	Treatment of chronic hyperuricemia in conditions where urate crystals deposition has already occurred (including a history, or presence of tophus and /or gouty arthritis).	Toxic Epidermal Necrolysis / Stevens Johnson Syndrome
4	Netilmicin	Aminoglycoside antibiotic	Used in the treatment of septicemia including neonatal sepsis and other severe systemic infections.	Tetany

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.

Meaning: Rabbit syndrome- A rare form of extra-pyramidal adverse effect of antipsychotic medicines in which perioral tremors occur like involuntary, fine, rhythmic motions of the mouth along a vertical plane, without involvement of the tongue.

Reference: www.ipc.gov.in ❑

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
Jan – Mar 2019					
Antineoplastic Agent	Everolimus	Oral	Tablet	Thrombotic microangiopathy	Evaluation is in progress.
Antimigraine / Central Nervous System Agent	Erenumab-aooe Fremanezumab-vfrm Galcanezumab-gnlm	Injection	Subcutaneous	Constipation	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
Antibacterial	• Amoxicillin, • amoxicillin and clavulanate potassium, omeprazole • amoxicillin and clarithromycin, • amoxicillin, clarithromycin and lansoprazole.	Oral	Tablet/ Suspension	Aseptic meningitis	Evaluation is in progress.
Antineoplastic Agent	Avelumab, durvalumab, nivolumab, atezolizumab	Injection	Intravenous	Solid organ transplant rejection	Evaluation is in progress.
Anti-Infective Agent / Antiviral	• Sofosbuvir and velpatisvir, • Ledipasvir and sofosbuvir, • Glecaprevir and pibrentasvir, • Sofosbuvir, Ombitsavir, paritaprevir and ritonavir, • Dasabuvir, ombitasvir, paritaprevir and ritonavir, • Elbasvir and grazoprevir	Oral	Tablet	Dysglycemia	Evaluation is in progress.

References:

1. http://www.fda.gov/
2. www.micromedexsolutions.com, Micromedex (R) 2.0, 2002-2019, IBM Corporation 2019.

Meanings: ***Thrombotic microangiopathy*** -a pathology that results in thrombosis in capillaries and arterioles, due to an endothelial injury, ***Aseptic meningitis-*** is the inflammation of the meninges, a membrane covering the brain and spinal cord, ***Dysglycemia-*** a broad term that refers to an abnormality in blood sugar stability. This can include hypoglycemia or hyperglycemia.

To be continued . . .

Drug News – Around the Globe

1. Drug: Istradefylline* **Country: USA**

Istradefylline is an antiparkinsonian drug.

Approved Indication: Istradefylline is approved as an add-on treatment to levodopa/carbidopa in adult patients with Parkinson's disease (PD) experiencing "off" episodes. An "off" episode is a time when a patient's medications are not working well, causing an increase in PD symptoms, such as tremor and difficulty walking.

Approved Dosage Form: Tablet.

Side-effects: Muscle movement (dyskinesia), dizziness, constipation, nausea, hallucination and sleeplessness (insomnia)[1].

2. Drug: Lefamulin* **Country: USA**

Lefamulin is an antibiotic.

Approved Indication: Lefamulin is approved to treat adults with community-acquired bacterial pneumonia.

Approved Dosage Form: Tablet

Side-effects: Diarrhea, nausea, reactions at the injection site, elevated liver enzymes and vomiting.

3. Drug: Fedratinib* **Country: USA**

Fedratinib is an antineoplastic agent**.**

Approved Indication: Fedratinib is approved to treat adult patients with certain types of myelofibrosis.

Approved Dosage Form: Capsules

Side-effects: Diarrhea, nausea, vomiting, fatigue and muscle spasms.

4. Drug: Pretomanid* **Country: USA**

Pretomanid is an antitubercular drug.

Approved Indication: Pretomanid in combination with bedaquiline and linezolid for the treatment of a specific type of highly treatment-resistant tuberculosis (TB) of the lungs.

Approved Dosage Form: Tablet.

Side-effects: Damage to the nerves (peripheral neuropathy), acne, anemia, nausea, vomiting, headache, increased liver enzymes (transaminases and gamma-glutamyltransferase), indigestion (dyspepsia), rash, increased pancreatic enzymes (hyperamylasemia), visual impairment, low blood sugar (hypoglycemia), and diarrhea

5. Drug: Glucagon* **Country: USA**

Glucagon is Endocrine-Metabolic Agent or antihypoglycemic agent.

Approved Indication: Glucagon is the first glucagon therapy approved for the emergency treatment of severe hypoglycemia that can be administered without an injection.

Approved Dosage Form: Nasal powder

Side-effects: Nausea, vomiting, headache, upper respiratory tract irritation, watery eyes, redness of eyes and itchiness.

Note – *Not available in India

Reference: https://www.fda.gov/

Safety Alert - Around the Globe

1. Drug: Hormone replacement therapy (HRT)* **Country: UK**

May cause increased risk of breast cancer.

Hormone replacement therapy is a form of hormone therapy used to treat symptoms associated with female menopause.

Alert: The Medicines and Healthcare products Regulatory Agency, UK has alerted that risk of breast cancer is increased during use of all types of HRT, except vaginal estrogens, and have also shown that an excess risk of breast cancer persists for longer after stopping HRT than previously thought.

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

2. Drug: Carfilzomib* **Country: UK**

May increase the risk of potentially fatal cardiac events

Carfilzomib is an anti-cancer drug.

Alert: The Medicines and Healthcare products Regulatory Agency, UK alerted that Carfilzomib has been associated with cases of cardiac arrest, cardiac failure and myocardial infarction, including in patients without pre-existing cardiac disorders. Monitor patients for signs and symptoms of cardiac disorders before and during exposure to carfilzomib.

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

3. Drug: Non-steroidal Anti-inflammatory drugs (NSAIDs)** **Country: New Zealand**

NSAIDs may cause risk of cardiovascular adverse events

Alert: The Medsafe has alerted that all nonsteroidal anti-inflammatory drugs (NSAIDs) can increase the risk of a cardiovascular adverse event.

Hence, KSPC-DIRC alerts the healthcare professionals to be cautious while prescribing NSAID's in patient with a history of cardiovascular diseases[2].

References:

1. https://www.gov.uk/
2. www.medsafe.govt.nz/

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

Continuing Pharmacy Education (CPE)

Dispensing Instructions to the Pharmacists

Autism-Drug Therapy

A serious complex neurobehavioral condition that impairs the ability to communicate and interact.

The symptoms include the following,

- Relationship problems
- Delayed articulatory and language development
- Altered growth and development: social skills
- Learning difficulties
- Epilepsy
- Aggressive behavior
- Self-injurious behavior

These symptoms begin in early childhood (though they may go unrecognized), persist and interfere with daily living. Because of the range of symptoms, this condition is now called as autism spectrum disorder (ASD). The primary goal of autism treatment is to optimize the functional level and quality of life of the patient.

Drug treatment includes the following:

- **Antipsychotics:** Haloperidol, olanzapine, clozapine, quetiapine, aripiprazole
- **Anticonvulsants:** Valproic acid, topiramate
- **Serotonin Reuptake Inhibitors:** citalopram, escitalopram, fluoxetine, fluvoxamine, sertraline
- **Tricyclic Antidepressants:** Clomipramine
- **CNS Stimulants:** methylphenidate, amphetamines

Below is a brief overview of few oral drugs.

Drugs/ Category	Use	Warnings	Less serious side effects	Advice
Antipsychotics				
Haloperidol **Oral forms available:** Tablet	Treats schizophrenia and symptoms of Tourette syndrome.	Prescription to be reconfirmed in case of patient is pregnant or breastfeeding or having kidney disease, liver disease, brain disease, bone marrow problems, heart or blood vessel disease, heart rhythm problems (including long QT syndrome), lung or breathing problems, mental health problems, Parkinson disease, allergies, thyroid problems or a history of breast cancer or seizures.	Hypotension, diminished sweating, dystonia, nasal congestion, constipation	Take with food. Do not drive a motor vehicle or operate machinery. Avoid excessive skin exposure to direct sunlight. 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 patient is pregnant or breastfeeding or having 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. Do not drive a motor vehicle or operate machinery while taking this medicine. Avoid excessive skin exposure to direct sunlight. Strictly avoid alcohol and smoking tobacco.
Anticonvulsant				
Sodium Valproate / Valproic Acid **Oral forms available:** Tablet, syrup	Treats and prevent seizures and helps to prevent migraine headaches.	Prescription to be reconfirmed in case of patient is pregnant or breastfeeding or having kidney disease, blood disease, pancreas problems, a viral infection (including HIV or cytomegalovirus infection), or a history of depression or mental health problems.	Diarrhea, stomach upset, hair loss, tiredness, sleepiness, trouble sleeping, tremor, vision changes, dizziness, headache.	Take this medicine with food to decrease stomach upset. Do not drive vehicle or operate machinery while taking this medicine.
Topiramate **Oral forms available:** Tablet	Treats and prevents seizures and helps prevent migraine headaches.	Prescription to be reconfirmed in case of patient is pregnant or breastfeeding or having kidney disease, liver disease, glaucoma, lung or breathing problems, osteoporosis or a history of depression or mood disorders.	Change in taste, nausea, diarrhea, stuffy or runny nose, weight loss.	Take this medicine with or without food. Swallow the whole tablet. Do not break, crush, or chew it. Advise the patient to drink more fluids to avoid kidney problems. (This will help the patient to pass more urine while using this medicine. This will keep the kidneys working well and help prevent kidney problems.) Strictly avoid alcohol.

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.

Meaning: Dystonia- a movement disorder in which a person's muscles contract uncontrollably.

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, 2002-2019, IBM Micromedex ®
3. https://www.nidcd.nih.gov/

Drug Usage in Special Population - Pediatrics and Geriatrics

(From KSPCDIRC publication)

Anti-infectives

Drug	Usage in Children (Pediatrics)	Usage in Elderly (Geriatrics)
Antiviral Drugs		
Acyclovir	Safety and efficacy have been established in pediatric patients above 2 years of age.	Dosage adjustment is necessary in patients with impaired renal function.
Darunavir	Safety and efficacy have been established in pediatric patients above 3 years of age.	Dose adjustment is not necessary in renal failure. Not recommended to use in severe hepatic insufficiency.
Famciclovir	Safety and efficacy have not been established.	No dosage adjustments required in patients with mild to moderate hepatic impairment and geriatric patients.
Oseltamivir	Safety and efficacy have been well established in pediatric patients.	Dosage adjustment is necessary in patients with impaired renal function. No dosage adjustments required in patients with hepatic impairment and geriatric patients.
Sofosbuvir	Safety and efficacy have been established in pediatric patients above 3 years of age.	No dosage adjustments required in geriatric patients.
Tenofovir	Safety and efficacy have not been established.	Not recommended in patients with hepatic impairment. No dosage adjustments required in patients with renal impairment and geriatric patients.

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

Drug Usage in Special Population - Pregnancy and Lactation

(From KSPCDIRC publication)

Anti-infectives

Drug	Usage in Pregnancy (Teratogenicity)	Usage in Breastfeeding (Lactation)
Antiviral Drugs		
Acyclovir	USFDA Category B (All Trimesters). No complete or well-controlled pregnancy studies have been performed to evaluate the use of acyclovir in humans.	Safe to use during breastfeeding.
Darunavir	Fetal risk cannot be ruled out. Available evidence is inconclusive or is inadequate for determining fetal risk when used in pregnant women or women of childbearing potential. Weigh the potential benefits of drug treatment against potential risks before prescribing this drug during pregnancy.	Infant risk cannot be ruled out. Caution to use.
Famciclovir	Fetal risk cannot be ruled out.	Infant risk cannot be ruled out. Weigh the benefits of breastfeeding with the mother's clinical need before use.
Oseltamivir	Fetal risk cannot be ruled out. There are no adequate and well-controlled studies of oseltamivir use during pregnancy. Use only if the benefit to the mother justifies any potential risk to the fetus.	Available evidence is inconclusive or is inadequate for determining infant risk when used during breastfeeding. Caution.

Drug	Usage in Pregnancy (Teratogenicity)	Usage in Breastfeeding (Lactation)
Sofosbuvir	USFDA Category B (All Trimesters). Use only if the potential benefit outweighs the potential fetal risk. Combination therapy with sofosbuvir and ribavirin or peginterferon/ribavirin is contraindicated during pregnancy.	Data not available during breast feeding. Caution if used.
Tenofovir	No adequate and well-controlled studies of tenofovir use in pregnant women. Weigh the potential benefits of drug treatment against potential risks before prescribing this drug during pregnancy.	Infant risk cannot be ruled out. Caution.

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).

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

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

(ಅಧ್ಯಾಯ–2)

4. ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರ ಸಾಮಾನ್ಯ ಕರ್ತವ್ಯಗಳು ಮತ್ತು ಹೊಣೆಗಳು:

4.4 ವಿದ್ಯಾರ್ಥಿ ಭೇಷಜಜ್ಞರಿಗೆ ಪ್ರಾಯೋಗಿಕ ತರಬೇತಿ:

(ಎ) ಭೇಷಜೀಯ ಡಿಪ್ಲೋಮಾದ ವಿದ್ಯಾರ್ಥಿಗೆ ಪ್ರಾಯೋಗಿಕ ತರಬೇತಿ ನೀಡುವ ಉದ್ದೇಶಕ್ಕಾಗಿ ಒಂದು ಭೇಷಜೀಯ ಅನುಮೋದನೆಗಾಗಿ ಆ ಭೇಷಜೀಯ ಮಾಲೀಕರು, ಭಾರತದ ಭೇಷಜೀ ಪರಿಷತ್ತಿನಿಂದ, ಮುಂಚಿತವಾಗಿ ಅನುಮೋದನೆಯನ್ನು ಪಡೆದಿರತಕ್ಕದ್ದು. ಭಾರತದ ಭೇಷಜೀ ಪರಿಷತ್ತಿನ ಅನುಮೋದನೆ ಇಲ್ಲದಿರುವಲ್ಲಿ ಆ ಭೇಷಜೀ ವಿದ್ಯಾರ್ಥಿಗಳು ತಮ್ಮನ್ನು ಕಾಯ್ದೆಯಡಿ ಭೇಷಜಜ್ಞ ಎಂದು ನೋಂದಾಯಿಸಿಕೊಳ್ಳಲು ಅರ್ಹರಾಗುವಂತೆ ಮಾಡಲು ಅಗತ್ಯವಾದ, ಭೇಷಜೀಯ ಡಿಪ್ಲೋಮಾದ (ಭಾಗ – III) ಅನ್ನು ತಾವು ಪೂರ್ಣಗೊಳಿಸಿರುವಂತೆ ತಿಳಿಯತಕ್ಕದ್ದಲ್ಲ.

(ಬಿ) ಕಾಯ್ದೆಯ ಅಧಿನಿಯಮ 10ರ ಅಡಿಯಲ್ಲಿ ಹೆಣೆಯಲಾದ ವಿದ್ಯಾ ನಿಬಂಧನೆಗಳ ಅಡಿಯಲ್ಲಿ ಕಾಲದಿಂದ ಕಾಲಕ್ಕೆ ನಿರ್ದಿಷ್ಟಪಡಿಸಲಾದಂತೆ ಪರೀಕ್ಷಾ ಪ್ರಧಿಕಾರಕ್ಕೆ ಮಾಹಿತಿ ನೀಡುವುದರೊಂದಿಗೆ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರು ಭೇಷಜೀ ವಿದ್ಯಾರ್ಥಿಗಳಿಗೆ ಪ್ರಾಯೋಗಿಕ ತರಬೇತಿ ನೀಡತಕ್ಕದ್ದು.

(ಸಿ) ಅಂತಹ ಪ್ರಾಯೋಗಿಕ ತರಬೇತಿ ನೀಡುತ್ತಿರುವಾಗ, ತರಬೇತಿ ಹೊಂದತಕ್ಕ ಭೇಷಜೀ ವಿದ್ಯಾರ್ಥಿಗಳ ಸಂಖ್ಯೆ, ಪ್ರಾಯೋಗಿಕ ತರಬೇತಿಯ ಸ್ವರೂಪ, ಪ್ರಾಯೋಗಿಕ ತರಬೇತಿಯ ಅವಧಿ ಇತ್ಯಾದಿಗಳಿಗೆ ಸಂಬಂಧಿಸಿದಂತೆ ಕಾಲಕಾಲಕ್ಕೆ ವಿದ್ಯಾ ನಿಬಂಧನೆಗಳ ಅಡಿಯಲ್ಲಿ ನಿಗದಿಪಡಿಸಿದ ಮಾನದಂಡಗಳನ್ನು ಆ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರು ಅನುಪಾಲನಗೊಳಿಸತಕ್ಕದ್ದು.

4. Duties and responsibilities of the registered pharmacist in general

4.4 Practical training to student pharmacists.

a) The owner of the pharmacy shall seek prior approval of the PCI for approval of the pharmacy for the purpose of imparting practical teaching to student of Diploma in Pharmacy. In the absence of approval from the PCI, the student pharmacists shall not be treated to have completed their Diploma in Pharmacy (Part-III) to make them eligible for registration as a pharmacist under the Act.

b) The registered pharmacist shall impart practical training to student pharmacists as prescribed from time to time under Education Regulation framed u/s 10 of the Act under intimation to the examining authority.

c) While imparting such practical training, the registered, pharmacists shall comply with the prescribed norms relating to number of students' pharmacists to be trained, nature of practical training, duration of practical etc. as laid down under the Education Regulations from time to time.

KSPC News

Antimicrobial resistance (AMR) and stewardship (AMS) program in Karnataka

Karnataka State Pharmacy Council (KSPC) organized an **'Antimicrobial resistance (AMR) and stewardship (AMS)'** seminar on 6th July 2019 at the seminar hall of KSPC. The meeting was addressed by the Sri.Gangadhar V. Yavagal, President, KSPC. He highlighted that the main objective of the project was to formalize the administrative and operational activities with key allies for synergistic Stewardship activities with

Dignitaries on the dias

different institutions like Acharya Institutes (Pharmacy Institute & Management Institute), Karuna Trust and St Louis College of Pharmacy, USA; Rhodes University and University of Western Cape, South Africa; and International Tropical Medicine Institute, Belgium.

A presentation on '**Antimicrobial Stewardship: From Policy to Implementation**' was presented by Dr.Renier Coetzee from University of Western Cape, South Africa along with Dr. Sunitha Srinivas, from Karuna Trust & a Visiting Professor, Rhodes University in which Dr.Renier Coetzee shared his experiences based on South Africa's National AMR program.

The stakeholders from various disciplines in health were invited for the seminar like academic faculty members, hospital pharmacists, microbiologists, nurses, dentists and other members. A broad overview of AMR and global policy preceded a panel discussion on the current activities within the field of AMS.

The panel members highlighted how the vision of this program at KSPC could address collaboration with other healthcare professionals and organizations while forming a core writing committee for the proposed Antibiotic policy draft. The need for expanding the advisory committee and a broad consultative committee, collaboratively working from various sectors of the health care teams, was one of the highlights during the discussion. The proposed Antibiotic policy was aimed to be presented to the Government of Karnataka, so they can pursue the consultative and adoption processes required at the provincial level.

27 participants including Pharm D student, Dental students, Academic Pharmacist, Doctors and other healthcare professionals attended the program.

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Additional Information on any article is available on request
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