

Pharmacy Practice Communicator



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Department of Pharmacy Practice

B-2, Justice K. S. Hegde Charitable

Hospital, Deralakatte, Mangalore

Phone:0824-2204471, ext.: 2368- 69

Email: pharmacypractice@nitte.edu.in

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Ph: 0824 - 2203991 / 92 / 93 | Fax: 0824 - 2203992

Web: nitte.edu.in.ngsmips

UPDATE ON FIXED DOSE COMBINATION DRUGS BANNED IN INDIA

Dr. Uday Venkat Mateti*

According to the Gazette Notification of India issued on the 10th March 2016, the Ministry of Health and Family Welfare by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, on the recommendations of an Expert Committee, banned the manufacture, sale and distribution (for human use) of 344 fixed dose combination drugs with immediate effect. These fixed-dose combination drugs have been found to have no therapeutic justification involving risk to human beings.

Some of the banned fixed-dose combinations of drugs are:

Aceclofenac + Paracetamol + Rabeprazole
Nimesulide + Diclofenac
Paracetamol + Cetirizine + Caffeine, Diclofenac + Tramadol + Chlorzoxazone
Dicyclomine + Paracetamol + Domperidone, Diclofenac + Tramadol + Paracetamol
Amoxicillin + Tinidazole
Cefixime + Levofloxacin
Azithromycin + Cefpodoxime
Metformin + Gliclazide + Chromium Polynicotinate

For further information with regard to the other banned fixed-dose combination drugs banned in India can be had from the website:<http://www.cdsc.nic.in/writereaddata/SO%20705%28E%29%20TO%201048%28E%29%20DATED%2010-03-2016.pdf>

* Asst. Professor, Department of Pharmacy Practice,
Nitte Gulabi Shetty Memorial Institute of
Pharmaceutical Sciences, Nitte University, Deralakatte, Mangalore, Karnataka, 575 018

TRAINING PHYSICIANS, PHARMACISTS AND NURSES ON PHARMACOVIGILANCE: NEED OF THE HOUR

Neethu Fathima Umar*

Initiating the concept of pharmacovigilance is very important for every country so as to ensure the safe use of medicines. Training the medical, pharmacy and nursing students in pharmacovigilance will create an awareness about their responsibility in reporting Adverse Drug Reactions (ADRs). Pharmacovigilance is a demanding science offering splendid opportunities for reducing harm to patients where by minimizing the costs to healthcare systems. The postgraduate students of all disciplines in medicine, pharmacy and nursing in India should be taught pharmacovigilance. Most of the medical colleges have a pharmacovigilance cell therefore postgraduate students should spend time attending to pharmacovigilance programmes in their teaching hospitals. They should be made aware of the need and importance of reporting ADRs and the reporting procedure. They should be sensitised to report ADRs during their internships.

Physicians working both in urban and rural India should be trained in pharmacovigilance and encouraged to report ADRs to the pharmacovigilance centre. The training programmes should be executed in small groups in structured modules. This will enable them to recognise ADRs and develop a culture of reporting ADRs in the future.

The need for pharmacovigilance is most felt in the rural areas where the public is not aware of the least important things like retaining their own prescriptions. In these areas continuous medical education programmes need to be conducted annually by the professional bodies. Another way of creating awareness is by distributing the newsletters developed by the Pharmacovigilance Programme of India (PvPI) to the health care professionals working at the primary healthcare centres.

References

1. WHO. The importance of pharmacovigilance. 2010. <http://apps.who.int/medicinedocs/en/d/Js4893e/>
2. Council for International Organizations of Medical Sciences. Practical Aspects of Signal Detection in Pharmacovigilance. Geneva: Council for International Organizations of Medical Sciences; 2010.

* PhD Research Scholar, Dept. of Pharmacy Practice,
Nitte Gulabi Shetty Memorial Institute of
Pharmaceutical Sciences, Nitte University, Deralakatte, Mangalore, Karnataka, 575 018

SAFE USE OF ANALGESICS IN PREGNANCY

Anisha Marita D Souza and Shannon Lianna Menezes*

Pregnant women may find the necessity of using analgesics to manage aches and pains, which may be due to injury, infection, fever, rheumatoid arthritis or pain related to pregnancy. Some of the analgesics are safe to take during pregnancy. Analgesics are of two types: non-opioid analgesics (aspirin, acetaminophen, non-steroidal anti-inflammatory drugs) and opioid analgesics (morphine, codeine, oxycodone, hydrocodone). In the past two decades, some of the analgesics are sold as over the counter (OTC) medicines and these medications are frequently used by the pregnant women for common symptoms like pain and fever. Persistent and severe pain, if not treated adequately can lead to depression, anxiety and high blood pressure in the mother.¹ If used appropriately, common analgesics such as acetaminophen, aspirin, non-steroidal anti-inflammatory drugs (NSAIDs) and opioids are relatively safe.

Acetaminophen is widely recommended analgesic and antipyretic during pregnancy. It belongs to United States Food and Drug Administration (USFDA) Category B and can be given during all three trimesters. At therapeutic dose, it is safe to use. Two high – quality cohort studies suggest an association between acetaminophen use in pregnancy and an increased risk of attention deficit hyperactivity disorder (ADHD).²

Aspirin is commonly used to treat mild pain and fever and it belongs to USFDA Category D. This drug increases the risk of haemorrhage. High doses may result in perinatal death, intrauterine growth retardation and teratogenic effects.³ Low doses are often prescribed with heparin to reduce the adverse outcomes in pregnant women with antiphospholipid syndrome and recurrent miscarriages.²

NSAIDs are used to treat mild to moderate pain and fever associated with cold, flu, headache and arthritis in pregnant women. NSAIDs like ibuprofen, diclofenac, naproxen, celecoxib, ketorolac belong to pregnancy Category C in the first and second trimester and Category D in the third trimester. These drugs should be avoided in third trimester due to the risk of premature closure of the ductus arteriosus and pulmonary hypertension.⁴ Indomethacin belongs to pregnancy Australian Drug Evaluation Committee (ADEC) Category C. It should be avoided in the third trimester due to adverse effects on the fetus.³ Eighty percentage of increased risk of miscarriage was seen during the first trimester with the use of NSAIDs, according to a Californian study.²

Opioids are used to treat moderate to severe pain and belong to the USFDA Category C. Opioids taken during the third trimester causes depression of neonatal respiration, withdrawal effects in the neonates of dependent mothers, gastric stasis and risk of inhalation pneumonia in mother during labor. Therefore, the opioids should be avoided in late pregnancy.³ In first and second trimester, opioids should be used cautiously as there may be risks of birth defects of the brain, spine, or spinal cord in babies born to women.¹

Analgesics used in therapeutic doses to manage pain appear to be relatively safe in pregnancy. Use of NSAIDs in the third trimester is not recommended. Though acetaminophen is recommended for the management of pain and fever in pregnant women, the safety of the use of drug is still under critical examination.

References

1. FDA Drug safety communication: FDA has reviewed possible risks of pain medicine use during pregnancy. U.S. Department of health and human services. Last updated on 19/01/2016.
2. Malhotra S, Khanna S. Safety of analgesics in pregnancy. International Journal of Obstetrics and Gynaecology Research 2016; 3: 208-212.
3. Drugs usage in special population- pregnancy and lactation 2014; 5: 55-64.
4. Kennedy D. Analgesics and pain relief in pregnancy and breastfeeding. Australian Prescriber. Feb 2011; 34: 8-10.

*First Year M. Pharm, Department of Pharmacy Practice,
Nitte Gulabi Shetty Memorial Institute of
Pharmaceutical Sciences, Nitte University, Deralakatte, Mangalore, Karnataka, 575 018

SHORT REVIEW ON ZIKA VIRUS

Sujan Basnet*

Introduction

Zika virus is mosquito-borne virus and belongs to the class of genus flavivirus, flaviviridae family. It was first identified in Uganda in the year 1947 in rhesus monkeys. The epidemics of Zika virus was identified in Africa, America, Asia and Pacific. It spreads through the bite of an infected Aedes mosquito. Other possibilities include Maternal-Fetal spread, sexual transmission, and blood transfusion. It also believed to be spread through organ transplantation and breast milk.

Signs and Symptoms

The incubation period of Zika virus disease is not known exactly, but it is expected to be few days. The symptoms are similar to other arthropod-borne viral infections such as dengue and chikungunya. The most common symptoms include fever, headache, joint pain, malaise, skin rashes and conjunctivitis.

Complications of Zika virus disease

The neurological and auto-immune complications of Zika virus disease has been reported. Guillain-Barre syndrome overlapped with Zika virus infections in the general public, as well as an increase in babies born with microcephaly.

Prevention

- Reduce the mosquito exposure
- Infected individuals necessary to protected from mosquito exposure during 1st week of infection to prevent further transmission
- Pregnant women must consider delaying travel to the areas with continuing Zika virus epidemics
- No vaccine or medication to prevent infection or disease

Treatment

Zika virus disease is typically mild and requires no specific treatment. People infected with Zika virus should take adequately of rest and fluids. The patients should treat pain and fever with common medicines. If symptoms worsen, they should seek medical care and advice.

References

1. <http://www.cdc.gov/zika/index.html>
2. <http://www.who.int/mediacentre/factsheets/zika/en/>

* Fourth Year Pharm. D, Department of Pharmacy Practice,
Nitte Gulabi Shetty Memorial Institute of
Pharmaceutical Sciences, Nitte University, Deralakatte, Mangalore, Karnataka, 575 018

RECENT ADVANCES IN DRUG DISCOVERY

FDA APPROVED NEW DRUGS

BRIVARACETAM

Thusha Punnose*

Brivaracetam has been approved by the food and drug administration in month of February 2016 as adjunctive therapy in the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy. It was approved based on the data available from three critical Phase III studies (N01252, N01253 and N01358).

Mechanism of action

It is selective affinity for synaptic vesicle protein 2A (SV2A) in the brain, which can contribute to the anticonvulsant effect. The exact mechanism of brivaracetam is unknown.

Dosage and administration

It is available in tablet, oral solution and injection. The recommended initial dose is 50 mg two times daily (100 mg/day). Based on the tolerability and therapeutic response of the patient, the dose can be attuned to 25 mg two times daily (50 mg/day) or up to 100 mg two times daily (200 mg/day).

Side effects

The most common side effects include nausea, vomiting, dizziness, sleepiness, mental symptoms, and tiredness.

Contraindications

It is contraindicated in patients with depression, mood disorder, liver problems, pregnant or plan to become pregnant women.

Drug interactions

Rifampin: Because of decreased brivaracetam concentrations, increasing brivaracetam dosage in patients on concomitant rifampin is recommended.

Carbamazepine: Because of increased exposure to carbamazepine metabolite, if tolerability issues arise, consider reducing carbamazepine dosage in patients on concomitant brivaracetam.

Phenytoin: Because phenytoin concentrations can increase, phenytoin levels should be monitored in patients on concomitant brivaracetam.

Levetiracetam: Brivaracetam had no added therapeutic benefit when co-administered with levetiracetam.

Patient counselling points

- It may cause drowsiness, tiredness, dizziness and problems with balance and coordination
- Do not drive or operate machinery
- Store at a room temperature (15°C to 30°C).
- Do not freeze the medication
- Keep all medicine out of reach of children

References

1. <http://www.centerwatch.com/drug-information/fda-approved-drugs/drug/100131/briviact-brivaracetam>
2. <http://www.briviact.com/briviact-medication-guide.pdf?v=1455925999>
3. <http://www.briviact.com/briviact-PI.pdf?v=1455912886>

* Fourth Year Pharm. D, Department of Pharmacy Practice,
Nitte Gulabi Shetty Memorial Institute of
Pharmaceutical Sciences, Nitte University, Deralakatte, Mangalore, Karnataka, 575 018

SELEXIPAG

Javedh Shareef*

Selexipag is a prostacyclin receptor agonist, which exerts vasodilating effects. Selexipag is specifically indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH.

Mechanism of action

Selexipag is an oral prostacyclin receptor (IP receptor) agonist that is structurally distinct from prostacyclin. Selexipag is hydrolyzed by carboxylesterase 1 to yield its active metabolite, which is approximately 37-fold as potent as selexipag. Selexipag and the active metabolite are selective for the IP receptor versus other prostanoid receptors (EP1-4, DP, FP and TP).

Dosage and administration

Selexipag is supplied as tablets for oral administration. The recommended starting dose of selexipag is 200 micrograms (mcg) given twice daily. Tolerability may be improved when taken with food. The dose should be increased in increments of 200 mcg twice daily, usually at weekly intervals, to the highest tolerated dose up to 1600 mcg twice daily. If a patient reaches a dose that cannot be tolerated, the dose should be reduced to the previous tolerated dose. Do not split, crush, or chew tablets.

Side effects

Side effects associated with the use of selexipag may include, but are not limited to, the following: Headache, diarrhea, jaw pain, nausea, myalgia, vomiting, pain in extremity, flushing, etc.

Over dosage

Isolated cases of overdose up to 3200 mcg were reported. Mild, transient nausea was the only reported consequence. In the event of overdose, supportive measures must be taken as required. Dialysis is unlikely to be effective because selexipag and its active metabolite are highly protein-bound.

Warnings and precautions

Pulmonary edema in patients with pulmonary veno-occlusive disease. If confirmed, discontinue treatment.

Contraindications

None

Drug interactions

Strong CYP2C8 inhibitors: increased exposure to selexipag and its active metabolite. Avoid concomitant use.

Use in special populations

- **Nursing mothers:** discontinue Selexipag or breastfeeding.
- **Severe hepatic impairment:** Avoid use.
- **Renal impairment:** No adjustment to the dosing regimen is needed in patients with estimated glomerular filtration rate > 15 mL/min/1.73 m². There is no clinical experience with Selexipag in patients undergoing dialysis or in patients with glomerular filtration rates < 15 mL/min/1.73 m²

References

1. <http://www.centerwatch.com/drug-information/fda-approved-drugs/drug/100126/uptravi-selexipag>
2. <https://uptravi.com/pdf/UPTRAVI-Full-Prescribing-Information.pdf>
3. <https://uptravi.com/pdf/UPTRAVI-Patient-Product-Information.pdf>

* Asst. Professor, Department of Pharmacy Practice,
Nitte Gulabi Shetty Memorial Institute of
Pharmaceutical Sciences, Nitte University, Deralakatte, Mangalore, Karnataka, 575 018

LESINURAD

Rajesh K*

Lesinurad is a urate transporter 1 (URAT1) inhibitor indicated in combination with a xanthine oxidase inhibitor for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor alone.

Limitations of use

Lesinurad is not recommended for the treatment of asymptomatic hyperuricemia. Lesinurad should not be used as monotherapy.

Mechanism of action

Lesinurad reduces serum uric acid levels by inhibiting the function of transporter proteins involved in uric acid reabsorption in the kidney. Lesinurad inhibited the function of two apical transporters responsible for uric acid reabsorption, uric acid transporter 1 (URAT1) and organic anion transporter 4 (OAT4), with IC₅₀ values of 7.3 and 3.7 μM, respectively. URAT1 is responsible for the majority of the reabsorption of filtered uric acid from the renal tubular lumen. OAT4 is a uric acid transporter associated with diuretic-induced hyperuricemia. Lesinurad does not interact with the uric acid reabsorption transporter SLC2A9 (Glut9), located on the basolateral membrane of the proximal tubule cell.

Dosage and administration

Lesinurad is recommended at 200 mg once daily in combination with a xanthine oxidase inhibitor, including allopurinol or febuxostat. The maximum daily dose is 200 mg. Failure to take Lesinurad with a xanthine oxidase inhibitor may increase the risk of renal adverse reactions.

Dosage forms and strengths

200 mg (Tablet)

Overdose

Lesinurad was studied in healthy subjects given single dose up to 1600 mg without evidence of dose limiting toxicities. In case of overdose, patients should be managed by symptomatic and supportive care including adequate dehydration.

Side effects

Adverse effects associated with the use of Lesinurad may include, but are not limited to, the following:

- Headache
- Influenza
- Blood creatinine increased
- Gastroesophageal reflux disease

Lesinurad comes with a boxed warning. Acute renal failure has occurred with Lesinurad and was more common when Lesinurad was given alone.

Drug interactions

- **CYP2C9 Inhibitors, CYP2C9 Poor Metabolizers, and CYP2C9 inducers:** Lesinurad exposure is increased when Lesinurad is co-administered with inhibitors of CYP2C9, and in CYP2C9 poor metabolizers. Lesinurad should be used with caution in patients taking moderate inhibitors of CYP2C9 (eg, fluconazole, amiodarone), and in CYP2C9 poor metabolizers.
- Lesinurad exposure is decreased when Lesinurad is co-administered with moderate inducers of CYP2C9 (eg, rifampin, carbamazepine), which may decrease the therapeutic effect of Lesinurad.
- **CYP3A substrates:** In interaction studies conducted in healthy subjects with Lesinurad and CYP3A substrates, lesinurad reduced the plasma concentrations of sildenafil and amlodipine. Although there was not a clinically significant interaction with atorvastatin, HMG-CoA reductase inhibitors that are sensitive CYP3A substrates may be affected. The

possibility of reduced efficacy of concomitant drugs that are CYP3A substrates should be considered and their efficacy (eg, blood pressure and cholesterol levels) should be monitored.

- **Epoxide hydrolase inhibitors:** In vitro studies suggest that Lesinurad is not an inhibitor of epoxide hydrolase; however, inhibitors of epoxide hydrolase (i.e., valproic acid) may interfere with metabolism of Lesinurad. Lesinurad should not be administered with inhibitors of epoxide hydrolase.
- **Hormonal contraceptives:** Hormonal contraceptives, including oral, injectable, transdermal, and implantable forms, may not be reliable when Lesinurad is co-administered. Females should practice additional methods of contraception and not rely on hormonal contraception alone when taking Lesinurad.
- **Aspirin:** Aspirin at doses higher than 325 mg per day may decrease the efficacy of Lesinurad in combination with allopurinol. Aspirin at doses of 325 mg or less per day (ie, for cardiovascular protection) does not decrease the efficacy of Lesinurad and can be co-administered with Lesinurad.

Contraindications

- Severe renal impairment, end stage renal disease (eCLcr less than 30 mL/min), kidney transplant recipients, or patients on dialysis.
- Tumor lysis syndrome or Lesch-Nyhan syndrome

Warnings

- **Renal events:** Adverse reactions related to renal function have occurred after initiating Lesinurad. A higher incidence was observed at the 400-mg dose, with the highest incidence occurring with monotherapy use. Monitor renal function at initiation and during therapy with Lesinurad, particularly in patients with eCLcr below 60 mL/min, and evaluate for signs and symptoms of acute uric acid nephropathy. Lesinurad should not be initiated in patients with an eCLcr less than 45 mL/min
- **Cardiovascular events:** Major adverse cardiovascular events were observed with Lesinurad; a causal relationship has not been established. In clinical trials, major adverse cardiovascular events (defined as cardiovascular deaths, non-fatal myocardial infarctions, or non-fatal strokes) were observed with Lesinurad. A causal relationship with Lesinurad has not been established.

Precautions

- It should be taken in the morning with food and water.
- Patients should be instructed to stay well hydrated.
- Assess renal function before initiating Lesinurad.
- Do not initiate Lesinurad if eCLcr is below 45 mL/min.
- Discontinue if eCLcr persistently falls below 45 mL/min.

Use in specific populations

- Renal impairment: Not recommended for patients with eCLcr below 45 mL/min.
- Hepatic impairment: Not recommended for patients with severe hepatic impairment.

References

1. <http://www.centerwatch.com/drug-information/fda-approved-drugs/drug/100127/zurampic-lesinurad>
2. <http://www.azpicentral.com/zurampic/zurampic.pdf>
3. <http://www.azpicentral.com/zurampic/zurampic.pdf#page=7>

* Asst. Professor, Department of Pharmacy Practice,
Nitte Gulabi Shetty Memorial Institute of
Pharmaceutical Sciences, Nitte University, Deralakatte, Mangalore, Karnataka, 575 018

DEPARTMENT OF PHARMACY PRACTICE NEWS

Guest Lecture on Community Pharmacy Practice in Canada



Ms. Neerja Kumar, Registered Pharmacist, Alberta, Canada, delivered a lecture on “Community Pharmacy Practice in Canada” held on 10th March 2016 at seminar hall, NGSM Institute of Pharmaceutical Sciences (NGSMIPS), Deralakatte, Mangalore. In her talk, she explained the requirements to become a registered pharmacist in Canada, roles, responsibilities and ethics of pharmacist. She has also shared her experiences in the community pharmacy practice in the Canada. The interactive session allowed students and faculty members to broaden their interest and knowledge in different aspects of rational use of drugs, patient counselling and patient safety. The lecture received an overwhelming response from the students and faculty members and more than 65 people including Pharm D and M. Pharm students attended the guest lecture.

PhD Award

Dr. Uday Venkat Mateti, Asst. Professor, Dept. of Pharmacy Practice, NGSMIPS, has been awarded Doctor of Philosophy (Ph.D) for his thesis entitled “Intervention of Pharmaceutical Care on Health Related Quality of Life and Pharmacoeconomic Evaluation of Hemodialysis Patients” by Manipal University, Manipal.

THE TRAINING ARENA



K.S.Hegde Charitable Hospital



Department of Pharmacy Practice



Drug Information Center



Out Patient Dispensing Counter



Dispensing and Retail Pharmacy



Ward Round Participation with Physicians



Library and Case Presentation Facility

NGSM Institute of Pharmaceutical Sciences



Nitte Institutions

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3. Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences, Mangaluru
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17. Nitte University Centre for Stemcell Research & Regenerative Medicine (NUCSReM), Mangaluru

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23. Sarosh Institute of Hotel Administration, Mangaluru
24. Nitte Institute of Banking & Finance, Mangaluru
25. Nitte Institute Communication, Mangaluru

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Science and Commerce Institutions

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29. Dr. Nitte Shankara Adyanthaya Memorial First Grade College, Bengaluru
30. Dr. Nitte Shankara Adyanthaya Memorial Pre-University College, Nitte
31. Dr. Nitte Shankara Adyanthaya Memorial Pre-University College, Mangaluru
32. Dr. Nitte Shankara Adyanthaya Memorial Pre-University College, Bengaluru

Schools

33. Dr. Nitte Shankara Adyanthaya Memorial Senior Secondary School, Nitte
34. Dr. Mundkur Ramanna Shetty Memorial English Medium High School, Thokur
35. Nitte International School, Bengaluru
36. Dr. Nitte Shankara Adyanthaya Memorial Higher Primary School, Bolakodi

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