DIRC Newsletter

Vol. 22 No. 2 July – September 2020

Newsletter of Drug Information and Research Center, KSPC

Member of International Society of Drug Bulletins (ISDB)

Official Desk

Sri. Gangadhar V. Yavagal
President
Karnataka State
Pharmacy Council

Dear Pharmacists,

Our Council have noticed that several Chemists and Druggists shops in the State have employed Registered Pharmacists only for the purpose of obtaining Drug Licenses without the physical presence of Pharmacists as required in Rule 65 (2) read with 65(15)(c) of Drugs and Cosmetics Rules, 1945. Those pharmacists are not present in the shop and are employed elsewhere or doing dual jobs by lending their Registration Certificate. Wherever such instances have come to the notice of this office, the Council has issued a notice in accordance with the provisions of the Pharmacy Act / Karnataka State Pharmacy Council Rules to put an end to professional misconduct.

The Pharmacy Council of India in its recent circular no. 2-26/2019-PCI (A)/2792-2897 dated 08-08-2020 informed that the state councils are empowered to appoint Pharmacy inspectors for strict implementation of Section 42 of the Pharmacy Act to inspect pharmacies where drugs are compounded or dispensed.

Hence, the Council is appointing the Pharmacy Inspectors u/s 26A of the Pharmacy Act, 1948 in Karnataka having the prescribed qualifications for the purposes of Chapters III, IV, and V of the Pharmacy Act, 1948.

I request all the Registered Pharmacist not to lend their registration certificate to any Chemist and Druggist shop / Hospital / Nursing Home /Wholesale Distributors / Clinics without physical presence which will be guilty of such infamous conduct and will be liable to have his/her name removed from the register under u/s 36(1) (ii) of the Pharmacy Act 1948. Such Registered Pharmacists are directed to withdraw their Certificate lent without being physical present to avoid legal action.

Renewals: I wish to remind all the Registered Pharmacists in the State of Karnataka to renew your registration for the year 2021 as per Section 34 of the Pharmacy Act 1948. The online renewal system will be opened from 1st December 2020 and you can renew your registration either through our KSPCDIC mobile app or through laptop/desktop. ❑

CONTENTS

Online Renewal of Registration-2021

The Renewal of Registration for the year 2021 will be opened from 1st December 2020. 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.

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

- Registrar

Guest Column
World Pharmacist Day 2020
Community Pharmacists Transforming Global Health

Dr. R. S. Thakur
Former President, FIPO
Email: drramsthakur@gmail.com

The World Pharmacists Day will be observed on 25th September 2020. The International Pharmaceutical Federation (FIP) has announced "Transforming Global Health" as theme of this year. The object is to focus the role of pharmacist in transforming global health. In every country largest number of the pharmacists serves the community as community pharmacist. Community pharmacists are easily approachable and always ready to help the masses through advice on health-related issues besides accurately dispensing the prescription and providing clinical assistance through counselling on medication related matters. The services rendered by community pharmacists make them an important facilitator in transforming global health. We know that health is wealth, and a healthy nation is productive and prosperous nation. In health care medicines play the most important role whether it is preventive, prophylactic, therapeutic or restorative aspect? Community pharmacist being back bone of health care delivery system assumes much important place in the health care team.

The term health was very broadly defined by WHO in 1948. It says health is a state of complete physical, mental, and social wellbeing and not merely the absence of disease or infirmity. According to this definition not only absence of disease but physical and mental fitness as well as normal social behaviour all form part of health. Thus, in transformation of health all these aspects of health must be given due importance and every individual must be guided properly to take care of all the elements of health and maintain harmony so that overall wellbeing is not only achieved but maintained regularly.

WHO (1) has earmarked the role of community pharmacists as under: -

> *"In addition to ensuring an accurate supply of appropriate products, their professional activities also cover counselling of patients at the time of dispensing of prescription and non-prescription drugs, drug information to health professional, patients and the general public, and participation in health promotion programmes."*

In this plight role of medicines is no doubt very important but equally important are factors like nutrition, hygiene, habits and physical activities. These help in avoiding diseases as well as maintaining good health. As drug-drug interaction is important in rational use of medicines and assuring safety of medication; so is drug-food and drug-beverage interaction. Therefore, not only communicating to the patients the instructions as to how, how many times a day and for how many days the medicines are to be taken forms part of patient counselling but also what food to be avoided, what drinks to be avoided during the therapy are important aspects of counselling. The hygiene aspect has both preventive and curative effect. Hygiene controls spread of infectious diseases, whereas wound hygiene promotes healing and quick recovery. The habit of coughing, sneezing and touching surfaces indiscriminately is a major source of contamination and spread of contagious diseases. It goes without saying that physical activities are essential both for physical and mental fitness. Appropriate yoga and other exercises rejuvenate the system and keep a person healthy and alert to diligently perform his routine duties and responsibilities.

From the above it is evident that health as such is a vast field and with advances in science and technology healthcare aspects are also changing extremely fast. The preventive and prophylactic aspects of health need deep attention to avoid the disease itself. Transforming health is not possible without properly popularising preventive and prophylactic measures in which nutrition, hygiene, habits, and physical activities play very important role. In preventive health campaign role of health education assumes prime place. School health education, Community health education measures must be applied in appropriate manner to convince the masses about role of balanced diet in prevention of disease and restoration of health. Role of balanced diet in improving immunity to fight against disease, enhancing recovery from illness, and providing sufficient energy for routine activities at the same time reducing the risk of non-communicable diseases must reach to the masses.

Whole grains, plenty of vegetables and fruits, dairy products are essential for proper nutrition and healthy life. Moreover, the food should be cooked and processed in hygienic manner to preserve nutritional value. Eating food in hygienic manner avoids contamination. Stale food may become poisonous and injurious to health. The nutrition programme should provide training in every aspect of food and nutrition so that people become conscious about their food and food habits that assures healthy life.

Personal and environmental hygiene have huge impact on health and wellbeing of individuals. Human body is good host of disease-causing microbes and parasites. Personal hygiene is of paramount importance in overcoming the risks of infection. Appropriately washing, brushing, bathing, cleaning clothes, cleaning utensils and cutlery are important for personal and domestic hygiene to promote good health. Proper sewage system and garbage disposal are important for avoiding environmental pollution.

Industrialization poses special threats to environment and air pollution is becoming increasingly problematic. Control of

particulate matter level besides obnoxious and injurious gases in the air and increasing carbon emission deserves special attention. The age-old axiom 'cleanliness is next to godliness' proves importance of hygiene. The rituals and traditions based on the principle of personal and environmental hygiene are time tested tools for control/preventing communicable diseases. Swatch Bharat Abhiyan is a forward step in this direction because it emphasises both on personal and social aspects of cleanliness. It is bound to bring demographic change in pattern of spread of communicable/ infectious diseases and building a healthy nation.

Good habits to cultivate are the prophetic sermon that also applies to health issues. Habits that are unhygienic affect health causing physical or mental problems and social isolation. Spiting, sneezing, and littering are the worst habits putting the society at risk of numerous health problems. Even the eating habits matter. Excessive eating makes a person prone to overweight, obese and vulnerable to high blood pressure, diabetes, hyperlipidemia, heart disease, cancer and so on. Habits that support normal physiological functions are useful for health. People must cultivate good and healthy habits to lead a healthy life.

Importance of physical exercise and fitness can be hardly ignored in the plight of maintaining good health. Yoga and aerobic exercises harmonize physiological functions and rejuvenates the body. Physical activities are directly linked to mental and psychological wellbeing. Regular participation in outdoor games and sports, yoga, aerobic exercises, and meditation etc. has very good effect on upkeep of health.

Transforming global health plight and initiative need sound attention on quality medicines, rational use of medicines and ancillary factors like nutrition, hygiene, habit, and physical activities with equal weightage. Community pharmacist being responsible citizen and crucial link between doctor and the patient is in advantageous position to contribute his best in transforming global health. The community should be eager to avail counselling on health and medication aspects for better outcomes of the prescription.

Medication errors are another front where community pharmacists have a major role to play. Inaccurate prescribing, inaccurate dispensing, and inaccurate administration of medicines account for medication errors. Pharmacist is in a unique position to check the prescription before dispensing to avoid prescribing errors and dispensing errors at the same time if instructions for use and administration of medicines are discretely conveyed and demonstrated to the patient or his care giver in his mother tongue and verified that it is fully understood, medication errors can be completely avoided and eliminated. Various research findings have report high incidence of errors. (2)

Inaccurate prescribing has many contributing factors including rational use of medicines, illegible handwriting, LASA medicinal products, absence of generic name of the drug in the prescription besides many others. Magnitude of irrational prescribing and consequences of medication error have been studied thoroughly (3, 4) holding medicine as third leading cause of death in US and Europe. Such revelations are matter of great concern for community at large and demand sense of professional responsibility and revolutionary transformation in prescribing habits of medical practitioners. Although clause 1.5 of Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 as amended on 8th October, 2016 stipulates how prescription has to be written it is hardly followed by physicians at large and every community pharmacist faces enormous difficulty due to that. The said clause 1.5 is reproduced below for information of our readers:

> ***"Every physician should prescribe drugs with generic names legibly and preferably in capital letters and he/ she shall ensure that there is a rational prescription and use of drugs"***

Therefore, without any ambiguity it can be concluded that accurate dispensing of prescription becomes a challenging task because of the illegible prescriptions and a major cause for inaccurate dispensing. Inaccuracy of dispensing adversely affects proper and rational use of medicines and effectiveness of prescription. The abundance of illegible prescription is such that it seems physicians believe that unless it is illegible patient will not believe that it is a prescription. If not so, then why don't they obey clause 1.5 of their own professional conduct, Etiquette and Ethics regulation, meticulously in the interest of health and happiness of their own patients?

Another transformation needed involvement of community pharmacists in pharmacovigilance. Reporting of adverse drug reaction is highly unsatisfactory in India. Without active involvement of community pharmacists this gigantic task cannot be performed at all. Vast majority of patients are ambulatory care patients served by community pharmacists. Documented reporting system of each and every feedback and encouraging patients and their care givers to compulsorily report adverse events to their community pharmacist is most important factor in safety assurance of medicines. Thus, community pharmacist has abundant role in transforming global health. They must work as team and maintain authentic records to help assess safety of the medicines available in the market. Unless this area is given proper attention, issue will persist.

On this World Pharmacists Day let us pledge to make prescriptions more rational, safe and efficacious.

References

1. The Role of the Pharmacist in the Health Care System. World Health Organization. WHO/PHARM/94.569, 1994 p 8-10.
2. K W Ridge, D B Jenkins, P R Noyce, N D Barber. Medication errors during hospital drug rounds. *Qual Health Care* 1995 4: 240-243. doi: 10.1136/qshc.4.4.240
3. Peter C. Gotzsche. Our prescription drugs kill us in large numbers. Pol Arch Med Wewn. 2014; 124 (11): 628-634.
4. Diane K. Wysowski. Surveillance of Prescription Drug-Related Mortality Using Death Certificate Data. *Drug Safety* 2007: 30: 533–540.

❑

Drug of the Season

Drug : **Remdesivir**

Class : **Antiviral**

Dosing Form : 100mg, 200mg

Strength : Injection

DCGI Approval : 22.06.2020

USFDA Approval : 1st May 2020, the FDA issued emergency use authorization (EUA)

Indication: Remdesivir is indicated for adults and pediatric patients (12 years of age or older and weighing at least 40 kg) for the treatment of coronavirus disease 2019 (COVID-19) requiring hospitalization. Remdesivir should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care.

Dosing Information:

Adult Dosing:

Intravenous route

COVID-19, Hospitalized patients

a) Patients NOT Requiring Invasive Mechanical Ventilation and/or Extracorporeal Membrane Oxygenation (ECMO)
   1) Loading dosage: 200 mg IV loading dose on day 1.
   2) Maintenance dosage: 100 mg IV once daily on days 2 through 5; may extend for an additional 5 days if clinical improvement is not demonstrated.

b) Patients Requiring Invasive Mechanical Ventilation and/or Extracorporeal Membrane Oxygenation (ECMO)
   1) Loading dosage: 200 mg IV loading dose on day 1.
   2) Maintenance dosage: 100 mg IV once daily on days 2 through 10.

Pediatric Dosing:

Intravenous route

COVID-19, Hospitalized patients

a) 12 Years or Older and 40 kg or Greater.
   1) Patients NOT Requiring Invasive Mechanical Ventilation and/or Extracorporeal Membrane Oxygenation (ECMO).
      a) Loading dosage: 200 mg IV loading dose on day 1.
      b) Maintenance dosage: 100 mg IV once daily on days 2 through 5; may extend for an additional 5 days if clinical improvement is not demonstrated.
   2) Patients Requiring Invasive Mechanical Ventilation and/or Extracorporeal Membrane Oxygenation (ECMO).
      a) Loading dosage: 200 mg IV loading dose on day 1.
      b) Maintenance dosage: 100 mg IV once daily on days 2 through 10.

Pharmacokinetics

Drug Concentration Levels

a) Peak Concentration: IV, single-dose, 3 to 225 mg: Linear pharmacokinetic profile.

b) Area Under the Curve: IV, single-dose, 3 to 225 mg: Linear pharmacokinetic profile.

ADME

Metabolism

- Multiple cell types: Extensive
- Remdesivir triphosphate (GS-443902; major): Active
- Substrate of CYP2C8, CYP2D6, CYP3A4
- Substrate of OAPT1B1 and P-gp transporters; impact likely limited with parenteral.
- administration
- Inhibitor of CYP3A4, OATP1B1, OATP1B3, BSEP, MRP4, and NTCP; impact likely limited by rapid clearance.

Excretion

- Renal excretion: 74%, changed and unchanged
- Fecal excretion: 18%

Contraindications: Known hypersensitivity to remdesivir or any component of the product.

Cautions

- **Concomitant use:** Not recommended in combination with chloroquine phosphate or hydroxychloroquine sulfate as it may result in reduced antiviral activity of remdesivir.
- **Hepatic:** Transaminase elevations have been reported, including serious cases; monitoring recommended and discontinuation may be necessary.
- **Immunologic:** Hypersensitivity reactions including infusion-related and anaphylactic reactions have been reported during and following administration; monitoring recommended and dose adjustment and discontinuation of therapy may be necessary.
- **Renal:** Use not recommended in patients with an estimated GFR less than 30 mL/min.

Mechanism of Action

Remdesivir is an adenosine nucleotide prodrug that distributes into cells where it is metabolized to form the pharmacologically active nucleoside triphosphate metabolite. Metabolism of remdesivir to remdesivir triphosphate has been demonstrated in multiple cell types. Remdesivir triphosphate acts as an analog of adenosine triphosphate (ATP) and competes with the natural ATP substrate for incorporation into nascent RNA chains by the SARS-CoV-2 RNA-dependent RNA polymerase, which results in delayed

chain termination during replication of the viral RNA. Remdesivir triphosphate is a weak inhibitor of mammalian DNA and RNA polymerases with low potential for mitochondrial toxicity.

Adverse Effects

Common

- **Gastrointestinal:** Nausea
- **Other:** Fever

Serious

- **Cardiovascular:** Cardiac arrest
- **Hepatic:** Hepatotoxicity, Increased liver aminotransferase level, abnormal liver function tests
- **Immunologic:** Anaphylaxis, Hypersensitivity reaction
- **Renal:** Acute injury of kidney
- **Respiratory:** Respiratory failure
- **Other:** Infusion reaction

Drug-Drug Interactions

Category	Drug/s (Examples)	Interaction Effect	Management
Antimalarial*	Chloroquine	May result in risk of reduced antiviral activity of remdesivir.	Contraindicated for concurrent use.
Antimalarial*	Hydroxychloroquine	May result in risk of reduced antiviral activity of remdesivir.	Contraindicated for concurrent use.

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

Effects in Pregnancy

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

Medication Counselling: Advice to watch for side effects like infusion-related reactions and hepatic adverse reactions.

References:

1. http://www.micromedexsolutions.com/
2. http://www.cdsco.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
August 2020				
1	Pramipexole	Dopamine Agonist	Treatment of sign and symptoms of idiopathic Parkinson's disease.	Photosensitivity Reaction

Sl. No	Suspected Drug/s	Category	Indication/Use	Adverse Reaction/s Reported
July 2020				
2	SGLT-2 Inhibitors	Antidiabetic Agents	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 Diabetes Mellitus.	Genital Pruritus
3	Fluconazole	Antifungal	Treatment of systemic candidiasis, mucosal candidiasis, prevention of fungal infections in patients with malignancy.	Symmetrical Drug related Intertriginous and Flexural Exanthema (SDRIFE)
June 2020				
4	Hydroxychloroquine Sulphate	Aminoquinoline/ Anti-Infective Agent	Used as prophylactic & treatment of COVID-19 disease.	Mouth Ulceration
March 2020				
5	Terlipressin	Pituitary Hormone	Treatment of bleeding oesophagal varices.	Atrial Fibrillation
February 2020				
6	Olanzapine	Antipsychotic	Schizophrenia.	Hyponatremia
7	Piperacillin + Tazobactam	Antibiotic	Treatment of LRTI/UTI/Intra-abdominal infections, skin and skin structure infections, bacterial septicemic polymicrobic infections.	Blurred Vision

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

❑

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
October - December 2019				
Antimigraine	Erenumab	Subcutaneous	Hypertension	Evaluation is in progress.
Central Nervous System Agent	Suvorexant	Oral	Fall, serious injuries	The labeling section of the product was updated to include falls.

Therapeutic Class / Category	Drug (Examples)	Route of Administration	Potential Signal of a Serious Risk / New Safety Information	Additional Information
Antiviral	Sofosbuvir and Velpatasvir; Ledipasvir and Sofosbuvir; Sofosbuvir, Velpatasvir, and Voxilaprevir	Oral	Interaction with bariatric surgery: treatment failure	Evaluation is in progress.
Antidiabetic/ Glucagon-like peptide-1 (GLP-1) receptor agonists	Lixisenatide, exenatide, semaglutide, liraglutide, insulin glargine and lixisenatide, albiglutide, dulaglutide, insulin degludec and liraglutide	Subcutaneous	Diabetic Ketoacidosis	Evaluation is in progress.
Anti-Infective Agent	Miltefosine	Oral	Eye disorders	Evaluation is in progress.
Immune Modulator	Ocrelizumab	Intravenous	Serious herpes viral infection	Evaluation is in progress.
Proton pump inhibitors	Rabeprazole, dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole	Oral	Acute generalized exanthematous pustulosis (AGEP)	Evaluation is in progress.
Central Nervous System Agent	Riluzole	Oral	Pancreatitis	Evaluation is in progress.
Endocrine-Metabolic Agent	Vasopressin	Intravenous	Diabetes insipidus	The labeling section of the product was updated to include the risk of diabetes insipidus.

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: Remdesivir** **Country: USA**

Remdesivir is an antiviral drug.

Approved Indication: Remdesivir is approved for use in adult and pediatric patients 12 years of age and older and weighing at least 40 kilograms (about 88 pounds) for the treatment of COVID-19 requiring hospitalization. Remdesivir should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care. Remdesivir is the first drug approved by USFDA for COVID-19 treatment.

Approved Dosage Form: Injection.

Side-effects: Increased levels of liver enzymes, allergic reactions, rash, nausea, sweating or shiverings[1].

2. Drug: Ivermectin** **Country: USA**

Ivermectin is a semisynthetic antiparasitic drug.

Approved Indication: Ivermectin lotion is approved to treat head lice for nonprescription, or over the counter (OTC), use through a process called a prescription (Rx)-to-OTC switch. The FDA initially approved ivermectin lotion, 0.5% for the treatment of head lice infestation in patients 6 months of age and older as a prescription drug in February 2012.

Approved Dosage Form: Lotion[1].

3. Drugs: Mepolizumab** **Country: USA**

Mepolizumab is an Antiasthma/ Immunological Agent.

Approved Indication: Mepolizumab is approved for adults and children aged 12 years and older with hypereosinophilic syndrome (HES) for six months or longer without another identifiable non-blood related cause of the disease. The new indication for Mepolizumab is the first approval for HES patients in nearly 14 years.

Approved Dosage Form: Subcutaneous.

Side-effects: Upper respiratory tract infection and pain in extremities (such as the hands, legs and feet)[1].

4. Drugs: Somapacitan* **Country: USA**

Somapacitan is an Endocrine-Metabolic Agent.

Approved Indication: Somapacitan is approved for adults with growth hormone deficiency. Somapacitan is the first human growth hormone (hGH) therapy that adult patients only take once a week by injection under the skin; other FDA-approved hGH formulations for adults with growth hormone deficiency must be administered daily.

Approved Dosage Form: Injection.

Side-effects: Back pain, joint paint, indigestion, a sleep disorder, dizziness, tonsillitis, swelling in the arms or lower legs, vomiting, adrenal insufficiency, hypertension, weight increase, and anemia[1].

5. Drugs: Risdiplam* **Country: USA**

Risdiplam is a musculoskeletal agent.

Approved Indication: Risdiplam is approved to treat patients two months of age and older with spinal muscular atrophy (SMA), a rare and often fatal genetic disease affecting muscle strength and movement. This is the second drug and the first oral drug approved to treat this disease.

Approved Dosage Form: Oral.

Side-effects: Fever, diarrhea, rash, ulcers of the mouth area, joint pain (arthralgia) and urinary tract infections[1].

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

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

Safety Alert - Around the Globe

1) Drug: Diphenhydramine** **Country: USA**

May cause serious heart problems, seizures, coma, or even death

Diphenhydramine is an antihistamine.

Alert: The U.S. Food and Drug Administration (FDA) is warning that taking higher than recommended doses of diphenhydramine can lead to serious heart problems, seizures, coma, or even death.

Hence, KSPC-DIRC alerts the healthcare professionals and public to be cautious while using this medicine[1].

2) Drug: Direct-acting oral anticoagulants** **Country: UK**

May increase the risk of bleeding often life-threatening or fatal

Direct-acting oral anticoagulants (DOACs) are used for anticoagulation.

Alert: The Medicines and Healthcare products Regulatory Agency, UK has alerted that use of direct-acting oral anticoagulants like apixaban, rivaroxaban, dabigatran can increase the risk of bleeding and can cause serious bleeds often life-threatening or fatal.

Hence, KSPC-DIRC alerts the healthcare professionals to be cautious while prescribing DOACs in older people and patients with low body weight or renal impairment[2].

3) Drug: Antipsychotic medicines** **Country: New Zealand**

May increase the risk of cardiovascular events

Antipsychotic medicines are generally indicated to treat psychosis

Alert: The Medsafe-New Zealand Medicines & Medical Devices Safety Authority alerted that use of antipsychotic medicines may increase the risks of cardiovascular adverse effects like QT-prolongation, tachycardia, arrhythmias and changes in blood pressure. Monitoring cardiovascular risk factors in patients taking antipsychotic medicines is necessary to minimize the risk of serious outcomes.

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

4) Drug: Flucloxacillin** **Country: New Zealand**

May cause risk of renal and hepatotoxicity

Flucloxacillin is beta-lactam antibiotic.

Alert: The Medsafe-New Zealand Medicines & Medical Devices Safety Authority has alerts that flucloxacillin can injure the kidneys as well as the liver. Early recognition of flucloxacillin-induced interstitial nephritis and prompt treatment reduces the risk of long-term renal impairment.

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

Note – **Available in India

References:

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

Continuing Pharmacy Education (CPE)

Dispensing Instructions to the Pharmacists

Thyroid storm

Thyroid storm is a very rare, but life-threatening condition of the thyroid gland that develops in cases of untreated thyrotoxicosis (hyperthyroidism, or overactive thyroid).

Causes

Thyroid storm occurs due to a major stress such as trauma, heart attack, or infection in people with uncontrolled hyperthyroidism. In rare cases, thyroid storm can be caused by treatment of hyperthyroidism with radioactive iodine therapy for Graves disease. This can occur even a week or more after the radioactive iodine treatment.

Symptoms

Symptoms are severe and may include any of the following:

- Agitation
- Change in alertness (consciousness)

- Confusion
- Diarrhea
- Increased temperature
- Pounding heart (tachycardia)
- Restlessness
- Shaking
- Sweating
- Bulging eyeballs

A thyroid storm can also be triggered by other conditions like,

- Pregnancy.
- Infection.
- Not taking thyroid medication correctly
- Damage to the thyroid gland
- Surgery
- Overgrowth of thyroid tissue
- Toxic multinodular goiter

Treatment

Treatment of thyrotoxic storm aims at rapidly inhibiting thyroid hormone synthesis, rapidly inhibiting release of preformed thyroid hormone, decreasing peripheral conversion of thyroxine(T_4) to triiodothyronine (T_3), and blocking the peripheral effects of thyroid hormones by beta-adrenergic blockade.

Drug treatment includes the following:

- **Antithyroid Agents:** propylthiouracil, methimazole, carbimazole
- **Iodine Supplements like various** iodine preparations
- **Beta-Adrenergic Blockers:** propranolol, esmolol
- **Calcium Channel Blockers:** diltiazem or verapamil

Below is a brief overview of few oral drugs.

Drugs/ Category	Use	Warnings	Less serious side effects	Advice
Methimazole **Dosage form available**: Tablet	Treatment of hyperthyroidism, used before thyroid surgery or radioactive iodine treatment.	Prescription to be reconfirmed in case of patient is pregnant or breastfeeding or have kidney disease, liver disease, lung disease, or breathing problems.	Rash, arthritis, headache, pruritus, drowsiness, abnormal loss of hair.	Advice the patient to consult the doctor before discontinuing this medicine and not to drive a vehicle or operate machinery while taking this medicine. Advice to promptly report symptoms of vasculitis (eg, new rash, hematuria, decreased urine output, dyspnea, or hemoptysis)
Propylthiouracil **Dosage form available**: Tablet	Treatment of Hyperthyroidism and thyroid storm.	Prescription to be reconfirmed in case of patient is pregnant or breastfeeding or have any liver problems.	Headache, stomach upset, vomiting, dizziness, changes in taste, mild skin rash or itching, mild joint or muscle pain, decreased sense of taste or thinning hair.	Advice to take this medicine with food. Advice the patient to avoid driving vehicle or operate machinery while taking this medicine. Advice to take this medicine at the same time each day to avoid missing any doses. If the patient misses any dose and if it is almost time for the next dose, advice the patient to wait until then and take a regular dose. Do not take extra medicine to make up for a missed dose.

Drugs/ Category	Use	Warnings	Less serious side effects	Advice
Lithium Carbonate **Dosage forms available:** Tablet, Capsule	Treats and helps prevent manic episodes of bipolar disorder.	Prescription to be reconfirmed in case of patient is pregnant or breastfeeding or patient have kidney problems, heart or blood vessel disease, brain or nerve problems, or thyroid problems.	Gastritis, nausea, xerostomia, dizziness, fatigue increased thirst.	Advice the patient to avoid driving vehicle or operate machinery while taking this medicine.
Propranolol Hydrochloride **Dosage forms available:** Tablet, Capsule	Treats certain heart rhythm problems and thyroid storm.	Prescription to be reconfirmed in case of patient is pregnant or breastfeeding liver problems or high blood pressure or lung problems or diabetes or kidney problems	Diarrhea, vomiting, dizziness, fatigue	Advice to take this medicine with or without food. Advice to take this medicine at the same time each day to avoid missing any doses.

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

❑

Drug Usage in Special Population - Pediatrics and Geriatrics

(From KSPCDIRC publication)

Antineoplastic Drugs

Drug	Usage in Children (Pediatrics)	Usage in Elderly (Geriatrics)
Interferon alfa-2a	Safety and efficacy have not been established in neonates and infants.	No dosage adjustment required in renal and hepatic impairment.
Interferon alfa-2b	Safety and efficacy have been well established in pediatric patients above one year. Carefully read the instructions to ensure that the correct dose form and strength of interferon alfa-2b are selected for the indication of use.	Dosage adjustment required in renal impairment and hepatic impairment.
Mercaptopurine	Safety and efficacy have been well established in pediatric patients.	Dosage adjustment required in renal and hepatic impairment.
Methotrexate	Safety and effectiveness of methotrexate in pediatric patients have only been established for cancer chemotherapy and polyarticular-course juvenile rheumatoid arthritis	Dosage adjustment required in geriatric and patients with hepatic impairment.
Vinblastine	Safety and efficacy have been well established in pediatric patients.	No dosage adjustment required in renal impairment. Dose reduction required in hepatic impairment.
Vincristine	Safety and efficacy have been well established in pediatric patients.	No dosage adjustment required in renal impairment. Dose reduction required in 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)

Antineoplastic Drugs

Drug	Usage in Pregnancy (Teratogenicity)	Usage in Breastfeeding (Lactation)
Interferon alfa-2a	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.	Infant risk cannot be ruled out. Weigh the benefits of breastfeeding with the mother's clinical need before use.
Interferon alfa-2b	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.	Infant risk cannot be ruled out. Weigh the benefits of breastfeeding with the mother's clinical need before use.
Mercaptopurine	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.	Avoid breastfeeding.
Methotrexate	Fetal risk has been demonstrated. Evidence has demonstrated fetal abnormalities or risks when used during pregnancy or in women of childbearing potential. An alternative to this drug should be prescribed during pregnancy or in women of childbearing potential.	Infant risk has been demonstrated. Evidence and/or expert consensus has demonstrated harmful infant effects when used during breastfeeding. An alternative to this drug should be prescribed or patients should be advised to discontinue breastfeeding.
Vinblastine	Fetal risk has been demonstrated. An alternative to this drug should be prescribed during pregnancy or in women of childbearing potential.	Infant risk cannot be ruled out. Weigh the benefits of breastfeeding with the mother's clinical need before use.
Vincristine	Fetal risk has been demonstrated. Advise pregnant women or women of reproductive potential that Vincristine sulfate has the potential to cause harm to the fetus.	Infant risk cannot be ruled out.

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

❑

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

(ಅಧ್ಯಾಯ–2)

6. ಉತ್ತಮ ಭೇಷಜೀ ಅಭ್ಯಾಸಗಳನ್ನು ಕಾಯ್ದುಕೊಳ್ಳುವುದು:

6.1 ಸಂಘ ಸಂಸ್ಥೆಗಳಲ್ಲಿ ಸದಸ್ಯತ್ವ:

ತನ್ನ ಪರಿಚರ್ಯೆಯ ಉನ್ನತೀಕರಣಕ್ಕಾಗಿ ಒಬ್ಬ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರು, ಅಲೋಪಥಿಕ್ ಭೇಷಜೀ ಪರಿಜರ್ಯೆಗಳ ಸಂಘ ಸಂಸ್ಥೆಗಳು ಮತ್ತು ಸಮಾಜಗಳೊಂದಿಗೆ ಸದಸ್ಯತ್ವ ಪಡೆಯತಕ್ಕದ್ದು ಮತ್ತು ಅಂತಹ ನಿಕಾಯಗಳ ವೃತ್ತಿಪರ ವಿದ್ಯಾ ಸಂಸ್ಥೆಗಳಿಂದ ಅಥವಾ ಯಾವುದೇ ಇತರ ಅಧಿಕೃತ ಸಂಘ/ಸಂಸ್ಥೆಗಳಿಂದ ಆಯೋಜಿಸಲ್ಪಟ್ಟ ವೃತ್ತಪರರ ಸಭೆಗಳಲ್ಲಿ, ಭೇಷಜೀ ವಿದ್ಯೆ ಮುಂದುವರಿಕೆಯ ಕಾರ್ಯಕ್ರಮದ ಭಾಗವಾಗಿ, ಒಬ್ಬ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರು ಭಾಗವಹಿಸತಕ್ಕದ್ದು, ಈ ಅಗತ್ಯತೆಯನ್ನು ಅನುಪಾಲನಗೊಳಿಸಿದ ಬಗ್ಗೆ ಸಂದರ್ಭಾನುಸಾರ, ಭಾರತದ ಭೇಷಜೀ ಪರಿಷತ್ತಿಗೆ ಅಥವಾ ರಾಜ್ಯ ಭೇಷಜೀ ಪರಿಷತ್ತಿಗೆ ಕ್ರಮಬದ್ಧವಾಗಿ ತಿಳಿಸತಕ್ಕದ್ದು.

6.2 ರೋಗಿ ದಾಖಲೆಗಳನ್ನು ಪಾಲಿಸುವುದು:

(ಎ) ಪ್ರತಿಯೊಬ್ಬ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರು, ಅವರ ರೋಗಿಗಳಿಗೆ ಸಂಬಂಧ ಪಟ್ಟ ವೈದ್ಯಕೀಯ / ವೈದ್ಯಲಿಖಿತಗಳ ದಾಖಲೆಗಳನ್ನು, ಶುಶ್ರೂಷೆ ಪ್ರಾರಂಭವಾದ ದಿನಾಂಕದಿಂದ ಐದು ವರ್ಷಗಳ ಅವಧಿಯವರೆಗೆ ಭಾರತದ ಭೇಷಜೀ ಪರಿಷತ್ತು ಅಡಕ II (Appendix II) ರಲ್ಲಿ ಉಲ್ಲೇಖಿಸಿದ ರೀತಿಯಲ್ಲಿ ಕಾಪಾಡಿ ಇಡತಕ್ಕದ್ದು.

(ಬಿ) ರೋಗಿಗಳಿಂದ / ಅವರ ಅಧಿಕೃತ ಸೇವಕರಿಂದ ಅಥವಾ ಸಂಬಂಧಪಟ್ಟ ಅಧಿಕಾರಿಗಳಿಂದ, ವೈದ್ಯಕೀಯ ದಾಖಲೆಗಳಿಗಾಗಿ ಯಾವುದೇ ಬೇಡಿಕೆ ಮಂಡಿಸಲ್ಪಟ್ಟರೆ, ಅದಕ್ಕೆ ಅಧಿಕೃತಿ ಸ್ವೀಕೃತಿ ನೀಡಬಹುದು ಮತ್ತು ದಾಖಲೆಗಳನ್ನು 72 ಗಂಟೆಗಳ ಅವಧಿಯೊಳಗಾಗಿ ನೀಡತಕ್ಕದ್ದು.

(ಸಿ) ತ್ವರಿತವಾಗಿ ಹಿಂದಕ್ಕೆ ಪಡೆಯಲು ಸಾಧ್ಯವಾಗುವಂತೆ, ಮಡಲು, ವೈದ್ಯಕೀಯ / ವೈದ್ಯಲಿಖಿತಗಳ ದಾಖಲೆಗಳನ್ನು ಗಣಕೀಕರಣಗೊಳಿಸಲು ಪ್ರಯತ್ನಶೀಲರಾಗತಕ್ಕದ್ದು.

6. Maintaining good pharmacy practice:

6.1 Membership in Association:

For the advancement of his profession, a registered pharmacist shall affiliate with associations and societies of allopathic pharmacy professions and involve actively in the functioning of such bodies. A registered pharmacist shall participate in professional meetings as part of Continuing Pharmacy Education programmes, organized by reputed professional academic bodies or any other authorized associations/organisations. The compliance of this requirement shall be informed regularly to Pharmacy Council of India or the State Pharmacy Councils as the case may be.

6.2 Maintenance of patient records:

a) Every registered pharmacist shall maintain the medical / prescription records pertaining to his / her patients for a period of 5 years from the date of commencement of the treatment as laid down by the Pharmacy Council of India in Appendix II.

b) If any request is made for medical records either by the patients/ authorized attendant or legal authorities involved, the same may be duly acknowledged and documents shall be issued within the period of 72 hours.

c) Efforts shall be made to computerize medical/prescription records for quick retrieval.

KSPC Publications

Sri. D.A.Gundu Rao, Vice-President, Karnataka State Pharmacy Council (KSPC) & Sri. Y. Veeranarayana Gowda, Executive Member, KSPC presenting KSPC Publications 2020 to Sri. Bhagoji T Khanapure, Drugs Controller for the State of Karnataka during their visit to Drugs Control Department.

GOLD MEDAL AWARD - 2020

The Rajiv Gandhi University of Health Sciences has awarded "Karnataka State Pharmacy Council, sponsored Gold Medal" for Ms. Vibha Deshpande who secured the highest marks in M.Pharm from P.E.S College of Pharmacy, Bangalore and Mr. Lohit K.C. who secured the highest marks in B.Pharm from Acharya & B.M.Reddy College of Pharmacy, Bangalore during the convocation held on 25th June 2020 at Nimhans Convention Center, Bangalore. The convocation was conducted through the online platform with minimal physical presence at venue due to the COVID-19 pandemic.

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

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