



PSG NEWS DIGEST

A newsletter from Drug Information Centre, Department of Pharmacy Practice

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FROM THE PHARMACIST'S DESK

“A new day in HEART FAILURE, A step closer to taking the FAILURE out of HEART FAILURE”



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According to the 2016 ACC/AHA/HFSA Update on New Pharmacological Therapy for Heart Failure introduction of a sinoatrial node modulator (Ivabradine) and an angiotensin receptor-neprilysin inhibitor (ARNI)

(valsartan/Sacubitril), represents a milestone in the evolution of care for patients with heart failure (HF).

Ivabradine reduces the heart rate by inhibiting funny channel. Ivabradine does not influence intra-cardiac conduction, contractility, or ventricular repolarization. It is the only agent shown to clinically lower the heart rate without negative inotropism or effects on conduction and contractility. When patients cannot tolerate beta blockers or the up titration is ineffective, Ivabradine is an effective alternative. It is also effective in post operative AF or tachyarrhythmia, which controls the spontaneous diastolic depolarisation in the sinus node that regulates the heart rate.

The daily recommended dose is 5 mg per oral BD in symptomatic chronic heart failure patients with LVEF $\leq 35\%$ and who are in sinus rhythm with resting heart rate ≥ 70 bpm. The newly introduced combination of valsartan, angiotensin II receptor blocker and sacubitril, a neprilysin

inhibitor (trade name: Vymada (in India) Entresto (in US) which is effective in symptomatic chronic heart failure patients with reduced ejection fraction. Now it is recommended as an effective alternative for ACE-inhibitors and ARB monotherapy.

PARADIGM – HF trial of angiotensin receptor – neprilysin inhibition versus enalapril in heart failure establish there is a 20 % reduction in the mortality rate with this combination of two drugs than the monotherapy of ACE-I or ARB. The inhibition of both the Angiotensin II Receptor and Neprilysin with entresto was more effective in reducing the risk of death from CV causes, hospitalization for HF risk of death from any cause, reducing symptoms and physical limitations of HF. These advantages were highly significant and clinically important (the drug compared was enalapril 10 mg bd proven drug for mortality benefit in HF). Entresto also needed hepatic and renal dose adjustment.

The recommended starting dose of ENTRESTO is 49/51 mg (sacubitril/valsartan) twice-daily. Double the dose of ENTRESTO after 2 to 4 weeks to the target maintenance dose of 97/103 mg (sacubitril/valsartan) twice-daily, as tolerated by the patient. Adverse reactions occurring $\geq 5\%$ are hypotension (due to greater vasodilatory effect), hyperkalemia, cough, dizziness, and renal failure. It can also cause angioedema.

In the current practice we are not using Vymada to avoid economic burden to the patients. In future these drugs can be introduced in the daily clinical practice for a better outcome. It's a step closer to taking failure out of heart failure.

CDSCO Approved drugs from December 2016 to March 2017

Drug Name	Indication
Lenvatinib 4mg/10mg Hard Gelatin Capsules (Lenvatinib Mesylate)	For the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine refractory differentiated thyroid cancer
Perampanel Tablets 2mg/4mg/6mg/8mg/10mg/12mg	The adjunctive treatment of partial onset Seizures with or without secondarily generalized seizures in patients with epilepsy aged 12 years and older
Azilsartan Medoxomil Bulk & 40mg/80mg Tablets	Indicated for the treatment of hypertension in adult patients, either alone or in combination with other antihypertensive agents
Hydrocortisone Aceponate 0.584mg/ml Cutaneous Spray Solution (Vet.)	For symptomatic treatment of inflammatory and pruritic dermatosis in dogs
Dexlansoprazole Delayed Release Capsule 30/60mg & Bulk	For the treatment of <ul style="list-style-type: none"> Healing of all grades of erosive esophagitis (EE). Maintaining healing of EE and relief of heartburn. Treating heartburn associated with symptomatic non erosive gastroesophageal reflux disease (GERD).
Carfilzomib Sterile Lyophilized Powder for Injection 60mg/vial (50ml vial)	Relapsed or refractory multiple myeloma <ul style="list-style-type: none"> Carfilzomib for injection is indicated in combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy. Carfilzomib for injection is indicated as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.
Dabrafenib 50mg/75mg Capsules (Dabrafenib Mesylate)	As a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an appropriate test. In combination with Trametinib for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an appropriate test.
Trametinib 0.5mg/2mg Tablets (Trametinib Dimethyl Sulfoxide)	As a monotherapy and in combination with Dabrafenib for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an appropriate test.
Alectinib 150mg Capsules (Alectinib Hydrochloride)	For the treatment of patients with anaplastic lymphoma kinase (ALK) Positive, metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to Crizotinib.
Eliglustat 84mg Capsules (Eliglustat Tartrate or Hemitartrate Salt)	For the long term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an appropriate test.
Sofosbuvir 400 mg film coated Tablet	In combination with other medicinal products for the treatment of Chronic Hepatitis C (CHC) in adults. With the condition: to be sold by retail on the prescription of Hepatologist only
Hydralazine Tablets BP 25 & 50mg (Additional Strength)	For moderate to severe hypertension (in conjunction with a β -adrenoceptor blocking agent or diuretic) and hypertensive crisis.
Bendamustine hydrochloride Injection 90 mg/mL (Fill volume 0.5 mL in 2 mL capacity vial & 2 mL filled in 2 mL capacity vial)	For the treatment of patients with chronic lymphocytic Leukemia. For the use in Indolent B-cell Non-Hodgkin's Lymphoma (NHL) that has Progressed During or Within six months of treatment with Rituximab or a Rituximab containing Regimen. With the condition: to be sold by retail on the prescription of Oncologist/specialist only
Eltrombopagolamine Tablets 25 /50 mg (Additional indication)	For the treatment of thrombocytopenia in paediatric patients 1 year and older with chronic immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy. (It should be used only in patients with ITP whose degree of Thrombocytopenia and clinical condition increase the risk for bleeding. It should not be used in an attempt to normalize platelet counts). Warning: Box warning with Hepatotoxicity

Reference: www.fda.gov/Drugs

■ FDA Approved drugs from December 2016 to March 2017

Drug Name	Active Ingredient	FDA - Approved use
Spinraza	Nusinersen	To treat children and adults with spinal muscular atrophy (SMA)
Rubraca	Rucaparib	To treat women with a certain type of ovarian cancer
Eucrisa	Crisaborole	To treat mild to moderate eczema (atopic dermatitis) in patients two years of age and older
Ocrevus	Ocrelizumab	To treat patients with relapsing and primary progressive forms of multiple sclerosis
Dupixent	Dupilumab	To treat adults with moderate-to-severe eczema (atopic dermatitis)
Zejula	Niraparib	For the maintenance treatment for recurrent epithelial ovarian, fallopian tube or primary peritoneal cancers
Symproic	Naldemedine	For the treatment of opioid-induced constipation
Bavencio	Avelumab	To treat metastatic Merkel cell carcinoma
Xadago	Safinamide	To treat Parkinson's disease
Kisqali	Ribociclib	To treat postmenopausal women with a type of advanced breast cancer
Xermelo	Telotristat ethyl	To treat carcinoid syndrome diarrhea
Siliq	Brodalumab	To treat adults with moderate-to-severe plaque psoriasis
Emflaza	Deflazacort	To treat patients age 5 years and older with Duchenne muscular dystrophy (DMD)
Parsabiv	Etelcalcetide	To treat secondary hyperparathyroidism in adult patients with chronic kidney disease undergoing dialysis
Trulance	Plecanatide	To treat Chronic Idiopathic Constipation (CIC) in adult patients.

Reference: www.cdsco.nic.in

NEWS ROOM

■ The following are the list of drugs that labeling has been changed

Drug Name	FDA Indications	Reported ADR Signals	Label Changes
Mepolizumab	Severe asthma	Anaphylaxis	Label was updated to include anaphylaxis
Macitentan	Pulmonary arterial hypertension	Fluid Overload	Label was updated to include information about fluid retention
Apremilast	Psoriatic arthritis	Diarrhoea, nausea, vomiting	FDA is evaluating the need for regulatory action
Droxidopa	Neurogenic orthostatic hypotension	Cerebrovascular accident	Labelling was updated to include information about stroke.
Glyburide	Diabetes mellitus	Skin reactions	Labeling was updated to include bullous reaction, erythema multiforma and exfoliative dermatitis.
Ibrutinib	Mantel cell lymphoma CLL,SLL,Waldenstrom Macroglobulinemia, Marginal zone lymphoma	Pneumocystis Jirovecii Pneumonia (PJP)	Warnings and precautions section of the labelling was updated to include PJP

Reference: www.medscape.com/viewarticle/878127

■ Reported Adverse Drug Reaction from December 2016 to March 2017

Causative Drugs	Adverse Reaction	Causative Drugs	Adverse Reaction
Gliclazide (Oral)	Constipation	Cilnidipine (oral)	Ankle edema
Azee (Oral)	Gastritis	Metronidazole (IV)	Glossitis
Fosolin (IV)	Ataxia and nystagmus	Clonidine (oral)	Mouth dryness
Tramadol (IV)	Chills and Rigor	Levipil (oral)	Agitation, anxiety
Metronidazole (IV)	Decreased sleep and anxiety	Piptaz (IV)	Elevation of liver enzymes
Olmесartan (Oral)	Increased serum creatinine	Atorvastatin (oral)	Insomnia
Covatil (Oral)	Acute kidney injury	Frisium (oral)	Anorexia and dyspepsia
Diclofenac (oral)	Eye lid edema	Atropine (IV)	Delirium
Pantoprazole (Oral)	Hyponatremia	Syndopa (Oral)	Disorientation

Reference: PSG ADR Monitoring Centre, Department of Pharmacology, PSGIMS&R, Coimbatore

Department Activities

Achievers Pharm.D a student's forum: A unique website platform for Pharm.D students was launched on 21-04-2017.

The Achiever's forum aims at eroding the barriers between colleges and uniting all the Pharm D students under one umbrella. This beautiful unification could result in colossal sharing of clinical knowledge exclusively amongst the students. Daily usage of the website promotes active participation in clinical case discussion and therefore increases the exposure to the current clinical practice among different institutions. It acts as a daily entry book for individuals who can record their activities in the website.



www.achieverspharmd.com



Student's Forum: A unique national level student's form was successfully completed on 21-04-2017 at PSGIMS & R campus.

The title of the forum was "Student's forum - Pharmacy practice, Current practice & Future perception" - for the students by the students.

Around 300 pharm.D students were participated from various colleges from southern region of India. Student speakers were presented their current practices and future perception of the practices. Open students forum were conducted with various government and non-governmental official members.

Dr. Ayyappan and Dr. Mega, Assistant professor, were attended the workshop on "effective communication and presentation skills" on March 4th, 2017 at PSG IM campus, conducted by PSG Center for academic research and excellence.

Mrs. Andhuvan and Dr. Ayyappan were published a research article in Asian Journal of Pharmaceutical and Clinical Research titled " knowledge of Modifiable risk factors of heart disease among patients with cardiovascular risk". Vol 10, Issue 1, 2017.

Dr.V.Sivakumar, published a research article in International journal of Pharmacy and Pharmaceutical Sciences titles "Comparison of treatment outcome of antihypertensive drugs in the management of pregnancy induced hypertension". Vol 9, Issue 3, 2017.

Dr.Prudence A Rodrigues published a research article entitled " Improving antibiotic prescribing pattern and assessment of co morbidities associated with respiratory infections "in the International journal of Pharmacy and Pharmaceutical Sciences Vol9 (2)2017.

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