# DIRC Newsletter

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## Official Desk

Sri. Gangadhar V. Yavagal
President
Karnataka State
Pharmacy Council

**Dear Pharmacists,**

***KSPCDIRC wishes you a Happy, Healthy & Prosperous New Year 2021.***

**Karnataka Pharmacy Council Registered Pharmacist Welfare Trust (KPCRPWT)**

Karnataka State Pharmacy Council had started a social welfare scheme called Karnataka Pharmacy Council Registered Pharmacist Welfare Trust (KPCRPWT) during 1998 a unique scheme established for the first time in India with a concern on the welfare of the pharmacist and his/her family.

The scheme is extended to the ailing pharmacists suffering from diseases such as Cancer, Kidney Failure, Bypass Surgery, etc., and other ailments of serious nature (in case the scheme is well responded by the members) as decided by the trust.

**Eligibility:**

1. The applicant should be between 18 to 60 years of age to enroll under KPCRPWT.
2. The applicant must be a Registered Pharmacists in Karnataka State Pharmacy Council.
3. The benefits / claims under scheme will be given only to the registered pharmacist who are on the rolls of the Karnataka State Pharmacy Council and renews his/her registration from time to time. The claim should be made within 3 months or 90 days from the date of medical ailment.

The trust has increased the welfare trust benefit for the registered pharmacist from Rs.1,25,000/- to Rs.2,00,000/- from 01-01-2021. A partial disbursement up to 1/3rd of the minimum amount for the medical treatment in case of serious illness such as cancer, cardiac surgery, kidney transplantation etc. will be released and the balance amount if any will be given to the nominee in case of death of the Registered Pharmacist. Else, if medical claims are not availed, then the full benefit will be released.

Registered Pharmacist who has not enrolled to this scheme and whose Registration validity is current and age <60 years can login to www.kspcdic.com and enroll for the Trust.

For more information regarding the scheme, you can visit https://kspcdic.com/krpwt

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## Online Renewal of Registration - 2021

**The Renewal of Registration for the year 2021 is opened. The Registered Pharmacist can avail this service through our website (https://kspcdic.com/renewals) and mobile app (http://bit.ly/2vtbwxL). Renew your registration without fail before the grace period 31-03-2021 as per the Pharmacy Act 1948.**

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

**- Registrar**

# Guest Column

## Harnessing Pharmacy Services in COVID-19

**Syed Mohsin Khadri**
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Certainly, the year 2020 will be remembered as the year of COVID-19. It has been over a year since this tiny virus has affected all of us in one way or the other which has compelled us to rethink many aspects of our life. It also has made us utilize the online platforms to its full potential.

Healthcare infrastructure has been challenged in a most vigorous way in this pandemic. Healthcare professionals and support service professionals have been working tirelessly for over a year. There also has been a plethora of research studies published in various journals all over the globe right from US, Saudi Arabia, China, Taiwan, Macao etc. In most of the studies pharmacists played an important role on the different fronts of the disease management right from the logistics in the procurement of medicines to direct patient care thereby validating pharmacy services in COVID-19 management.

COVID-19 has compelled the pharmacy community to rethink the kind of services which can be offered by pharmacists with the set of skills they possess.

There are few areas where pharmacy services can be harnessed like

1. Drug Information Services: As there is no definite treatment for the management of COVID-19 the treatment is directed towards symptomatic treatment and some medication indicated based on scarcely available literature. Pharmacists can be a good resource of unbiased drug information to the healthcare professionals, patients, caregivers, and families of patients
2. Protocol/ guidelines development: With the overwhelming influx of the patient in the hospitals and to standardize the care protocols/ guidelines approach is adopted in many institutions. Pharmacist have been an active member of the multidisciplinary team in drafting protocols and guidelines
3. Optimizing the medication use: Procurement of the medications has become challenging for the healthcare institutions where the predictability for the medication use is uncertain. Shortage of medication can be detrimental to the patient care and unnecessary stockpiling the medication will also render the financial burden. It is pertinent for pharmacists to deliver their expertise in optimizing the medication use in the patients who are genuinely in need.
4. Remote pharmacy Services: This pandemic have driven the pharmacy community to explore the possibility of offering pharmacy services remotely
   a. Provide online health consultation to the stable patients with chronic conditions as they refrain from going to their scheduled visits to the hospitals. Owing to that hospitals provide online consultations to their patients. Pharmacists can provide online consultations to the patients regarding their medication use.
   b. Multidisciplinary Healthcare: In line with the requirement of isolation wards for restricted entries in hospitals pharmacist can provide their recommendations remotely
5. Discharge Counselling: There has been incidences of readmission due to lack of medication adherence to the post discharge protocols. Pharmacist can provide patient education at the time of discharge to positively affect the patient outcome.
6. Medication Reconciliation: At transition of care medication reconciliation becomes challenging therefore pharmacist can review the medications if the patient is taking at the time of admission and also, he can make sure the patient is put back on those medication at the time of discharge.
7. Evidence Based Drug Evaluation: As there is still no specific medicine for the treatment for COVID – 19 pharmacist with their background can be an important resource for conducting evidence based drug evaluation studies with respect to anti-viral, antibiotics, steroids and immunomodulators.
8. Multimedia based health information: Pharmacist can spread the awareness of the pandemic to the public and regional if not at least at an institutional level by delivering unbiased health information which can be multimedia based.

**References:**

1. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7334137/pdf/main.pdf
2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7303584/pdf/40545_2020_Article_241.pdf
3. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7102520/
4. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7194937/pdf/main.pdf

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# Drug of the Quarter

**Drug** : **Favipiravir**
**Class** : Antiviral
**Dosing Form** : 200mg, 400mg
**Strength** : Tablet, Injection (unapproved)
**DCGI Approval** : 19.06.2020
**USFDA Approval** : 23.06.2020

**Indication:** Favipiravir is an unapproved antiviral drug under investigation and available only for compassionate use in patients with COVID-19.

**Dosing Information:**

**Adult:**

Normal Dosage: Oral route: COVID-19

a) Investigational Dosage

1) Dosage: 1600 mg orally twice daily on day 1, then 600 mg twice daily on days 2 to 5
2) Duration: 5 days

**Pharmacokinetics**

**Distribution**

A) Distribution Sites

1) Protein Binding

a) Faviparivir protein binding was 53.4% to 54.4% in humans across the concentration range of 0.3 to 30 mcg/mL, based on in vitro study.
b) Favipiravir was 65% bound to human serum albumin; favipiravir binds primarily to albumin.
c) Faviparivir was 6.5% bound to alpha-1-acid glycoprotein in humans.
d) Faviparivir hydroxide metabolite (M1) was 28.8% to 36.9% protein-bound across the concentration range of 0.5 to 50 mcg/mL.

**Metabolism**

A) Metabolism Sites and Kinetics

1) Nicotinamide adenine dinucleotide phosphate (NADPH)-independent enzymes and partially by NADPH-dependent enzymes

a) In vitro, favipiravir is metabolized to favipiravir hydroxide (M1) mainly by NADPH-independent enzymes and partially by NADPH-dependent enzymes in human hepatic cytosol.

B) Metabolites

1) Favipiravir hydroxide (M1)

a) In vitro, favipiravir is metabolized to favipiravir hydroxide (M1) mainly by NADPH-independent enzymes and partially by NADPH-dependent enzymes in human hepatic cytosol.

2) Favipiravir ribosyl triphosphate (favipiravir RTP)

a) Favipiravir is metabolized into favipiravir RTP by an intracellular enzyme.

C) Other

1) Metabolic Enzymes and Transporters: Inhibitor of CYP2C8: Favipiravir inhibited CYP2C8 activity in a concentration-dependent manner in an in-vitro study.

**Excretion**

A) Kidney

1) Renal Excretion: After a single dose of faviparivir 400 mg, urinary excretion rate was 0.1% to 0.4%; excretion of the M1 metabolite, favipiravir hydroxide, was 82% to 92.4% and the mean total urinary recovery rate was 90.5%.

**Elimination Half-life**

A) Parent Compound: Following oral administration of favipiravir 600 mg in healthy adult patients (29 to 58 years), mean t (1/2) was 1.4 +/- 0.2 hours in male subjects and 1.2 +/- 0.1 hours in female subjects.

2) Geriatric: Following oral administration of favipiravir 400 mg in healthy Japanese elderly patients (65 to 77 years), mean t (1/2) was 2 +/- 0.3 hours in male subjects and 1.7 +/- 0.3 hours in female subjects.

**Contraindications:** Women who are pregnant or may possibly be pregnant.

**Cautions:**

- **Gastrointestinal**: Hematochezia has been reported.
- **Hepatic**: Plasma concentrations of favipiravir may increase in patients with hepatic impairment; the relationship between the severity of hepatic impairment and the plasma concentration has not been investigated.
- **Immunologic**: Cellulitis has been reported.
- **Ophthalmic**: May cause phototoxicity.
- **Renal**: Information on the safety in patients with renal impairment is not sufficiently obtained.
- **Reproductive**: Women of childbearing potential and men whose partner is of childbearing potential should be advised to use contraception. Avoid use in women at the early stage of pregnancy, in which a pregnancy test may give a negative result.
- **Respiratory:** Pneumonia has been reported.

### Mechanism of Action

Favipiravir is metabolized into favipiravir ribosyl triphosphate (favipiravir RTP) by an intracellular enzyme, and favipiravir RTP selectively inhibits RNA polymerase (RNA-dependent RNA polymerase) of the influenza virus, preventing viral replication.

Spectrum of Activity: Favipiravir has a mechanism of action different than existing influenza antiviral drugs and is effective against all types and subtypes of influenza A, B, and C viruses in-vitro.

### Adverse Effects

- **Dermatologic:** Cellulitis
- **Endocrine/Metabolic:** Hypertriglyceridemia, Hyperuricemia
- **Gastrointestinal:** Diarrhea, Gastroenteritis, Nausea, Vomiting

### 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 |
|---|---|---|---|---|
| | | | **December 2020** | |
| 1. | Beta-Blockers (Atenolol + Bisoprolol + Metoprolol) | Anti-arrhythmic agent | Treatment of hypertension, angina pectoris, cardiac arrhythmias, Congestive Heart Failure (CHF). | Lichen Planus |
| 2. | Omeprazole | Anti-Ulcer | Short term treatment of duodenal ulcer, gastric ulcer, reflux oesophagitis, management of Zollinger Ellison Syndrome. | Dysuria |
| | | | **November 2020** | |
| 3. | Clarithromycin | Antibiotic / Anti-Infective Agent | Treatment of mild to moderately severe infections like acute exacerbation of chronic bronchitis community acquired pneumonia including infections due to Chlamydia, Mycoplasma spegiocella acute streptococcal pharyngitis and skin and soft tissue infections. | Acute Generalised Exanthematous Pustulosis (AGEP) |
| 4. | Tamsulosin + Deflazacort | Adrenergic Blocker + Adrenal Glucocorticoid | For the treatment of sign & symptoms of benign prostate hyperplasia. For Asthma, Rheumatoid Arthritis when Glucocorticosteriod therapy is warranted. | Ear pain |
| | | | **October 2020** | |
| 5. | Clindamycin | Antibiotic / Anti-Infective Agent | Antibiotic-Indicated in the treatment of gram +ve organism pathogens, staphylococcus & streptococci, pneumococci. | Symmetrical Drug Related Intertriginous and Flexural Exanthema (SDRIFE) |
| | | | **September 2020** | |
| 6. | Fluvoxamine | Antidepressant | Treatment of Obsessive Compulsive Disorder and Depression. | Intracranial / Pulmonary Hypertension |

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:** ***Symmetrical drug-related intertriginous and flexural exanthema (SDRIFE)*** - A symmetrical erythematous rash on the flexures after systemic exposure to a drug.

**Reference:** www.ipc.gov.in

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# Serious Risks/Safety Information – USFDA

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

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

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

| Therapeutic Class / Category | Drug (Examples) | Route of Administration | Potential Signal of a Serious Risk / New Safety Information | Additional Information |
|---|---|---|---|---|
| **January – March 2020** | | | | |
| Antidote / Central Nervous System Agent | Sugammadex | Injection | Arteriospasm coronary (coronary vasospasm) | Evaluation is in progress. |
| Antidiabetic/ Endocrine-Metabolic Agent | Exenatide | Subcutaneous | Thrombocytopenia | The labeling section of the product was updated to include to include thrombocytopenia |
| Dermatological Agent | Crisaborole | Topical | Contact dermatitis | The labeling section of the product was updated to include allergic contact dermatitis. |
| Diagnostic Agent | Ethiodized oil | Injection | Hypothyroidism | Evaluation is in progress. |
| Anti-Infective Agent | Hydroxychloroquine sulfate | Oral | Phospholipidosis | Evaluation is in progress. |
| Proton pump inhibitors | Rabeprazole, dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole | Oral | Syndrome of inappropriate antidiuretic hormone secretion (SIADH) | Evaluation is in progress. |
| Antibiotic | Secnidazole | Oral | Alcohol interaction | Evaluation is in progress. |
| Antiretroviral Agent | Ibalizumab-uiyk | Intravenous | Anaphylactic Reaction. | The labeling section of the product was updated to include hypersensitivity reactions including infusion-related reactions and anaphylactic reactions. |
| Central Nervous System Agent / Immune Modulator | Natalizumab | Intravenous | Thrombocytopenia | Evaluation is in progress. |
| Antineoplastic Agent | Axitinib, Bevacizumab, Cabozantinib, Vandetanib, Ramucirumab, Ponatinib, Lenvatinib, Bevacizumab-awwb, Sorafenib tosylate, Nintedanib, Regorafenib, Sunitinib malate, Pazopanib, Ziv-aflibercept, Bevacizumab-bvzr | Oral/Intravenous | Aneurysm and artery dissection | Evaluation is in progress. |

| Therapeutic Class / Category | Drug (Examples) | Route of Administration | Potential Signal of a Serious Risk / New Safety Information | Additional Information |
|---|---|---|---|---|
| Antineoplastic Agent | Ipilimumab | Intravenous | Hemophagocytic lymphohistiocytosis | Evaluation is in progress. |
| Anticonvulsant | Zonisamide | Oral | Acute myopia and secondary angle closure glaucoma | The labeling section of the product was updated to include acute myopia and secondary angle closure glaucoma. |
| Anticonvulsant | Zonisamide | Oral | Hyperammonemia and encephalopathy | The labeling section of the product was updated to include hyperammonemia and encephalopathy. |

**References:**


1. http://www.fda.gov/
2. www.micromedexsolutions.com, Micromedex (R) 2.0, 2002-2020, IBM Corporation 2020.


# Drug News – Around the Globe

**1. Drug: Oliceridine*** **Country: USA**

Oliceridine is an opioid agonist.

**Approved Indication:** Oliceridine is approved for the management of moderate to severe acute pain in adults, where the pain is severe enough to require an intravenous opioid and for whom alternative treatments are inadequate. This drug is indicated for short-term intravenous use in hospitals or other controlled clinical settings, such as during inpatient and outpatient procedures.

**Approved Dosage Form:** Intravenous.

**Side-effects:** Nausea, vomiting, dizziness, headache and constipation[1].

**2. Drug: Lumasiran*** **Country: USA**

Lumasiran is a genitourinary agent.

**Approved Indication:** Lumasiran is approved as the first treatment for primary hyperoxaluria type 1 (PH1), a rare genetic disorder.

**Approved Dosage Form:** Subcutaneous.

**Side-effects:** Injection site reaction and abdominal pain[1].

**3. Drug: Setmelanotide*** **Country: USA**

Setmelanotide is an Endocrine-Metabolic Agent.

**Approved Indication:** Setmelanotide is approved for chronic weight management (weight loss and weight maintenance for at least one year) in patients six years and older with obesity due to three rare genetic conditions: pro-opiomelanocortin (POMC) deficiency, proprotein subtilisin/kexin type 1 (PCSK1) deficiency, and leptin receptor (LEPR) deficiency. Setmelanotide is the first FDA-approved treatment for these genetic conditions.

**Approved Dosage Form:** Subcutaneous.

**Side-effects:** Injection site reactions, skin hyperpigmentation (skin patches that are darker than surrounding skin), headache and gastrointestinal side effects[1].

**4. Drug: Liraglutide**** **Country: USA**

Liraglutide is an Antidiabetic/Endocrine-Metabolic Agent drug.

**Approved Indication:** Liraglutide is approved for chronic weight management among patients aged 12 and older who are obese. Liraglutide is an adjunct (additional therapy) to a reduced-calorie diet and greater physical activity.

Liraglutide should not be administered with other liraglutide-containing products, nor with any other GLP-1 receptor agonist. Use of Liraglutide for pediatric patients with type 2 diabetes has not been established. The drug has also not been proven to treat weight loss in combination with other products (such as prescription drugs, over-the-counter drugs, and herbal preparations).

**Approved Dosage Form:** Subcutaneous.

**Side-effects:** Gastrointestinal side effects (such as nausea, vomiting, and diarrhea), dizziness and fever[1].

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

**Reference:** 1. https://www.fda.gov/

# Safety Alert - Around the Globe

**1) Drug: Tranexamic acid **** **Country: USA**

*May cause serious life-threatening injuries, including seizures, cardiac arrhythmias, paraplegia, permanent neurological injury, and death*

Tranexamic acid injection is an antifibrinolytic indicated in patients with hemophilia for short-term use (2 to 8 days) to reduce or prevent hemorrhage and reduce the need for replacement therapy during and following tooth extraction.

**Alert:** The U.S. Food and Drug Administration (FDA) is warning that Intrathecal administration of tranexamic acid injection may result in serious life-threatening injuries, including seizures, cardiac arrhythmias, paraplegia, permanent neurological injury, and death.

**Hence, KSPC-DIRC alerts the healthcare professionals to be cautious while prescribing Tranexamic acid injection[1].**

**Note –** **Available in India

**Reference:** 1. https://www.fda.gov/

## Continuing Pharmacy Education (CPE)

# Dispensing Instructions to the Pharmacists

### Asthma-Drug therapy

A chronic lung disease characterized by reversible air flow obstruction, airway inflammation, and airway hyperresponsiveness.

The signs and symptoms include:

- Shortness of breath
- Chest tightness or pain
- Wheezing when exhaling, which is a common sign of asthma in children
- Trouble sleeping caused by shortness of breath, coughing or wheezing
- Coughing or wheezing attacks that are worsened by a respiratory virus, such as a cold or the flu

### Asthma triggers

Exposure to various irritants and substances that trigger allergies (allergens) can trigger signs and symptoms of asthma. Asthma triggers are different from person to person and can include:

- Airborne allergens, such as pollen, dust mites, mold spores, pet dander or particles of cockroach waste
- Respiratory infections, such as the common cold
- Physical activity
- Cold air
- Air pollutants and irritants, such as smoke
- Certain medications, including beta blockers, aspirin, and nonsteroidal anti-inflammatory drugs, such as ibuprofen and naproxen sodium.
- Strong emotions and stress
- Sulfites and preservatives added to some types of foods and beverages
- Gastroesophageal reflux disease

### Classification includes:

- **Intermittent-** The symptoms are mild, lasting fewer than two days per week or two nights per month but does not interfere with daily activities.
- **Mild persistent-** The symptoms occur more than twice a week — but not daily — and up to four nights per month.
- **Moderate persistent-**The symptoms occur daily and at least one night every week, but not nightly. They may limit some daily activities.
- **Severe persistent**. The symptoms occur several times every day and most nights. Daily activities are extremely limited.

### Treatments for asthma fall into three primary categories:

- breathing exercises
- quick-acting treatments
- long-term asthma control medications

Most of the asthma medicines are administered using an inhaler or nebulizer. But some asthma medicines are in tablet form. An inhaler or nebulizer allows the medicine to go directly to the lungs.

The drugs used to treat asthma can be classified as following,

- ➢ Mast cell stabilizers: Cromolyn sodium, nedocromil
- ➢ Immunomodulators (12 years and older): omalizumab
- ➢ Inhaled corticosteroids (ICS): beclomethasone, budesonide, ciclesonide, flunisolide, fluticasone, mometasone, triamcinolone

- Leukotriene receptor antagonist (LTRA): montelukast, zafirlukast
- 5-lipoxygenase inhibitor: zileuton
- Long-acting inhaled beta-2 agonists (LABA): formoterol, salmeterol
- Methylxanthines: theophylline, sustained release

**Quick relief medications:**

- Anticholinergic inhaled agents: ipratropium
- Corticosteroids, oral: methylprednisolone, prednisolone, prednisone
- Short-acting inhaled beta-2 agonists: albuterol, bitolterol, levalbuterol, pirbuterol

Below is a brief overview of few drugs used for inhalation and as oral therapy.

| Drugs/ Category | Use | Warnings | Less serious side effects | Advice |
|---|---|---|---|---|
| Cromolyn sodium<br><br>**Dosage form:** Inhalation | Used for management (prophylaxis) of bronchial asthma. | Prescription to be reconfirmed in case of patient is pregnant or breastfeeding or have kidney disease, liver disease. | Headache, Cough, Bad taste in mouth | Advise the patient that this drug is not indicated for acute asthma attacks.<br><br>Do not discontinue this drug without the advice of the doctor.<br><br>Advice the patient to check the amount of medicine left in the inhaler by placing it in a glass of water. Full inhalers will sink, empty inhalers will float and half-full inhalers will partially submerge. |
| Beclomethasone Dipropionate<br><br>**Dosage form:** Inhalation | Treatment as asthma, as prophylactic therapy in the maintenance treatment | Prescription to be reconfirmed in case of patient is pregnant or breastfeeding or have cataracts, glaucoma, or osteoporosis | Upper respiratory infection, nasopharyngitis, allergic rhinitis, oropharyngeal pain and sinusitis. | Advice that drug is not indicated for acute asthma attacks or bronchospasm.<br><br>Advice patient to rinse mouth with water without swallowing after use to reduce risk of oral candidiasis. |
| Budesonide<br><br>**Dosage forms:** Inhalation / Oral | Indicated for maintenance therapy of asthma. | Prescription to be reconfirmed in case of patient is pregnant or breastfeeding or have osteoporosis, cataracts, glaucoma, or any type of infection, especially a lung infection such as tuberculosis. | Headache, nausea, diarrhea, abdominal pain or distension, fatigue, flatulence, acne or constipation. | Advice patient to discontinue inhalation powder if bronchospasm occurs.<br><br>Advice to swallow capsule whole once daily in the morning.<br><br>Advise patients taking the oral forms to avoid consumption of grapefruit and grapefruit juice during therapy. |

**(to be continued…….)**

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

**References:**

1. Handbook of Pharma SOS, Educational Series-I, 9th Edition 2020, published by Karnataka State Pharmacy Council, Bangalore.

2. www.micromedexsolutions.com, Micromedex® 2.0,2002-2020, IBM Corporation 2020.

3. www.mayoclinic.org

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# Drug Usage in Special Population - Pediatrics and Geriatrics

**(From KSPCDIRC publication)**

**Antianaemia Drugs**

| Drug | Usage in Children (Pediatrics) | Usage in Elderly (Geriatrics) |
|---|---|---|
| Cyanocobalmin, Cobalamin Hydroxy cobalmin (Vitamin B12) | Safety and efficacy have been well established. | No dosage adjustment required in in renal and hepatic impairment. |
| Folic Acid | Safety and efficacy have been well established. | No dosage adjustment required in in renal and hepatic impairment. |
| Iron Dextran | Safety and efficacy not established in paediatric patients younger than 4 months. | No dosage adjustment required in in renal and hepatic impairment. |

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

# Drug Usage in Special Population - Pregnancy and Lactation

**(From KSPCDIRC publication)**

**Antianaemia Drugs**

| Drug | Usage in Pregnancy (Teratogenicity) | Usage in Breastfeeding (Lactation) |
|---|---|---|
| Cyanocobalmin, Cobalamin Hydroxy cobalmin (Vitamin B12) | 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. But it is an essential vitamin and requirements are increased during pregnancy. | Excreted into breast milk, but minimal risk. |
| Folic Acid | Fetal risk is minimal. The weight of an adequate body of evidence suggests this drug poses minimal risk when used in pregnant women or women of childbearing potential. Nutritional supplement doses of vitamins and minerals are generally considered safe during pregnancy. | Compatible with breastfeeding. |
| Iron Dextran | Fetal risk cannot be ruled out. Administer iron dextran during pregnancy only if potential maternal benefit outweighs potential fetal risk | Infant risk cannot be ruled out. Use with caution. |

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

# DCGI approved Drugs from January to October 2020

| S.No | Name of drug | Category | Indication | Date of issue |
|---|---|---|---|---|
| 1 | Cidofovir dihydrate bulk drug and Cidofovir injection 75 mg/ ml (5 ml single use vial) | Antiviral | Treatment of CMV retinitis in adults with acquired immune deficiency syndrome (AIDS) and without renal dysfunction. It should be used only when other medicinal products are considered as unsuitable. | 03.01.2020 |
| 2 | Dacomitinib tablet 15mg, 30mg and 45mg | Antineoplastic Agent | First line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations | 03.01.2020 |
| 3 | Alpelisib film coated tablets 50mg, 150mg, 200mg | Antineoplastic Agent | Alpelisib in combination with Fulvestrant for the treatment of postmenopausal women, and men, with Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer following progression on or after an endocrine-based regimen. | 03.01.2020 |

| S.No | Name of drug | Category | Indication | Date of issue |
|---|---|---|---|---|
| 4 | Isavuconazole sulfate 100mg capsules | Antifungal | Used for patients 18 years of age and older for the treatment of Invasive Aspergillosis and Invasive Mucormycosis | 14.02.2020 |
| 5 | Azelnidipine tablets IP 8 mg | Antihypertensive | Treatment of Stage I Hypertension | 04.03.2020 |
| 6 | Pixantrone 29mg powder for concentrate for solution for infusion | Antineoplastic Agent | Indicated as 3rd line and 4th line therapy for the treatment of adult patients with multiply relapsed or refractory aggresive Non-Hodgkins B- Cell Lymphomas (NHL) | 11.03.2020 |
| 7 | Fixed Drug Combination of Bilastine 20mg and Montelukast 10mg tablets | Antihistamine | Treatment of allergic rhinitis in adults. | 11.03.2020 |
| 8 | Obeticholic acid bulk drug and Obeticholic acid 5mg/10mg tablets | Gastrointestinal Agent | Treatment of primary biliary cholangitis (also known as primary biliary cirrhosis) in combination with ursodeoxycholic acid (UDCA) in adult with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA | 11.03.2020 |
| 9 | Isavuconazole (as Isavuconazoniumsulfate) 200mg powder for concentrate for solution for infusion | Antifungal | Indicated for patients above 18 years of age for Invasive Aspergillosis and Invasive Mucormycosis. | 11.03.2020 |
| 10 | Polymyxin B for injection 500000 IU | Antibiotic | Treatment of infections of the urinary tract, meninges, and blood stream caused by susceptible strains of Ps. Aeruginosa. Also used as subconjunctival infection in the treatment of infections of the eye caused by susceptible strains of Ps. aeruginosa. It may be indicated in serious infections caused by susceptible strains of the following organisms,<br>1. H. influenzae, specifically meningeal infections<br>2. Escherichia coli, specifically urinary tract infections<br>3. Aerobacter aerogenes, specifically bacteremia<br>Klebsiella pneumoniae, specifically bacteremia | 30.03.2020 |
| 11 | Sucroferric oxyhydroxide bulk and Sucroferric oxyhydroxide chewabale tablet 500mg | Genitourinary Agent / Phosphate Binder | Phosphate binder indicated for the control of serum phosphorous levels in patients with chronic kidney disease on dialysis | 18.04.2020 |
| 12 | Remdesivir Injection 5 mg/mL and Remdesivir lyophilised powder for Injection 100 mg | Antiviral | Treatment of suspected or laboratory confirmed corona virus disease 2019 (COVID-19) in adults and children hospitalised with severe disease, in light of Covid 19 outbreak, for restricted emergency use in the country. | 01.06.2020 |
| 13 | Favipiravir bulk and Favipiravir film coated tablet 200mg | Viral RNA Polymerase Inhibitor | Treatment of patients with mild to moderate Covid-19 disease, in light of Covid 19 outbreak, for restricted emergency use in the country. | 19.06.2020 |
| 14 | Remdesivir bulk drug | Antiviral | - | 20.06.2020 |
| 15 | Pretomanid bulk and Pretomanid tablets 200mg | Antitubercular | Indicated as part of a combination regimen with Bedaquiline and Linezolid, in adults for the treatment of pulmonary extensively drug resistant (XDR), or treatment intolerant or nonresponsive multidrug- resistant (MDR) tuberculosis (TB) | 15.07.2020 |

| S.No | Name of drug | Category | Indication | Date of issue |
|---|---|---|---|---|
| 16 | Favipiravir film coated tablet 400mg | Viral RNA Polymerase Inhibitor | Treatment of patients with mild to moderate Covid-19 disease, in light of Covid 19 outbreak for restricted emergency use in the country | 22.07.2020 |
| 17 | Defetilide bulk and Dofetilide capsules 125mcg, 250mcg, 500mcg | Antiarrhythmic | Maintenance of Normal Sinus Rhythm (Delay in AF/AFl Recurrence) | 31.07.2020 |
| 18 | Netarsudil mesylate bulk and Netarsudil ophthalmic solution 0.02%w/v | Antiglaucoma | For the reduction of elevated intraocular pressure in patients with open angle galucoma or ocular hypertension | 14.10.2020 |
| 19 | Risdiplam powder for oral solution 60mg | Musculoskeletal Agent | Treatment of Spinal Muscular Atrophy (SMA) in patients 2 months of age and older | 16.10.2020 |
| 20 | Fixed Drug Combination of Azelnidipine 8mg and Telmisartan 40mg tablet | Antihypertensive | Treatment of Stage-II hypertension | 16.10.2020 |

**Reference:** www.cdsco.gov.in

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# ಭೇಷಜೀ ಪರಿಕರ್ಮ ನಿಬಂಧನೆಗಳು, 2015 (Pharmacy Practice Regulation, 2015)

(ಅಧ್ಯಾಯ–2)

**6. ಉತ್ತಮ ಭೇಷಜೀ ಅಭ್ಯಾಸಗಳನ್ನು ಕಾಯ್ದುಕೊಳ್ಳುವುದು:**

**6.3. ರೋಗಿಯ ಆರೈಕೆಯಲ್ಲಿ ಅತ್ಯುತ್ತಮ ಗುಣಮಟ್ಟ ಖಾತ್ರಿ ಪಡಿಸುವುದು:**

ನೈತಿಕ ಶೀಲದ ಕೊರತೆ ಅಥವಾ ವಿದ್ಯಾರ್ಹತೆಯಲ್ಲಿ ಕೊರತೆ ಇರುವಂತಹ ವ್ಯಕ್ತಿಗಳು, ವೃತ್ತಿಪರ ಪರಿಚರ್ಯೆಗೆ ಸೇರ್ಪಡೆಗೊಳ್ಳುವುದರ ವಿರುದ್ಧ ಪರಿಚರ್ಯೆಯನ್ನು ರಕ್ಷಿಸಿಕೊಳ್ಳುವಲ್ಲಿ ಪ್ರತಿಯೊಬ್ಬ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರೂ ನೆರವು ನೀಡತಕ್ಕದ್ದು. ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರು, ತಮ್ಮ ವೃತ್ತಿಪರ ಪರಿಕರ್ಮದ ಅನುಷ್ಠಾನದ ಸಂಬಂಧವಾಗಿ, ನೋಂದಾವಣೆ ಮಾಡಿಸಿಕೊಳ್ಳದ ಅಥವಾ ಚಾಲ್ತಿಯಲ್ಲಿರುವ ಭೇಷಜೀ ಕಾಯ್ದೆಯ ಅಡಿಯಲ್ಲಿ ಹೆಸರು ಪಟ್ಟಿ ಮಾಡಲ್ಪಡದ ಯಾವುದೇ ಸೇವಕರನ್ನು ನೇಮಿಸಿಕೊಳ್ಳತಕ್ಕದ್ದಲ್ಲ ಮತ್ತು ಎಲ್ಲೆಲ್ಲಿ ವೃತ್ತಿಪರ ತಾರತಮ್ಯ ಅಥವಾ ಕೌಶಲ್ಯದ ಅಗತ್ಯತೆ ಇದೆಯೋ ಅಂತಲ್ಲಿ ಅಂತಹ ವ್ಯಕ್ತಿಗಳಿಗೆ ರೋಗಿಗಳ ಸೇವೆಗೆ ಅವಕಾಶ ನೀಡತಕ್ಕದ್ದಲ್ಲ.

**6.4 ನೀತಿಗೆಟ್ಟ ನಡತೆಯನ್ನು ಬಯಲು ಮಾಡುವುದು:**

ಪರಿಚರ್ಯೆಯ ಸದಸ್ಯರ ಪಾಲಿನಲ್ಲಿ ಅನರ್ಹತೆ, ಲಂಚಗುಳಿತನ, ಧೂರ್ತ ವರ್ತನೆ ಅಥವಾ ದುರ್ನೀತಿಯುಕ್ತ ನಡತೆಯನ್ನು ಯಾವುದೇ ಭಯ ಅಥವಾ ಅನುಗ್ರಹವಿಲ್ಲದೇ, ಒಬ್ಬ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರು ಬಹಿರಂಗಪಡಿಸತಕ್ಕದ್ದು.

**6.5 ವೃತ್ತಿಪರ ಸೇವೆಗಳಿಗೆ ಸಂಭಾವನೆ:**

ಭೇಷಜೀ ಪರಿಚರ್ಯೆಯ ಪರಿಕರ್ಮದಲ್ಲಿ ತೊಡಗಿರುವಂತಹ ಆ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರು, ರೋಗಿಗಳ ಹಿತಾಸಕ್ತಿಗಳಿಗೆ ಆದ್ಯತೆ ನೀಡತಕ್ಕದ್ದು. ಒಬ್ಬ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರ ವೈಯಕ್ತಿಕ ಹಣಕಾಸು ಹಿತಾಸಕ್ತಿಗಳು, ರೋಗಿಗಳ ವೈದ್ಯಕೀಯ ಆದ್ಯತೆಗಳ ಜೊತೆ ಘರ್ಷಣೆ ಉಂಟು ಮಾಡತಕ್ಕದ್ದಲ್ಲ. ಒಬ್ಬ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರು ಸೇವೆ ಪ್ರಾರಂಭಿಸುವ ಮುನ್ನ ತನ್ನ ಶುಲ್ಕವನ್ನು ಘೋಷಿಸತಕ್ಕದ್ದೇ ವಿನ: ಸೇವೆ ಮುಗಿದ ನಂತರ ಅಲ್ಲ. ಅಂತಹ ಸೇವೆಗೆ ಸ್ವೀಕರಿಸಲಾದ ಸಂಭಾವನೆಯು, ಸೇವೆ ಸಲ್ಲಿಸುತ್ತಿರುವಾಗ, ರೋಗಿಗೆ, ನಿರ್ದಿಷ್ಟವಾಗಿ ಘೋಷಿಸಲಾಗಿದ್ದ ನಮೂನೆಯಲ್ಲೇ ಮತ್ತು ಅಷ್ಟೇ ಮೊತ್ತದ್ದಾಗಿರುತಕ್ಕದ್ದು. "ಗುಣಮುಖರಾಗದಿದ್ದಲ್ಲಿ ಸಂಭಾವನೆಯೂ ಇಲ್ಲ" ಎಂಬಂತಹ ಒಪ್ಪಂದ ಮಾಡಿಕೊಳ್ಳುವುದು ನೀತಿಗೆಟ್ಟ ನಡತೆಯಾಗಿದೆ. ರಾಜ್ಯದ ಪರವಾಗಿ ಸೇವೆ ಸಲ್ಲಿಸುತ್ತಿರುವ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರು, ಯಾವುದೇ ಪ್ರತಿಫಲ ನಿರೀಕ್ಷಿಸುವುದು ಅಥವಾ ಸ್ವೀಕರಿಸುವುದರಿಂದ ದೂರ ಉಳಿಯತಕ್ಕದ್ದು.

**6. Maintaining good pharmacy practice:**

**6.3 Highest Quality Assurance in patient care:** Every registered pharmacist shall aid in safeguarding the profession against admission to it of those who are deficient in moral character or education. Registered pharmacist shall not employ in connection with his professional practice any attendant who is neither registered nor enlisted under the Pharmacy Act in force and shall not permit such persons to attend, to patients wherever professional discretion or skill is required.

**6.4 Exposure of Unethical Conduct:** A registered pharmacist should expose, without fear or favour, incompetent or corrupt, dishonest or unethical conduct on the part of members of the profession.

**6.5 Payment of Professional Services:** The registered pharmacist, engaged in the practice of pharmacy profession shall give priority to the interests of patients. The personal financial interests of a registered pharmacist shall not conflict with the medical interests of patients. A registered pharmacist shall announce his fees before rendering service and not after. Remuneration received for such services shall be in the form and amount specifically announced to the patient at the time the service is rendered. It is unethical to enter into a contract of "no cure no payment". Registered pharmacist rendering service on behalf of the state shall refrain from anticipating or accepting any consideration.

# KSPC News

## 59th National Pharmacy Week - 2020

***Theme – Pharmacists: Frontline Health Professionals***

### 1. NITTE College of Pharmaceutical Sciences, Bengaluru

The NITTE College of Pharmaceutical Sciences, Bengaluru organized a webinar to embrace the glorious 59th National Pharmacy Week, 2020 from 16th to 21st November 2020.

Dr.Kusum Devi, Principal, Dr.Roopa Karki, Professor and Mrs. N.V.L Sirisha Mulukuri, Asst. Professor arranged the 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 speaker for the event and he highlighted on this year theme 'Pharmacists: Frontline Health Professionals' and further detailed on the **'KSPC & DIRC Activities'** on 20th November 2020.

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






Additional Information on any article is available on request

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*BOOK–POST*

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