



DIRC Newsletter



Vol. 23

No. 3

October – December 2021

Newsletter of Drug Information and Research Center, KSPC



Member of International Society of Drug Bulletins (ISDB)

Official Desk



Dear Pharmacists,

PHARMADISHA-Training of Teachers (ToT) program for D.Pharm teachers

Karnataka State Pharmacy Council (KSPC) will be conducting a Training of Teachers program in the interest of enhancing the quality of profession of Pharmacy and upgrading the skills of Pharmacy teachers teaching Diploma students in Pharmacy in Karnataka.

This programme is an extension of the PHARMADISHA programme (an Orientation Programme for PG students of Pharmacy in collaboration with Rajiv Gandhi University of Health Sciences) conducted during the year 2020.

Karnataka State Pharmacy Council is willing to organize this event as a joint venture with the Pharmacy Council of India (PCI), New Delhi.

It is proposed to plan this training programme for Diploma teachers teaching D.Pharm course in the Pharmacy colleges across Karnataka, keeping in view the new Education Regulation 2020 which is notified by the Pharmacy Council of India.

This Pharmacy teachers training program is expected to enhance the quality of teachers in academic and research activities at the institutional level so that all the professionals are empowered with professional skills and will be ready to face the challenges of the profession of Pharmacy.

This will be conducted in seven centers across Karnataka which can train approximately 400 trainers and thus trained teachers can train their colleagues in the next phases.

More development of this program will be discussed in the next upcoming issues of newsletter.



Sri. Gangadhar V. Yavagal
President
Karnataka State
Pharmacy Council



CONTENTS

- Official Desk
- Guest Column - Communication:
Key to Pharmacist Success
- Drug of the Quarter
- Drug Safety Alerts
- Serious Risks / Safety Information – USFDA
- Drug News - Around the Globe
- Continuing Pharmacy Education (CPE)
 - Dispensing Instructions to the Pharmacists
 - Drug Usage in Special Population
 - Pediatrics and Geriatrics
 - Pregnancy and Lactation
- ಭೇಷಜೀ ಪರಿಕರ್ಮ ನಿಬಂಧನೆಗಳು, 2015
(Pharmacy Practice Regulation, 2015)
- KSPC News

Guest Column

Communication: Key to Pharmacist Success

*'Good communication is the bridge
between confusion and clarity'*

- Ned Turner.

Success is defined as the achievement of predefined experiences. For instance, when a patient walks in with a prescription in hand, from patient's point of view, getting the right medication and tips to administer the medicines for safety and effectiveness,



Sunil S Chiplunkar

M Pharm (Pharmacology)
MBA (Marketing) PGDHRM (PhD)
VP – Business Development
Group Pharmaceuticals, Bangalore

is the goal. Seeing a patient go out satisfied from his or her pharmacy - is the pharmacist's expectation. And the force that makes this happen is communication or the process of sending messages, from sender to recipient.

Being alive is communication: in fact, being withdrawn and silent is also a form of communication or message sending. A person who is depressed is likely to be in a shell, and he or she is silently sending a message of request - for help. A person writhing with pain may not be asking for direct help, but his behavior of agony itself is a message: seeking help. Thus, the sharp pharmacist perceives the two types of silent and open messages, and uses his professionalism to understand the patient's requirement, and then provides best value.

If a patient comes in with a prescription for certain antidiabetic drugs, then the sharp pharmacist sees an opportunity in this communication or message, after all the prescription is also a message. Many diabetics are prone to hyposalivation and thereby mild gingivitis or gumline inflammation happens. A diabetic is also vulnerable to gum infection, gum bleeding and halitosis or bad breath. This knowledge can be used by a pharmacist, to provide value added communication and counseling on right use of a suitable oral care product for patient well-being. This will be appreciated by the diabetic patient as it shall enhance his quality of life and avoids oral complications in the diabetic mouth. It is a fact that chronic gum infection also impacts heart health negatively, leading to pathologies like endocarditis.

The pharmacist is a bridge who clears confusion about disease and medicines. This brings about clarity and confidence in the patient. The pharmacist is the harbinger of hope. And this expertise power will bear fruit only when the pharmacist has suitable communication prowess. The attractive and succinct briefing of technical aspects in an understandable language shall provide tips for improved healthcare outcomes in a patient. The pharmacist is a foremost and most accessible healthcare professional as per various survey studies. The informed pharmacist is a valuable asset to the society.

The pharmacist apron: foundation to communication process

Most of people think communication is the ability to write well or speak with impact. However, the reality is most of communication happens through body language; in fact, about 55% of message transfer from sender to recipient happens through body language, say experts. The appearance, attire, facial expressions, the smile, posture and gestures convey more messages to the recipient than the spoken word itself.

If a pharmacist wearing a clean and well ironed apron with his name plate and registration number, meets the patient, then the trust build up in the patient is amazing. Professional attire provides social signals and people make judgements of credibility, likeability, education level and trustworthiness seeing the attire of a person. Such is the impact of the white apron worn by a pharmacist. Studies have revealed that the white apron wearing pharmacist is seen as more approachable by patients. There is an age old adage **dress for the job you want, not the job you have.** Thus, a pharmacist aspiring to establish his pharmacy as a prime healthcare provider should aim to present himself with right body language using the pharmacist apron.

The tone of our voice makes all the difference

Vocalization is critical for successful message transfer. Using the right pronunciation, with emphasis on key words or phrases, and using words with right pitch, pace and pause provides for effective messaging. Right mix of local language words, works to make the technical message palatable. One need not burden the patient with all technicalities, because he or she is looking for confidence building rather than a bundle of tongue twisting facts. This boost in confidence and giving hope to patient or purchaser happens only with the way you speak along with what you speak. The tonal quality of your life will put life into what you wish to say.

Verbalization or the text

It is important to think before we say some technical fact or figure. The reason is that a layman may not grasp fully, or he or she may misunderstand, hence when the pharmacist counsels the patient or purchaser, it is essential to empathize. After understanding the patient or purchaser's frame of mind, only the relevant facts with right intonation should be provided. Holding the pack insert of the medicine or pointing to the words on the label, an audio visual impact can be achieved to improve understanding of the patient or purchaser. The pharmacist should necessarily be updated with medicine knowledge and this will make the interaction with purchasers beneficial.

Communication quality and quantity improves pharmacist patient interaction and conversing with the purchaser without a pharmacist apron will reduce the impact and acceptance of the message. So pharmacists are advised to spruce up communication, improve presentation by using the pharmacist apron, and thanks to *KSPC for the pharmacist apron abhiyan* - there is greater awareness on this aspect now, and certainly communication skill shall improve pharmacist status ensuring enduring success. □

Drug of the Quarter

Drug : Molnupiravir

Class : Antiviral

Dosing Form : Capsules

Strength : 200 mg

DCGI Approval : Not available

USFDA Approval : 23-12-2021

Indication: Treatment of COVID-19 (Mild to Moderate), Patients at high risk for progression to severe COVID-19 mild to moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19

Dosing Information:

Adult: 800 mg (four 200 mg capsules) orally every 12 hours for 5 days with or without food; administer as soon as possible after COVID-19 diagnosis and within 5 days of symptom onset (emergency use dosage)

Pediatric: The safety and efficacy of molnupiravir have not been established in pediatric patients

Pharmacokinetics

Absorption

- N-hydroxycytidine (NHC), Tmax, oral: 1.5 hours
- N-hydroxycytidine (NHC), effects of food: No effect on AUC; 35% decrease in Cmax

Distribution

- N-hydroxycytidine (NHC), protein binding: 0%
- N-hydroxycytidine (NHC), Vd: 142 L

Metabolism

- Molnupiravir is a prodrug that is metabolized to the ribonucleoside analogue N-hydroxycytidine (NHC)

Excretion

- N-hydroxycytidine (NHC), renal excretion: 3%
- N-hydroxycytidine (NHC), total body clearance: 76.9 L/hr

Elimination Half Life

- N-hydroxycytidine (NHC): 3.3 hours

Contraindications:

- Hypersensitivity to molnupiravir or any component of the product
- Cautions:

- Musculoskeletal: May affect bone and cartilage growth; molnupiravir is not authorized for use in patients less than 18 years of age.
- Reproductive: May cause fetal harm; advise women of childbearing potential to use effective contraception during treatment and for 4 days after the last dose.

Mechanism of Action

Molnupiravir is a prodrug that is metabolized to the ribonucleoside analogue N-hydroxycytidine (NHC) which distributes into cells where it is phosphorylated to form the pharmacologically active ribonucleoside triphosphate (NHC-TP). NHC-TP incorporation (as NHC-monophosphate [NHC-MP]) into SARS-CoV-2 RNA by the viral RNA polymerase (nsp12) results in an accumulation of errors in the viral genome leading to inhibition of replication. The mechanism of action (known as viral error catastrophe or viral lethal mutagenesis) is supported by biochemical and cell culture data, studies of SARS-CoV-2 infection in animal models, and analyses of SARS-CoV-2 genome sequences in human subjects treated with molnupiravir.

Adverse Effects

Common

- Gastrointestinal: Diarrhea, Nausea
- Neurologic: Dizziness, Headache

Drug-Drug Interactions: Information not available.

Effects in Pregnancy

Severity	Management
Moderate	Fetal risk cannot be ruled out. Available evidence is inconclusive or is inadequate for determining fetal risk when Molnupiravir is used in pregnant women or women of childbearing potential. Weigh the potential benefits of drug treatment against potential risks before prescribing Molnupiravir during pregnancy.

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

Patient Education:

- Advise the patient to swallow capsules whole with a glass of water.
- Advise female patient of childbearing potential to use effective contraception during treatment and for 4 days after the last dose.
- Advise the patient to take a missed dose as soon as possible

if within 10 hours of usual dosing time, but if dose is missed by more than 10 hours, to skip the missed dose, take the next dose at the regularly scheduled time, and not double the dose to make up for a missed dose.

References:

1. <http://www.micromedexsolutions.com/>
2. <http://www.cdsc.nic.in/>



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
December 2021				
1	Remdesivir	Antiviral	Broad spectrum antiviral medication. Restricted emergency use for treatment of patients with severe COVID-19.	Sinus Bradycardia
November 2021				
2	Diclofenac	Analgesic	Treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, gout, painful post-operative pain following dental surgery, migraine attack and postoperative inflammation in patients who have undergone cataract operation.	Skin hyperpigmentation
September 2021				
3	Dimethyl Fumarate	Immunological agent	Used for Relapsing remitting multiple sclerosis.	Alopecia.
4	Cefazolin	Antibiotic	Cephalosporin antibiotic-indicated in the treatment of serious infections due to susceptible organisms – respiratory tract infections, urinary tract infections, skin & skin structure infection, biliary tract infections, septicemia	Acute Generalized Exanthematous Pustulosis.
August 2021				
5	Sofosbuvir	Antiviral	Used in combination with other medicinal products for the treatment of chronic hepatitis C in adults.	Stevens-Johnson Syndrome.

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

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

Meaning: Acute Generalized Exanthematous Pustulosis-a rare skin reaction characterized by skin eruptions.

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	Potential Signal of a Serious Risk / New Safety Information	Additional Information (as of March 23, 2021)
July - September 2021				
Antimigraine	Fremanezumab, Galcanezumab, Rimegepant, Ubrogapant, Eptinezumab	Sub-cutaneous	Hypertension	FDA decided regulatory action is not needed at this time.
Gastrointestinal Agent	Mesalamine, Sulfasalazine, Balsalazide disodium, Osalazine disodium	Oral	Severe cutaneous adverse reactions	The labelling section of the product was updated to include severe cutaneous adverse reactions
Antineoplastic Agent	Bevacizumab, Bevacizumab	Intravenous	Pancreatitis	Evaluation in progress.
Antineoplastic Agent	Bevacizumab, Bevacizumab	Intravenous	Anaphylactic shock	Evaluation in progress.
Antineoplastic Agent	Avapritinib	Oral	Photosensitivity reaction	Evaluation in progress.
Antineoplastic Agent	Azacitidine	Injection/oral	Pericarditis	Evaluation in progress.
Antineoplastic Agent	Avelumab, Durvalumab, Cemiplimab, Pembrolizumab, Nivolumab, Atezolizumab, Ipilimumab	Intravenous	Tumour lysis syndrome	Evaluation in progress.
Antianxiety	Duloxetine hydrochloride	Oral	Anosmia, Hyposmia	Evaluation in progress.
Antineoplastic Agent	Daratumumab, daratumumab and hyaluronidase	Intravenous	Blood stem cell transplant failure	Evaluation in progress.
Antidiabetic	Empagliflozin and Linagliptin, Metformin hydrochloride and Sitagliptin phosphate, Linagliptin and Metformin hydrochloride, Alogliptin and metformin hydrochloride, Metformin hydrochloride and Saxagliptin, Alogliptin, Saxagliptin, Alogliptin and Pioglitazone, Ertugliflozin and sitagliptin, Linagliptin, Empagliflozin, Linagliptin and Metformin hydrochloride, Saxagliptin and Dapagliflozin	Oral	Tubulointerstitial nephritis	Evaluation in progress.
Antiasthma	Dupilumab	Subcutaneous	Angioedema	Evaluation in progress.

Therapeutic Class / Category	Drug (Examples)	Route of Administration	Potential Signal of a Serious Risk / New Safety Information	Additional Information (as of March 23, 2021)
Antidiabetic	Lixisenatide, Exenatide, Semaglutide, Liraglutide, Insulin glargine and Lixisenatide injection, Dulaglutide, Liraglutide, Insulin degludec and Liraglutide injection	Oral/ Subcutaneous	Gallbladder related disorders	Evaluation in progress.
Antineoplastic Agent	Leuprolide acetate, Histrelin acetate, Nafarelin acetate, Triptorelin	Intramuscular/ Subcutaneous	Idiopathic intracranial hypertension	Evaluation in progress.
Dermatologic agent	Ruxolitinib Phosphate	Topical	Herpes simplex virus (HSV) reactivation and/or disseminated HSV	Evaluation in progress.
Antineoplastic Agent	Palbociclib, Ribociclib, Letrozole and Ribociclib	Oral	Embolic and thrombotic events, venous	Evaluation in progress.
Immune modulator	Ocrelizumab	Intravenous	Myocardial infarction	Evaluation in progress.
Antidiabetic	Dapagliflozin, Empagliflozin and Linagliptin, Canagliflozin and Metformin hydrochloride, Canagliflozin, Empagliflozin, Saxagliptin and Dapagliflozin, Ertugliflozin and Sitagliptin, Ertugliflozin and Metformin hydrochloride, Empagliflozin, Linagliptin and Metformin hydrochloride, Dapagliflozin and Metformin	Oral	Tubulointerstitial nephritis	Evaluation in progress.
Anthelmintic	Ivermectin	Oral	Neurotoxicity	Evaluation in progress.
CNS Stimulant	Solriamfetol Hydrochloride	Oral	Hypersensitivity	Evaluation in progress.
Anticonvulsant	Cenobamate	Oral	Psychiatric disorders	Evaluation in progress.

References:

1. <http://www.fda.gov/>
2. www.micromedexsolutions.com, Micromedex (R) 2.0, 2002-2022, IBM Corporation 2022.



Drug News – Around the Globe



1. Drugs: Nirmatrelvir/Ritonavir*

Country: USA

Nirmatrelvir/Ritonavir is antiviral drugs.

Approved Indication: Nirmatrelvir/Ritonavir is the first oral antiviral approved for the treatment of mild-to-moderate coronavirus disease (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kilograms) with positive results of direct SARS-CoV-2 testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death. Nirmatrelvir/Ritonavir is not recommended in patients

with severe kidney or severe liver impairment.

Approved Dosage Form: Oral kit

Side-effects: Impaired sense of taste, diarrhea, high blood pressure and muscle aches¹.

2. Drug: Inclisiran*

Country: USA

Inclisiran is an Antihyperlipidemic drug.

Approved Indication: Inclisiran injection is used as an add-on therapy along with diet and maximally tolerated statin therapy for

adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease who require additional lowering of low-density lipoprotein cholesterol (LDL-C). Inclisiran acts by reducing the circulating levels of LDL-C, commonly known as "bad cholesterol."

Approved Dosage Form: Subcutaneous

Side-effects: Injection site reaction, joint stiffness, urinary tract infection, diarrhea, bronchitis, pain in extremity, and difficulty breathing¹.

3. Drug: Tezepelumab*

Country: USA

Tezepelumab is an Antiasthmatic drug.

Approved Indication: Tezepelumab is used as an add-on maintenance treatment to improve severe asthma symptoms when used with a patient's current asthma medicine. Tezepelumab is approved for adults and children aged 12 years and older with severe asthma not controlled by their current asthma medicine. Tezepelumab is the first asthma treatment targeting thymic stromal lymphopoietin, a molecule involved in airway inflammation. Tezepelumab is also the first treatment for severe asthma that is not limited to a specific type of severe asthma. Tezepelumab should not be used to treat short-term asthma symptoms or short-term asthma attacks.

Approved Dosage Form: Subcutaneous Solution

Side-effects: Injection site reaction, arthralgia, backache¹.

4. Drug: Efgartigimod*

Country: USA

Efgartigimod is a blood modifying agent.

Approved Indication: Efgartigimod is used for the treatment of generalized myasthenia gravis (gMG) in adults who test positive for the anti-acetylcholine receptor (AChR) antibody. In myasthenia gravis, the immune system produces AChR antibodies that interfere with communication between nerves and muscles, resulting in weakness. Severe attacks of weakness can cause breathing and swallowing problems that can be life-threatening.

Approved Dosage Form: Intravenous Solution

Side-effects: Respiratory tract infections, headache and urinary tract infections¹.

5. Drug: Voxelotor*

Country: USA

Voxelotor is a blood modifying agent.

Approved Indication: Voxelotor tablet is used to treat sickle cell disease in pediatric patients aged four up to 11 years. USFDA had previously granted accelerated approval for Voxelotor for patients aged 12 years and older with sickle cell disease.

Approved Route of administration: Oral

Approved Dosage Form: Tablet

Side-effects: Headache, vomiting, diarrhea, abdominal pain, nausea, rash, and fever¹.

6. Drug: Maribavir*

Country: USA

Maribavir is an Antiviral drug.

Approved Indication: Maribavir is the first drug for treating adults and pediatric patients (12 years of age and older and weighing at least 35 kilograms) with post-transplant cytomegalovirus (CMV) infection/disease that does not respond (with or without genetic mutations that cause resistance) to available antiviral treatment for CMV. Maribavir act by preventing the activity of human cytomegalovirus enzyme pUL97, thus blocking virus replication.

Approved Dosage Form: Tablet

Side-effects: Taste disturbance, nausea, diarrhea, vomiting and fatigue¹.

7. Drug: Sutimlimab*

Country: USA

Sutimlimab is an immunological agent.

Approved Indication: Sutimlimab is approved to decrease the need for red blood cell transfusion due to hemolysis (red blood cell destruction) in adults with cold agglutinin disease (CAD). Patients with allergies to sutimlimab or any of the inactive ingredients must not take sutimlimab. Individuals should be vaccinated against encapsulated bacteria and monitored for early signs and symptoms of infection.

Approved Dosage Form: Injection

Side-effects: Respiratory tract infection, viral infection, diarrhea, dyspepsia (indigestion), cough, arthralgia (joint stiffness), arthritis, and swelling in the lower legs and hands.

8. Drug: Inclisiran*

Country: USA

Inclisiran is an Antihyperlipidemic agent.

Approved Indication: Inclisiran injection is approved as a treatment to be used along with diet and maximally tolerated statin therapy for adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD) who require additional lowering of low-density lipoprotein cholesterol (LDL-C). Inclisiran works to reduce circulating levels of LDL-C, commonly known as "bad cholesterol."

Approved Dosage Form: Injection

Side-effects: Site reaction, joint stiffness, urinary tract infection, diarrhea, bronchitis, pain in extremity, and difficulty breathing.

Note – *Not available in India.

**Available in India

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



Continuing Pharmacy Education (CPE)

Dispensing Instructions to the Pharmacists

Asthma-Drug Therapy - Continuation from the previous newsletter issue

(Oral/Inhalation/Nasal spray)

Drugs/ Category	Use	Warnings	Less serious side effects	Advice
Zafirlukast Dosage forms: Oral	Used for the prophylaxis and chronic treatment of asthma.	Prescription to be reconfirmed in case of patient is pregnant or breastfeeding, or if you have liver disease or history of depression or mental health problems.	Headache, aggressive behavior, agitation, hallucinations.	Advise patient that drug is not indicated for acute asthma attacks and to report asthma episodes that are not responsive to bronchodilators. Advise patient to take at least 1 hour before or 2 hours after a meal. Advise patient to continue with other asthma medications as prescribed unless instructed by a healthcare professional.
Ipratropium Dosage forms: Inhalation/ Nasal	Treats long-term treatment of chronic obstructive pulmonary disease including chronic bronchitis and emphysema. Also used in Asthma attacks.	Prescription to be reconfirmed in case of patient is pregnant or breastfeeding or having glaucoma or an enlarged prostate or any problems with urination.	Abnormal taste in mouth, dryness of nasal mucosa, nasal irritation, sinusitis	Advise the patient that inhalation form is not indicated for acute asthma attacks. Advise patient to avoid medication contact with eyes. Advise the patient to avoid activities requiring mental alertness or coordination (such as driving or operating machinery).

(to be continued.....)

Storage: Advise 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, 9th Edition 2020, published by Karnataka State Pharmacy Council, Bangalore.
2. www.micromedexsolutions.com, Micromedex® 2.0,2002-2022, IBM Corporation 2022.



Drug Usage in Special Population - Pediatrics and Geriatrics

(From KSPCDIRC publication)

Blood products and Plasma Substitutes

Drug	Usage in Children (Pediatrics)	Usage in Elderly (Geriatrics)
Albumin	Safety and efficacy in children less than 12 years not established.	Dose adjustment requires in renal impairment.
Dextran	Safety and efficacy have been established.	Dose adjustment requires in renal impairment.

Reference: Drug Usage in special Population-Pediatrics and Geriatrics, Educational Series-II, 9th Edition 2020, published by Karnataka State Pharmacy Council, Bengaluru.



Drug Usage in Special Population - Pregnancy and Lactation

(From KSPCDIRC publication)

Blood products and Plasma Substitutes

Drug	Usage in Pregnancy (Teratogenicity)	Usage in Breastfeeding (Lactation)
Albumin	Fetal risk cannot be ruled out. Use with caution.	Infant risk cannot be ruled out. Use with Caution.
Dextran	Fetal risk cannot be ruled out.	Infant risk cannot be ruled out. Use with Caution.

Reference: Drug Usage in special Population-Pregnancy and Lactation, Educational Series-I, 8th Edition 2020, published by Karnataka State Pharmacy Council, Bangalore.



ಭೇಷಜೇ ಪರಿಕರ್ಮ ನಿಬಂಧನೆಗಳು, 2015 (Pharmacy Practice Regulation, 2015)

(ಅಧ್ಯಾಯ-4)

9. ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರ ಕರ್ತವ್ಯಗಳು:

9.3 ರೋಗಿಯೊಡನೆ ಸಮಾಲೋಚನೆ:

ಎ) ಒಂದು ವೈದ್ಯಲಿಖಿತ (ವೈದ್ಯಲಿಖಿತ /ಔಷಧಿ ಆದೇಶ) ಸ್ವೀಕರಿಸಿದ ನಂತರ ಮತ್ತು ರೋಗಿಯ ದಾಖಲೆಗಳ ಪುನರ್ ಪರಿಶೀಲನೆಯ ನಂತರ, ಒಬ್ಬ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರು, ಔಷಧೋಪಚಾರವನ್ನು ಮೇಲ್ವಿಚಾರಣೆಗೊಳಿಸುವ ಅಥವಾ ಗರಿಷ್ಠ ಲಾಭಕರವಾಗಿ ಪರಿವರ್ತಿಸುವಂತಹ ವಿಚಾರಗಳ ಬಗ್ಗೆ, ಪ್ರತಿಯೊಬ್ಬ ರೋಗಿಯೊಡನೆ ಅಥವಾ ಅಂತಹ ರೋಗಿಯ ಆರೈಕೆದಾರರೊಡನೆ, ಚರ್ಚೆಯನ್ನು ಖುದ್ದಾಗಿ ಪ್ರಾರಂಭಿಸತಕ್ಕದ್ದು. ಸಾಧ್ಯವಾದಾಗಲೆಲ್ಲ ಅಂತಹ ಚರ್ಚೆಯು, ಮುಖ್ಯತಃ ಅಥವಾ ದೂರವಾಣಿ ಮೂಲಕ ಆಗತಕ್ಕದ್ದು ಮತ್ತು ರೋಗಿ ಸಮಾಲೋಚನೆಯ ಸೂಕ್ತ ಎಳೆಗಳನ್ನು ಒಳಗೊಂಡಿರತಕ್ಕದ್ದು ಅಂತಹ ಸೂಕ್ತ ಎಳೆಗಳು, ಈ ಕೆಳಗಿನವುಗಳನ್ನು ಹೊಂದಿರಬಹುದು:

- ಔಷಧಗಳ ಹೆಸರು ಮತ್ತು ವಿವರ
- ಸೇವಿಸುವ ನಮೂನೆ, ಪರಿಮಾಣ, ಅನುಪಾನ ವಿಧಾನ ಮತ್ತು ಔಷಧೋಪಚಾರದ ಕಾಲಾವಧಿ.
- ಔಷಧ ಉಪಯೋಗದ ಉದ್ದೇಶ ಮತ್ತು ನಿರೀಕ್ಷಿತ ಫಲಿತಾಂಶ
- ಆ ಔಷಧಿಗೆ ಇರುವ ವಿಶೇಷ ನಿರ್ದೇಶನಗಳು ಮತ್ತು ಮುಂಜಾಗ್ರತೆಗಳು
- ಎದುರಾಗಬಹುದು ಸಾಮಾನ್ಯ / ತೀಕ್ಷ್ಣ ಅಡ್ಡಪರಿಣಾಮಗಳು, ಅಥವಾ ವ್ಯತಿರಿಕ್ತ ಪರಿಣಾಮಗಳು, ಅಥವಾ ಅಂತರ್ರಾಶಿಯಗಳು ಮತ್ತು ಶುಶ್ರುಷಾ ವಿರೋಧಿ ಸೂಚನೆಗಳು ಮತ್ತು ಅವುಗಳನ್ನು ತಪ್ಪಿಸುವ ವಿಧಾನಗಳ ಸಹಿತ, ಅವುಗಳು ಸಂಭವಿಸಿದರೆ ಕೈಗೊಳ್ಳತಕ್ಕ ಪ್ರಕ್ರಿಯೆಗಳು.
- ಔಷಧೋಪಚಾರವನ್ನು ಸ್ವಯಂ ನಿಯಂತ್ರಿಸುವ ತಾಂತ್ರಿಕತೆ.
- ಔಷಧಗಳನ್ನು ಸೂಕ್ತ ವಿಧಾನದಲ್ಲಿ ಶೇಖರಿಸಿಡುವುದು.
- ವೈದ್ಯಲಿಖಿತವನ್ನು ಪುನಃ ತುಂಬಿಸುವ ಮಾಹಿತಿ.
- ಒಂದು ಬಾರಿಯ ಔಷಧ ಸೇವನೆ ತಪ್ಪಿಹೋದ ಪ್ರಸಂಗದಲ್ಲಿ ಕೊಳ್ಳಬೇಕಾದ ಕ್ರಮ.
- ಔಷಧಗಳ ತರ್ಕಸಮ್ಮತ ಉಪಯೋಗ ಖಾತ್ರಿ ಪಡಿಸುವುದು.

ಸೂಚನೆ: ಒಬ್ಬ ರೋಗಿ ಅಥವಾ ಆರೈಕೆದಾರರು ಅಂತಹ ಸಮಾಲೋಚನೆಯನ್ನು ನಿರಾಕರಿಸಿದಾಗ, ಒಬ್ಬ ಭೇಷಜಜ್ಞರು ಆ ರೋಗಿಯೊಡನೆ ಅಥವಾ ಆರೈಕೆದಾರರೊಡನೆ ಸಮಾಲೋಚಿಸುವ ಅಗತ್ಯವಿಲ್ಲ.

ಬಿ) ರೋಗಿಗಳಿಗೆ ನೀಡಲಾಗಿರುವ ಔಷಧಗಳಿಗೆ ಸಂಬಂಧಿಸಿದ ದಾಖಲೆಗಳನ್ನು (ಡ್ರಗ್ ಕಾರ್ಡ್) ಔಷಧೋಪಚಾರದ ಮೌಲ್ಯಮಾಪನಕ್ಕೆ ಉಪಯೋಗಿಸಬಹುದಾಗಿದ್ದು, ಅವುಗಳನ್ನು ಭೇಷಜಜ್ಞರು ಪಾಲಿಸತಕ್ಕದ್ದು.

9. DUTIES OF REGISTERED PHARMACIST

9.3 Patient counselling:

a) Upon receipt of a prescription (prescription drug order) and following a review of the patient's record, a Registered Pharmacist shall personally initiate discussion of matters that will enhance or optimize drug therapy with each patient or care given of such patient. Such discussion shall be in person, whenever practicable or by telephone and shall include appropriate elements of patient counseling. Such elements may include the following:

- Name and description of the drugs
- The dosage form, dose, route of administration, and duration of drug therapy
- Intended use of the drug and expected action
- Special directions and precautions for the drug
- Common severe side effects or adverse effects or interactions and therapeutic contra indications that may be encountered, including their avoidance, and the action required if they occur;
- Techniques for self-monitoring drug therapy
- Proper storage of the drugs
- Prescription refill information
- Action to be taken in the event of a missed dose
- To ensure rational use of drugs

Note : The pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultations.

b) The pharmacist shall maintain the/ records pertaining to drugs administered to the patients (drug card) that may be utilized for the evaluation of the drug therapy

ಸಿ) ವಿಧಾನಗಳ ಮತ್ತು ಫಲಿತಾಂಶಗಳ ಸಂಶೋಧನೆ ಕೈಗೊಳ್ಳಲು, ಆರೋಗ್ಯವರ್ಧನೆ ಮತ್ತು ವಿದ್ಯಾಭ್ಯಾಸ ಮುಂದುವರಿಸಲು ಮತ್ತು ಆರೋಗ್ಯ ಮಾಹಿತಿ ನೀಡಲು (ಒಬ್ಬ ಆರೋಗ್ಯ ರಕ್ಷಣಾ ವೃತ್ತಿಪರನಾಗಿ) ಭೇಷಜಙ್ಗರು ಅಧಿಕಾರಯುಕ್ತರಾಗಿದ್ದಾರೆ. ಇದರೊಂದಿಗೆ ಸಾಂಕ್ರಾಮಿಕ ರೋಗದ ಔಷಧೋಪಚಾರದ ಬಗ್ಗೆ ಅಧ್ಯಯನ ನಡೆಸುತ್ತಾರೆ. ಡಿ) ರೋಗಿ ಬಗ್ಗೆ ಸಮಾಲೋಚನೆ ಒದಗಿಸುತ್ತಿರುವ ಭೇಷಜಙ್ಗರು, ಈ ಕೆಳಗಿನವಕ್ಕೆ ಗಮನ ಕೊಡತಕ್ಕದ್ದು. i) ನೋಂದಾಯಿತ ಭೇಷಜಙ್ಗರು ಮಾತ್ರ ಸಮಾಲೋಚನೆ ವೃತ್ತಿಯಲ್ಲಿ ತೊಡಗಿರತಕ್ಕದ್ದು. ii) ಗುಪ್ತ ಸಮಾಲೋಚನೆಗೆ ಸೌಕರ್ಯ ಒದಗಿಸತಕ್ಕದ್ದು ಮತ್ತು ರೋಗಿಯ ಬಗ್ಗೆ ಗೌಪ್ಯತೆ ಕಾಪಾಡತಕ್ಕದ್ದು. iii) ಸಮರ್ಪಕವಾದ ದಾಖಲೀಕರಣ ಮಾಡಿಕೊಳ್ಳುತ್ತಿರಬೇಕು. iv) ಅನಗತ್ಯವಾದ ಸಮಾಲೋಚನೆಯನ್ನು ತ್ಯಜಿಸತಕ್ಕದ್ದು. v) ರೋಗಿಯ ಲಾಭಕ್ಕಾಗಿ ಸಮಾಲೋಚನೆ: ಪ್ರತೀ ಸಮಾಲೋಚನೆಯಲ್ಲೂ ರೋಗಿಗೆ ಲಾಭವಾಗತಕ್ಕದ್ದು. ಪ್ರಕರಣದಲ್ಲಿ ತೊಡಗಿರುವ ಎಲ್ಲಾ ನೋಂದಾಯಿತ ಭೇಷಜಙ್ಗರು ರೋಗಿಯೊಡನೆ ಮತ್ತು ಆತನ ಆರೈಕೆದಾರರೊಡನೆ ಬಿಚ್ಚು ಮನಸ್ಸುಳ್ಳವರಾಗಿರತಕ್ಕದ್ದು. vi) ಸಮಾಲೋಚನೆಯಲ್ಲಿ ಕಾಲಿನಿಷ್ಠೆ: ಸಮಾಲೋಚನೆಗೆ ತಾವು ಲಭ್ಯವಾಗುವಂತೆ ಮಾಡುವಲ್ಲಿ ಒಬ್ಬ ನೋಂದಾಯಿತ ಭೇಷಜಙ್ಗರು ಅತ್ಯಂತ ಹೆಚ್ಚಿನ ಕಾಲಿನಿಷ್ಠೆಯನ್ನು ಪಾಲಿಸತಕ್ಕದ್ದು.	c) The pharmacist is authorized (as a Health care professional) to undertake process and outcome research, health promotion and education and provide health information. Also to undertake the Pharmacopidemiological studies. d) Pharmacies providing patient counseling shall have regard to the following: i) Only Registered pharmacists are involved in counseling. ii) Facilities are provided for confidential conversation and patient confidentiality is maintained. iii) Patient information leaflets are provided. iv) Proper documentation is made. v) Unnecessary counselling should be avoided. vi) Counselling for Patient's Benefit: In every consultation, the benefit to the patient is of foremost importance. All registered pharmacists engaged in the case should be frank with the patient and his attendants. vii) Punctuality in counselling: Utmost punctuality should be observed by a registered pharmacist in making themselves available for counselling.
--	---

KSPC News



60th National Pharmacy Week Theme – Pharmacists-Integral Part of Healthcare

1) Acharya & BM Reddy College of Pharmacy, Bengaluru

The Acharya & BM Reddy College of Pharmacy, Bengaluru in association with IPA, Peenya Branch organized a webinar to embrace the glorious 60th National Pharmacy Week, 2021 from 21st to 27th November 2021.

Dr. Amith Kumar Das, Principal, Dr. Geetha Jayaprakash, Professor and their team convened this webinar.

Mr. Samson P. George, Deputy Registrar & Drug Information Pharmacist, Drug Information and Research Center (DIRC), Karnataka State Pharmacy Council (KSPC) was one of the guest's speakers for the event and he highlighted this year theme 'Pharmacists Integral part of Healthcare' and further detailed on the 'KSPC & DIRC Activities' on 25th November 2021.

The programme was concluded with vote of thanks by Dr. Amith Kumar Das, Principal of the institution. The students of 1st and 2nd year B.Pharm and faculties attended the program.

2. D.R.Karigowda College of Pharmacy, Hassan

The Karnataka State Pharmacy Council (KSPC) in collaboration with the D.R.Karigowda College of Pharmacy, Hassan in association with Karnataka Registered Pharmacist Association (KRPA)® Hassan and Hassan District Chemists Welfare Association (HDCWA) ® organised a motivation event for the Hassan district

registered pharmacist on 12th December 2021 at Pavanputra Resort, Hassan. The theme of the event was 'Distribution of appreciation kit to the registered pharmacists of Hassan District.' The appreciation kit consisted of a white apron with KSPC logo, a key chain and the name plate of the registered pharmacists with KSPC registration number on it.

The guests of honour of the event were Superintendent of Police Dr. Srinivas Gowda R, IPS and ACD of Hassan District Sri Girish Gowda. The event was graced by Shri D.A.Gundu Rao, Vice-President KSPC, Sri Y.Veeranarayana Gowda, EC member KSPC, Sri Samson P. George, Dy.Registrar cum DI Pharmacist, Sri K.M. Sannamanje Gowda, Hon. President of HDCWA, Sri Giri Gowda, Hon. Secretary of HDCWA and Sri. Sunil Chiplunkar, Marketing Head of Group Pharmaceuticals. The proactive organizing committee members were Dr. Meena Purohit, Principal of D.R Karigowda College of Pharmacy, Hassan district, Sri Santhosh Jain, KRPA president and district nominee KCDA Bangalore, and Dr. Kaushik Devaraju, State President KRPA. Dr. Almas Shireen, Assistant Professor, Mr. Mahaveer Singh, Associate Professor and Ms. Mythree B.N., Assistant Professor from D.R.Karigowda College of Pharmacy anchored the event and arranged the distribution of kits.



KSPC members delivered talks on the important role of the registered pharmacist at a pharmacy and how they can bring a change in the health system by their knowledge and importance of pharmacy practice as a community pharmacist. Dr.Meena Purohit highlighted the pride of being a pharmacist and insisted every pharmacist wear the apron with their name plate on it at their workplace to honour the pharmacy profession.

Around 30 registered pharmacists representing each taluk of Hassan were called on the stage and distributed apron, name plate and key chain. Around 150 registered pharmacists of Hassan district attended the event.

3. JSS College of Pharmacy, Mysuru

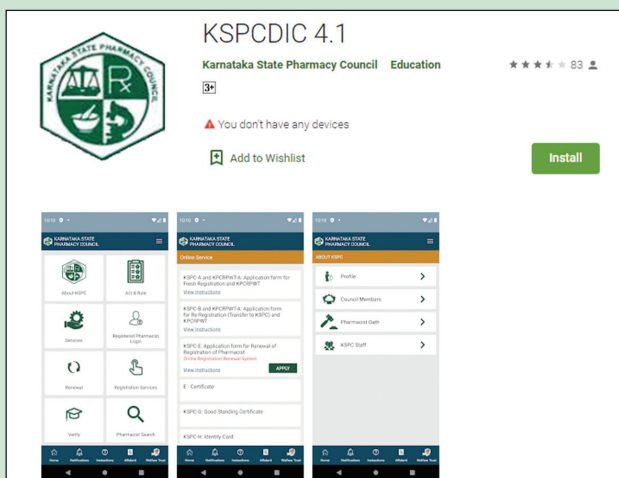
The JSS College of Pharmacy, Mysuru in association with Karnataka State Pharmacy Council and Indian Pharmaceutical Association-Community Pharmacy division jointly organized a webinar on World Antibiotic Awareness Week 2021 on 23rd November 2021. The organizing committee consists of Dr.T.M. Pramod Kumar, Principal, Dr.M. Ramesh, Prof. & HOD, Dept. of Pharmacy Practice and other associate professors and lectures from the Pharmacy Practice department. Various speakers from the different sectors highlighted about the importance of Antibiotic Stewardship Program.

Online Renewal of Registration - 2022

The Renewal of Registration for the year 2022 is opened. The Registered Pharmacist can avail this service through our website (<https://kspcdic.com/renewals>) and mobile app (<http://bit.ly/3t6YcqO>). Renew your registration without fail before the grace period 31-03-2022 as per the Pharmacy Act 1948.

For more information refer general instructions KSPC-E on www.kspcdic.com

- Registrar



'KSPCDIC' Mobile App

The Registered Pharmacist
can install 'KSPCDIC' application from

Google Play Store

through

<http://bit.ly/3t6YcqO>

Disclaimer: Information provided by the center is authentic and should be used judiciously by the healthcare professionals only. The center will not accept any responsibility of liability arising on using the provided information and it rests entirely on the user.

KSPC OFFICE BEARERS

President: Mr. Gangadhar V. Yavagal **Vice-President:** Mr. Gundu Rao D.A. **Registrar:** Prof. B. G. Shivananda
Executive Committee Members: Dr. Jagadish V. Kamath, Dr. Kishore Singh Chatrapathi, Mr. Y. Veeramarayana Gowda
Members: Mr. M.S. Nagaraj, Mr. Madarkandhi R.S, Prof. Hippargi Shivakumar Mallappa, Dr. Salma Khanam, Dr. Veerabhadraiah T.A.
Ex-officio: The Director of Health & Family Welfare Services, Karnataka, The Drugs Controller for the State of Karnataka
& The Govt. Analyst, Drugs Controller for the State of Karnataka

EDITORIAL BOARD

Editor: Mr. Samson P. George **Associate Editor:** Ms. Usha M. J.
Members: Mr. Gundu Rao D.A., Mr. Jaiprakash S. Vastrad, Dr. Kshama Devi, Dr. Lakshmi P.K., Prof. Mahendra Setty C.R.,
Mr. Manoj Kumar Yadava, Dr. Mueen Ahmed K.K., Dr. Noor Zahra, Dr. Purnima Ashok, Mr. Ramesh Babu H.V., Dr. Roopa S. Pai,
Dr. Sunitha Srinivas, Dr. Thakur R.S., Mr. Veeramarayana Gowda Y., Dr. Vithya T.

Additional Information on any article is available on request

Contact:

KARNATAKA STATE PHARMACY COUNCIL

Drug Information and Research Center

514/E, I Main, II Stage, Vijayanagar, Bengaluru-560 104. Ph : 080- 46729800 (800 to 899 lines), 23383142, 23404000

E-Mail : kspcdic@gmail.com, Visit us at : www.kspcdic.com

BOOK-POST