



# PSG NEWS DIGEST

A news letter from PSG College of Pharmacy, Department of Pharmacy Practice,

Pulse of the Issue Pharmacist's Desk Drugs Approved News Room Department Activities

## FROM THE PHARMACIST'S DESK



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### WILSON DISEASE

#### Copper

Copper is an essential metal that is an important cofactor for many proteins. Recommended intake of copper is 0.9mg/day. Copper is absorbed by enterocytes mainly in the duodenum and proximal small intestine and transported in the portal circulation in association with albumin and amino acid histidine to the liver. The liver utilizes this copper for metabolic needs, synthesis and secretes ceruloplasmin and excretes excess of copper into bile. Impaired biliary copper excretion increases hepatic copper content which leads to Liver damage.

Autosomal recessive disorder causing accumulation of toxic level of copper in organs usually liver, brain and eye. ATP7B gene encodes the trans membrane copper transport assists copper excretion into bile. In Wilson disease, absent or reduced function of ATP7B protein leads to hepatic copper accumulation and liver injury.

### CLINICAL FEATURES

HEPATIC	NEUROLOGICAL	PSYCHIATRIC	OTHERS
Cirrhosis (compensated /decompensated)	Movement disorders (tremor, involuntary movements)	Depression	Ocular; kayser- fleischer rings
Acute liver failure	Seizures	Personality changes	Hypothyroidism
Elevated AST/ALT	Rigid dystonia	Psychosis	
Autoimmune/Acute hepatitis	Insomnia		
Fatty liver	Migraine headache		
Splenomegaly			

### DIAGNOSTIC TESTING

**Biochemical liver test:** serum amino transferase generally abnormal. **Ceruloplasmin :** found low

**Urinary copper excretion:** First urine copper content is analyzed and if the copper content seems to be more than 40µg/24h(0.6µmol/24h) a 500mg oral dose of Penicillamine is administered at beginning and again 12 hours later during the 24 hours urine collection. If this contains more than 1600µg/24h (>25µmol/24h), it is a reliable indicator of Wilson disease.

### TREATEMENT

**D-Penicillamine is a chelator :** (ADULT DOSING) Starting 250-500 mg /day, increased by 250 mg increments every 4-7 days to a maximum 1000-1500mg/day in 2-4 divided doses .(PEDIATRICDOSING) 20mg/Kg/day in 2-3 divided doses . D-Penicillamine should be administered 1 hour prior or 2 hour after meals because food inhibits its absorption. Excretion via kidney. Side effects include neutropenia, thrombocytopenia, proteinuria, worsening of neurological symptoms (10-50% reported cases).

**Zinc:** Interferes with the uptake of copper from the gastrointestinal tract. Zinc also induces enterocyte metallothioneine which has greater affinity for copper than zinc and thus preferentially binds copper present in the enterocyte and inhibits its entry into the portal circulation.

DOSING FOR ADULTS AND PEDIATRICS -150mg/day in 3 divided doses. Taking zinc with food interferes zinc absorption. Side effects include gastric irritation.

**Liver Transplantation:** This is the only effective option for those with Wilson disease who present with acute liver failure and decompensated liver failure. Liver transplantations correct the hepatic metabolic defects of Wilson's disease and may serve to initiate normalization of extra hepatic copper metabolism.

**Diet:** Copper free diet. Avoid shell fish, chocolates, nuts, mushrooms, organ meats. Copper containers or cookware should not be used to store or prepare foods or drinks. A water purifying system is advisable.

#### CDSCO List of new drugs approved in the year 2019

S.NO	DRUG NAME	INDICATION	APPROVAL DATE
1	Fenspiride hydrochloride film coated extended release tablet 80 mg and Fenspiride hydrochloride bulk	1. Acute Rhinosinusitis 2. Moderate persistent asthma as an add-on therapy	04.02.2019
2	Bilastine tablets 20 mg and Bilastine Bulk	For symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria in adults	06.02.2019
3	Iguratimod film coated tablets 25mg and Iguratimod Bulk	For the treatment of active rheumatoid arthritis symptoms	18.02.2019
4	Fingolimod Capsules 0.5mg and Fingolimodhydrochloridebulk	For the treatment of patients with relapsing forms of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.	25.03.2019

5	Remogliflozinetabonate bulk and Remogliflozinetabonate film coated tablets 100 mg	Indicated in adults aged 18 years and older with type2 diabetes mellitus to improve glycemic control as:-Monotherapy when diet and exercise alone do not provide adequate glyceamic control.  Add on therapy with metformin, together with diet and exercise, when these do not provide adequate glyceamic control	26.04.2019
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Ref - [https://cdsco.gov.in/opencms/opencms/en/Approval\\_new/Approved-New-Drugs/](https://cdsco.gov.in/opencms/opencms/en/Approval_new/Approved-New-Drugs/)

### FDA New Drug Approvals in 2019

S.NO	DRUG NAME	ACTIVE INGREDIENT	APPROVAL DATE	FDA- approved use on approval date
1	Vyndaqel	Tafamidis meglumine	5/3/2019	To treat heart disease (cardiomyopathy) caused by transthyretin mediated amyloidosis (ATTR-CM) in adults
2	Skyrizi	Risankizumab	4/23/2019	To treat moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy
3	Balversa	Erdaftinib	4/12/2019	To treat adult patients with locally advanced or metastatic bladder cancer
4	Evenity	Romosozumab-aqqg	4/9/2019	To treat osteoporosis in postmenopausal women at high risk of fracture
5	Mayzent	Siponimod	3/26/2019	To treat adults with relapsing forms of multiple sclerosis
6	Sunosi	Solriamfetol	3/20/2019	To treat excessive sleepiness in adult patients with narcolepsy or obstructive sleep apnea
7	Zulresso	Brexanolone	3/19/2019	To treat postpartum depression (PPD) in adult women
8	Egaten	Triclabendazole	2/13/2019	To treat fascioliasis, a parasitic infestation caused by two species of flatworms or trematodes that mainly affect the liver, sometimes referred to as "liver flukes"

9	Cablivi	Caplacizumab	2/6/2019	To treat adult patients with acquired thrombotic thrombocytopenic purpura (aTTP)
10	Jeuveau	Prabotulinumtoxina	2/1/2019	For the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients

Ref:[www.fda.gov/drugs](http://www.fda.gov/drugs)

## NEWS ROOM - COLORS OF BOOK



**Orange Book** - (The publication Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act related patent and exclusivity information.

**Purple Book** - FDA recently released the "Purple Book," a resource that lists innovator biological products, as well as any biosimilar and interchangeable biological products licensed by FDA under the Public Health Service Act.

**Green Book** - The Generic Animal Drug and Patent Restoration act requires that each sponsor of an approved animal drug must submit to the FDA certain information regarding patents held for the animal drug or its method of use. The Act requires that this information, as well as a list of all animal drug products approved for safety and effectiveness, be made available to the public.

Ref:[www.fda.gov/drugs](http://www.fda.gov/drugs)



## Current Drug Safety Communications

- 4/30/2019 FDA adds Boxed Warning for risk of serious injuries caused by sleepwalking with certain prescription insomnia medicines
- 4/9/2019 FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering
- 2/25/2019 Safety trial finds risk of blood clots in the lungs and death with higher dose of tofacitinib (Xeljanz, Xeljanz XR) in rheumatoid arthritis patients; FDA to investigate
- 2/21/2019 FDA adds Boxed Warning for increased risk of death with gout medicine Uloric (febuxostat)
- 12/20/2018 FDA warns about increased risk of ruptures or tears in the aorta blood vessel with fluoroquinolone antibiotics in certain patients

## DEPARTMENT ACTIVITY

Department of Pharmacy Practice conducted CPE (Continuing Pharmacy Education) programme for every month.

DATE	TITLE	RESOURCE PERSON
26-2-2019	Stereochemistry and Drug action	Dr. G .Umaa Professor, Department of Chemistry, PSGCP
20-3-2019	Ethical Aspects in Research	Dr.G Subashini Associate Professor, Department of Community Medicine, PSGIMS&R
29-4-2019	Perspectives of a Clinical Pharmacist in Improving Patient Care	Dr. Anita Ann Sunny, Clinical Pharmacist, Department of Neurology, PSG Hospitals



Mrs.P.Rama, Assistant Professor participated in the National Level Symposium held at Annamalai University, Chidambaram on 8<sup>th</sup> and 9<sup>th</sup> February 2019. Dr.G.Andhuvan, Associate Professor, Dr.Nadhini. RK and Dr.Sheryl ELizabeth jess Assistant Professors attended two days Seminar entitled Partcipation of women in Science and Technology-A Vision on Challenge and Prospects on 8<sup>th</sup> and 9<sup>th</sup> March held at KMCH College of Pharmacy, Coimbatore. Pharm D Interns have actively participated in creating awareness about the public health and welfare along with NSS Team of PSG College of Pharmacy at Anjanur community Coimbatore.



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