Clinical Pharmacy News Letter

S.J.M COLLEGE OF PHARMACY

Department of Pharmacy Practice

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World AIDS Day 2016
Hands up for HIV Prevention

World AIDS Day program was organized on December 07th & 08th 2016 by the TB/HIV Control Pogram Centre, District Government Hospital, Chitradurga in collaboration with SJM College of Pharmacy and Basaweawara Medical College and Hospital, Chitradurga. The programme was carried out for two days. On day one the speech competetion was conducted, students of Pharmacy college were actively participated. The programme was felicitated by Dr. Yogananda R, HOD, Dept. of Pharmacy Practice, SJM College of Pharmacy, Dr. Srinath, Medical Officer, ART Centre, District Government Hospital, Chitradurga and other faculty members of SJM College of Pharmacy.

On second day, rally was organized with the slogan of **Hands up for HIV Prevention** & pamplet distribution over the Chitradurga city, followed by awareness program organized in Basaveshwara Medical College & Hospital.

Dr. Ranganath R, District Aids & TB Control Program Officer, in his welcome speech given the statistics of HIV patients in Chitradurga district and how to over come the barriers. Sri S. B. Vastramath, District Civil Judge, Chitradurga had given a valuable insights regarding HIV/AIDS. A folk song was conducted by the janapada artists with the theme of HIV Infection and its prventive measures. Students of SJM College of Pharmacy performed a short skit and short tele film entitled “AMMA” a pathetic story of daughter and mother .

Winners of the Speech Competition

Miss.Vaishnavi II Pharm D- I Prize
Felicitated by: Dr. B V Niraj, D H O, Chitradurga

Mr. Arun Chandran IV Pharm D- II Prize
Felicitated by: Smt. Veena, Vice President
District Law Association, Chitradurga

By: Mr. B. Shankar Reddy
Assistant Professor
Dept. of Pharmacy Practice
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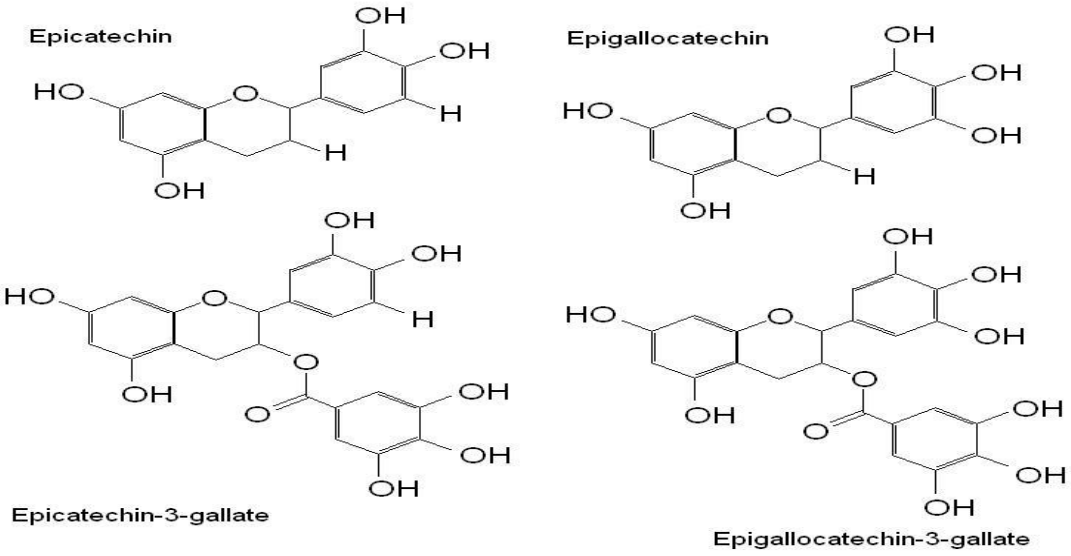
Effect of Green tea Polyphenols on Alzheimer's disease

Alzheimer's diseases is an acute neurodegenerative disorder having early symptoms like confusion, irritability and aggression, mood fluctuation, trouble with language and long term memory loss. Though the actual cause of the disease is still not comprehensible, several competing hypothesis are proposed. One among them is cholinergic hypothesis. This mainly describes about the reduction in availability of acetyl choline due to super activity of acetyl cholinesterase enzyme. Second theory is amyloid hypothesis, which explains the disease is due to depositions of amyloid β in neurons. Though the exact cause for the disease is known but until now, no drug of choice for the treatment of this disease. In Alzheimer's disease brain cells may have metabolic rate which turns ending up in generation of reactive oxidative species.

Tea is one of the most popular beverages taken throughout world. Among different varieties of tea; Green tea is most widely consumed in few countries like Japan and china from centuries owing its outstanding medicinal importance. Green tea is obtained from leaves of plant ***Camellia semensis***. It is enriched with Monoterpenoids, catechins and polyphenols. Green tea mainly contains Flavonoids which are largest group of polyphenols. Various polyphenols in green tea include epicatechin, (-)-epigallocatechin-3-gallate, (-)-epigallocatechin, epicatechin-3-gallate.

These polyphenols present in green tea act on free oxidative species and acts as radical scavengers and prevent oxidative damage of neurons. These evidences were shown by animal models. Consumption of green tea as regular basis may not completely cure the Alzheimer's disease but can reduce risk of severing the disease.



By: Miss. Shravanti. K,
Assistant Professor
Dept. of Pharmaceutical Chemistry

Drug Information Center Activities from October to December 2016

1. Adverse drug reactions

Sl. No	Drug name	Adverse effect	Severity	Number of reports
1.	Syp. Paracetamol 150mg+ Camylofin Hcl 10 mg Tab. Ondansetron 4mg	Generalized rashes all over the body, itching (red spots)	Severe	01
2.	Inj. Ceftriaxone 500mg	Severe rashes associated with itching developed over the palm, between the fingers of upper limbs, over the sole and feet of legs.	Severe	01
3.	Inj. Ceftriaxone	Skin rashes, Peeling of skin, swelling of face, white patches in the mouth, angioedeme, diarrhoea	Moderate	07
4.	Tab. Clonazepam 0.25mg	Itching with skin rashes and swelling in legs	Moderate	01
5.	Tab. Carbamazepine 200mg	Abdominal pain over right upper	Moderate	01

		abdomen, vomiting 2episodes		
6.	Tab. Glibenclamide 5mg Tab. Metformin 500 mg	Hypoglycaemic attack	Moderate	01
7.	Tab. Ibuprofen 400mg	Blood clots over upper limbs	Moderate	01
8.	Inj. Levofloxacin 500mg	Diarrhoea and abdominal pain	Moderate	01
9.	Cap. Loperamide 2mg	Puffiness of the face	Moderate	01
10.	Tab. Nifedipine 20mg	Pedal edema	Moderate	01

02. Drug-Drug Interactions

S.NO	**Drugs**	**Dose**	**Interaction**	**Severity**
1	Tab. Clonidine Tab. Metoprolol	100mcg 50mg	This drugs combination cause bradycardia	Serious (D)
2	Inj, Artemether /Lumafantrine Inj. Ondansetron	120mg 1amp(4mg)	Prolonged QT interval and bradyarythmias	Serious (X)
3	Inj. Azithromycin Inj. Amiodarone	500mg 200mg	This combination prolonged QT interval. Since the two drugs were prescribed at same frequency patient had developed Tachycardia	Serious (X)
4	Tab. Desvenlafaxine Tab. Escitalopram	50mg 10mg	Both drugs increases serotonin level	Serious (C)
X= Avoid Combination, D=Therapy Modification, C= Monitor Therapy				

03. Drug Interventions

Sl.No	**Drugs**	**Dose**	**Brief Description**	**Intervention**
1	Tab. Metoprolol Tab. Clonidine	50mg 100mg	Causes Bradycardia	Drug withdrawn (D)
2	Inj.Artemether/Lumefantrine Inj. Ondansetron	120mg 1amp(4mg)	Both increases QTC interval, Bradyarrhythmia (decrese HR)	Drug altered (X)

3	Inj. Azithromycin Inj. Amiodarone	500mg 200mg	Amiodarone will increases the effect of Azithromycin by P-Glycoprotein efflux transported. Both increases heart rate and increases QTC interval	Drug altered (X)
4	Tab. Clobazam	5mg	Stevenson Johnson syndrome	Drug withdrawn (PMS)
X= Avoid Combination, D=Therapy Modification, PMS= Post Marketing Surveillance				

An Ounce of Prevention is worth a Pound of Cure

Benjamin Franklin

Osteoarthritis is a degenerative joint disease which usually occurs in the older age-group. It results from structural changes of the articular cartilage in the joints, usually those which are weight-bearing bones such as the spine and knees. The chief symptoms of osteoarthritis are pain and stiffness in the joints. The pain usually increases after exercise.

Early counseling about diet and life style modification plays a vital role in management of osteoarthritis which also improves the patient quality of life and minimize the cost effectiveness of the treatment.

A recent expert review of the management of osteoarthritis by the Osteoarthritis Research Society International (OARSI) supports a combination of nonpharmacological and pharmacological strategies. It indicates that patient education is critical in the early stages of care, weight loss and exercise is key to any non-pharmacological treatment. The guidelines are expanded for practical implementation of evidence-based, conservative management of hip and knee osteoarthritis.

OARSI recommendations

All patients with hip and knee OA should be given information access and education about the objectives of treatment and the importance of changes in lifestyle, exercise, pacing of activities, weight reduction, and other measures to unload the damaged joint(s). The initial focus should be on self-help and patient-driven treatments rather than on passive therapies delivered by health professionals. Subsequently emphasis should be placed on encouraging adherence to the regimen of non-pharmacological therapy. SOR: 97% (95% CI 95–99)[2]

References:

1. http://www.healthlibrary.com/reading/ncure/index.htm (1 of 2) (Accessed date: 5/19/1999 9:11:19 PM)
2. Ministry of health Malaysia. Management of osteoarthritis, Malaysian society of Rheumatology; 2nd edition: Page 6-8.
3. Hawkeswood J, Reebye R. Evidence-based guidelines for the nonpharmacological treatment of osteoarthritis of the hip and kneeI. BCMJ 2010; 52(8): 399-403.

SYMPTOMATIC OSTEOARTHRITIS

Education,
Weight loss exercise, Physiotherapy,
Occupational therapy
Orthosis / assistive devices

Paracetamol (oral) ±Topical NSAIDS

Persistent symptoms

Tramadol with
NSAIDS (Lowest effective dose, for the shortest duration)
Selective NSAIDS ±Proton pump inhibitor in patient with high GI risk

Persistent symptoms

Consider intra-articular cardio steroids
(Especially if knee joint effusion present)

Persistent symptoms

Referral to orthopedics for evaluation of Arthroplasty

Other considerations at any time
- **Glucosamine sulfate**
- **Diacerein**
- **Alternative treatments**

The diet of the arthritis patient should be planned along alkaline lines and should include fruits and vegetables for protection and proteins &carbohydrates for energy.

- The alkaline action of raw juices dissolves the accumulation of deposits around the joints and in other tissues. Fresh pineapple is also valuable as the enzyme in fresh pineapple juice, ***Bromelain reduces swelling and inflammation in O A & R A.*** Repeated juice fasts are recommended at intervals of every two months.
- The raw potato juice therapy is considered one of the most successful biological treatments for O A& R A.
- Black gingerly seeds, soaked overnight in water, have been found to be effective in preventing frequent joint pains. The water in which the seeds are soaked should also be taken along with the seeds the first thing in the morning.

The body should be kept warm at all times. Joints should not be bandaged tightly as this limits movement and interferes with the free circulation of blood.

Constipation should be avoided as it poisons the system and adds to the irritation and inflammation of the joints.

By: Dr. Mamatha. P
Mr. Shankar Reddy. B

Comparative Study of Azithromycin and Ceftriaxone in Treatment Of Uncomplicated Typhoid Fever

Dr.Sreenivasa .B[1], Dr. Nivil Joseph

1. M.B.B.S, M.D. Associate Professor of Paediatrics Basaveshwara Medical College & Hospital. Chitradurga

Typhoid fever is a life threatening systemic infection caused by Salmonella typhi or Salmonella paratyphi. It is a major public health problem. It is more prevalent in the areas of poor sanitization substandard water supply and overcrowding. It is estimated that more than 26.9 million typhoid fever cases occurs annually, of which 1% results in death. The vast of this disease burden is witnessed in Asia [1-4].

Emergence of multidrug-resistant (MDR) *S. typhi* has complicated therapy by limiting treatment options [5]. Reports of infection with fluoroquinolone-resistant *salmonella* species have raised concern that soon no available oral medication will exist to treat the infection [6, 7]. Although Ceftriaxone and other third-generation cephalosporins are still highly effective against *S.* typhi, they are considered to be less than ideal routine treatments [8–10]. In addition to the high cost and requirement of parenteral administration associated with ceftriaxone, *S.* typhi isolates resistant to this drug have begun to appear [11]. Therefore, other regimens are required for the treatment of typhoid fever.

Azithromycin, a member of the macrolide class of antibiotics, possesses many characteristics for effective and convenient treatment of typhoid fever, including in vitro activity against many enteric pathogens, excellent penetration into most tissues, and achievement of concentrations in macrophages and neutrophils that are 100-fold higher than concentrations in serum [12–14]. These encouraging results led us to study the clinical effect of azithromycin. Initially, azithromycin was demonstrated, in an open-labeled, nonrandomized trial, to be effective in the treatment of adults with uncomplicated typhoid fever. A subsequent randomized trial demonstrated that azithromycin was as effective as ciprofloxacin for the treatment of uncomplicated typhoid fever in adults. The results of these studies prompted the present study of azithromycin versus ceftriaxone for the treatment of uncomplicated typhoid fever in children.

Very few studies on azithromycin against s. typhi and paratyphi have been done in India . So, this study was carried out to determine the efficacy of azithromycin. **Methods:** Children between 2-17 years age who were diagnosed as having uncomplicated enteric fever with positive blood culture were grouped as group A (50 cases) and group B (50 cases) . Blood cultures are sent on 1st and 10th day for salmonella. Group A had given oral azithromycin 10 mg/kg/day, OD (azithromycin trial group) and group B had given Inj. Ceftriaxone IV, 75 mg/kg/day in 2 divided doses (ceftriaxone trial group) for 6 and 7 days respectively. Every day the child was examined and study result were assigned as clinical and microbiological cure or failure. **Results:** A total of 100 patients with sex ratio of 1.2:1 (Male : Female) with uncomplicated enteric fever were enrolled in the study. Mean duration to become afebrile was less with azithromycin (2.72 days) as compared to ceftriaxone (5.52 days) treatment (p=0.000). 96% of the cases treated with azithromycin attained defervescence by the 5th day of treatment, but only 27% of cases treated with ceftriaxone attained defervescence by the 5 th day of treatment. Clinical cure was earlier with azithromycin than with ceftriaxone treatment (p=0.027). Microbiological cure was achieved in 100% and 98% cases treated with azithromycin and ceftriaxone, respectively (p=0.5). **Conclusion :** Oral azithromycin (10 mg/kg/day OD for 6 days) was more efficacious in

treatment of uncomplicated enteric fever in children and adolescents as compared to intravenous ceftriaxone (75 mg/kg/day for 7 days).

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First drug for Spinal Muscular Atrophy

The U.S. Food and Drug Administration approved Spinraza (nusinersen) on 23-December-2016, the first drug approved to treat children and adults with spinal muscular atrophy (SMA), a rare and often fatal genetic disease affecting muscle strength and movement. Spinraza is an injection administered into the fluid surrounding the spinal cord.

"There has been a long-standing need for a treatment for spinal muscular atrophy, the most common genetic cause of death in infants, and a disease that can affect people at any stage of life," said Billy Dunn, M.D., director of the Division of Neurology Products in the FDA's Center for Drug Evaluation and Research. SMA is a hereditary disease that causes weakness and muscle wasting because of the loss of lower motor neurons controlling movement. There is wide

variability in age of onset, symptoms and rate of progression. Spinraza is approved for use across the range of spinal muscular atrophy patients.

The FDA worked closely with the sponsor during development to help design and implement the analysis upon which this approval was based. The efficacy of Spinraza was demonstrated in a clinical trial in 121 patients with infantile-onset SMA who were diagnosed before 6 months of age and who were less than 7 months old at the time of their first dose. Patients were randomized to receive an injection of Spinraza, into the fluid surrounding the spinal cord, or undergo a mock procedure without drug injection (a skin prick). Twice the number of patients received Spinraza compared to those who underwent the mock procedure. The trial assessed the percentage of patients with improvement in motor milestones, such as head control, sitting, ability to kick in supine position, rolling, crawling, standing and walking. The FDA asked the sponsor to conduct an interim analysis as a way to evaluate the study results as early as possible; 82 of 121 patients were eligible for this analysis. Forty percent of patients treated with Spinraza achieved improvement in motor milestones as defined in the study, whereas none of the control patients did.

Additional open-label uncontrolled clinical studies were conducted in symptomatic patients who ranged in age from 30 days to 15 years at the time of the first dose, and in presymptomatic patients who ranged in age from 8 days to 42 days at the time of first dose. These studies lacked control groups and therefore were more difficult to interpret than the controlled study, but the findings appeared generally supportive of the clinical efficacy demonstrated in the controlled clinical trial in infantile-onset patients. The most common side effects found in participants in the clinical trials on Spinraza were upper respiratory infection, lower respiratory infection and constipation. Warnings and precautions include low blood platelet count and toxicity to the kidneys (renal toxicity). Toxicity in the nervous system (neurotoxicity) was observed in animal studies. The FDA granted this application fast track designation and priority review. The drug also received orphan drug designation, which provides incentives to assist and encourage the development of drugs for rare diseases. The sponsor is receiving a rare pediatric disease priority review voucher under a program intended to encourage development of new drugs and biologics for the prevention and treatment of rare pediatric diseases. A voucher can be redeemed by a sponsor at a later date to receive priority review of a subsequent marketing application for a different product. This is the eighth rare pediatric disease priority review voucher issued by the FDA since the program began.

Spinraza is marketed by Biogen of Cambridge, Massachusetts and was developed by Ionis Pharmaceuticals of Carlsbad, California.

Reference: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm534611.htm

By: Dr. Mamatha. P, Miss. Sharvani Hugar

Accelerated approval to new treatment for advanced Soft Tissue Sarcoma

The U.S. Food and Drug Administration granted accelerated approval to Lartruvo (olaratumab) on 19-October-2016 with doxorubicin to treat adults with certain types of soft tissue sarcoma (STS), which are cancers that develop in muscles, fat, tendons or other soft tissues. Lartruvo is approved for use with the FDA-approved chemotherapy drug doxorubicin for the treatment of patients with STS who cannot be cured with radiation or surgery and who have a type of STS for which an anthracycline (chemotherapy) is an appropriate treatment.

"For these patients, Lartruvo, added to doxorubicin, provides a new treatment option," said Richard Pazdur, M.D., director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research and acting director of the FDA's Oncology

Center of Excellence. "This is the first new therapy approved by the FDA for the initial treatment of soft tissue sarcoma since doxorubicin's approval more than 40 years ago."
The National Cancer Institute estimates that 12,310 new cases of STS and nearly 5,000 deaths are likely to occur from the disease in 2016. The most common treatment for STS that cannot be removed by surgery is treatment with doxorubicin alone or with other drugs. STS includes a wide variety of tumors arising in the muscle, fat, blood vessels, nerves, tendons or the lining of the joints. Lartruvo is a platelet-derived growth factor (PDGF) receptor-alpha blocking antibody. When stimulated, PDGF receptors cause tumor growth. Lartruvo works by blocking these receptors, which may help slow or stop tumor growth.

The safety and efficacy of Lartruvo were studied in a randomized clinical trial involving 133 patients with more than 25 different subtypes of metastatic STS. Patients received either Lartruvo with doxorubicin or doxorubicin alone. This trial measured the length of time patients lived after treatment (overall survival), the length of time tumors did not grow after treatment (progression-free survival) and the percentage of patients who experienced shrinkage of their tumors (overall response rate). Patients in this trial who received Lartruvo with doxorubicin had a statistically significant improvement in overall survival: the median survival was 26.5 months compared to 14.7 months for patients who received doxorubicin alone. Patients who received Lartruvo with doxorubicin had a median progression-free survival of 8.2 months compared to 4.4 months for patients who received doxorubicin alone. Tumor shrinkage was 18.2 percent for patients who received Lartruvo with doxorubicin and 7.5 percent for those who received doxorubicin alone. Lartruvo has serious risks including infusion-related reactions and embryo-fetal harm. Infusion-related reactions include low blood pressure, fever, chills and rash. The most common side effects of treatment with Lartruvo are nausea, fatigue, low levels of white blood cells (neutropenia), musculoskeletal pain, inflammation of the mucous membranes (mucositis), hair loss (alopecia), vomiting, diarrhea, decreased appetite, abdominal pain, nerve damage (neuropathy) and headache.

The FDA granted the Lartruvo application fast track designation, breakthrough therapy designation and priority review status because preliminary clinical evidence indicated that it may offer a substantial improvement in effectiveness in the treatment of a serious or life-threatening disease or condition. The FDA is approving Lartruvo under the agency's accelerated approval program, which allows approval of a drug to treat a serious or life-threatening disease or condition based on clinical data showing the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The sponsor is conducting a larger study, which is currently underway, to further explore the effectiveness of Lartruvo across the multiple subtypes of STS.

Lartruvo also received orphan drug designation, which provides incentives such as tax credits, user fee waivers and eligibility for exclusivity to assist and encourage the development of drugs intended to treat rare diseases. Lartruvo is marketed by Eli Lilly and Company based in Indianapolis, Indiana

Reference: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm525878.htm/ accessed date: 28/12/2016

By: Dr. Mamatha. P, Miss. Sharvani Hugar

Eucrisa (Crisaborole) for Eczema

Date of approval: 14-December-2016

The U.S. Food and Drug Administration approved Eucrisa (crisaborole) ointment to treat mild to moderate eczema (atopic dermatitis) in patients two years of age and older. Atopic dermatitis, a chronic inflammatory skin disease, is often referred to as "eczema," which is a general term for the several types of inflammation of the skin. Atopic dermatitis is the most common of the many types of eczema and onset typically begins in childhood and can last through adulthood. The cause of atopic dermatitis is a combination of genetic, immune and

environmental factors. In atopic dermatitis, the skin develops red, scaly and crusted bumps, which are extremely itchy. Scratching leads to swelling, cracking, "weeping" clear fluid, and finally, coarsening and thickening of the skin.

"Eucrisa approval provides another treatment option for patients dealing with mild to moderate atopic dermatitis," said Amy Egan, deputy director of the Office of Drug Evaluation III in the FDA's Center for Drug Evaluation and Research (CDER).

Eucrisa, applied topically twice daily, is a phosphodiesterase 4 (PDE-4) inhibitor, although its specific mechanism of action in atopic dermatitis is not known. The safety and efficacy of Eucrisa were established in two placebo-controlled trials with a total of 1,522 participants ranging in age from two years of age to 79 years of age, with mild to moderate atopic dermatitis. Overall, participants receiving Eucrisa achieved greater response with clear or almost clear skin after 28 days of treatment.

Serious side effects of Eucrisa include hypersensitivity reactions. Eucrisa should not be used in patients who have had a hypersensitivity reaction to Eucrisa's active ingredient, crisaborole. The most common side effect of Eucrisa is application site pain, including burning or stinging.

Eucrisa is manufactured by Palo Alto, California-based Anacor Pharmaceuticals, Inc

Reference: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm533371.htm Accessed date: 28-12-2016

By: Dr. Mamatha. P, Miss. Sharvani Hugar

Potential risk of drugs reports by PVPI 2016

Sl. no	Drug name	Potential risk of drug	Number of reports received by NCC-PVPI
1.	Antirabies vaccine	Erythema multiforme	Two reports between 2011 to 2015
2.	Azithromycin	Exanthematous pustulosis	Five reports between 2011 to March 2016.
3.	Cefixime	Exanthematous pustulosis	Three reports between 2011 to March 2016
4.	Cloxacillin	Exanthematous pustulosis	Two reports between 2011 to March 2016
5.	Betamethasone	Photosensitivity reaction	Six reports between 2011 to March 2016
6.	Ceftriaxone	Stevens Johnson Syndrome	Twenty seven reports between 2011 and March 2016
7.	Ibuprofen	Stevens Johnson Syndrome/ toxic epidermal necrolysis	Twenty seven reports between 2011 and March 2016
8.	Itraconazole	Photosensitivity reaction	Three reports between 2011 and March 2016
9.	Lamotrigine	Stevens Johnsons Syndrome / toxic epidermal necrolysis	Thirty six reports of SJS/TEN with exposure to lamotrigine between 2011 and March 2016
10.	Mannitol	Hypokalaemia	Eighteen reports between 2011 to 2015
11.	Ranitidine	Cardiac arrest	One report between 2011 and 2015
12.	Rotavirus vaccine	Intussusceptions	Ten reports between 2011 to 2015

The IPC, NCC-PvPI has requested the revision of the drug safety label for the above mentioned drugs . The reports were reviewed by the PvPI-SRP, IPC and the WHO Collaborating Centre for International Drug Monitoring (UMC).
Reference: WHO Phamaceutical Newsletter. 2016;No.05:page 05-14 (www.ipc.gov.in)
By: Dr. Mamatha. P, Miss. Sharvani Hugar

Achievements:

I Prize for Poster presentation in 68th IPC- 2016

Mr. Anto John, VI Pharm D student of SJMCP was awarded I Prize for his research poster, presented during 68th Indian Pharmaceutical Congress, held at Vizag, from 16th to 18th December 2016

Title: A study on prescription patterns and efficacy of antibiotics in orthopedic department in a teaching hospital

"We congratulate him for his achievement"

Online consultation:

Our department has started online consultation request for drug information queries. Please go through the link http://www.sjmcp.org/online-consultation-request-form.php

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