

KMCH INSTITUTE OF HEALTH SCIENCES AND RESEARCH

(A unit of Kovai Medical Centre and Hospital Limited)

Coimbatore, Tamilnadu

SERIES 5 DEC 2019

DEPARTMENT OF PHARMACOLOGY- NEW DRUG UPDATE

Innovation drives progress.



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FDA - NEW DRUG APPROVALS

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- > Novel drugs
- Former drugs with formulation change

| S.No | Drug Name | Mechanism of Action | Indications | Dosage Formulation | Date of FDA Approval |
|------|---|--|--|--------------------------------|-------------------------|
| 1. | Methotrexate | Folate analog metabolic inhibitor | Rheumatoid arthritis, Juvenile idiopathic arthritis, Psoriasis | Subcutaneous Injection | November 27, 2019 |
| 2. | Voxelotor | Hb5 (sickle hemoglobin) polymerization inhibitor | Sickle cell anemia | Tablet | November 25, 2019 |
| 3. | Riluzole | Glutamate inhibitor | Amyotrophic lateral sclerosis patients with dysphagia | Oral Film | November 22, 2019 |
| 4. | Cenobamate | Selective blocker of the inactivated state of voltage-gated sodium channel | Partial-onset seizures in adult patients | Tablet | November 21, 2019 |
| 5. | Givosiran | Aminolevulinate synthase 1-directed small interfering RNA | Acute hepatic porphyria | Injection | November 20, 2019 |
| 6. | Crizanlizumab- tmca | P-Selectin inhibitor | Prevention of vaso-occlusive crises in Sickle cell disease | Injection | November 15, 2019 |
| 7. | Adalimumab- afzb (Biosimilar) | Tumor necrosis factor blocker | Rheumatoid arthritis , Juvenile idiopathic arthritis, Psoriatic arthritis, Ankylosing spondylitis, Crohn's disease & Ulcerative colitis, Plaque psoriasis | Injection | November 15, 2019 |
| 8. | Zanubrutinib | Bruton's tyrosine kinase inhibitor | Adult patients with Mantle cell lymphoma who have received at least one prior therapy | Capsule | November 14, 2019 |
| 9. | Cefiderocol | Siderophore cephalosporin - inhibits bacterial cell wall synthesis | Complicated urinary tract infections- in patients with limited / no alternative treatment options | Injection | November 14, 2019 |
| 10. | Luspatercept- aamt | First-in-class erythroid maturation agent. Recombinant fusion protein that binds several endogenous TGF-B superfamily ligands, thereby diminishing Smad2/3 signaling | Transfusion-dependent Beta- thalassemia-associated anemia | Injection | November 8, 2019 |
| 11. | Amoxicillin, Omeprazole and Rifabutin | Amoxicillin inhibits cell wall biosynthesis, Omeprazole inhibits proton pump, Rifabutin inhibits DNA-dependent RNA polymerase | Helicobacter pylori infection | Delayed- Release Capsule | November 4, 2019 |
| 12. | Pegfilgrastim- bmez (Biosimilar) | PEGylated growth colony-stimulating factor | Reduce the incidence of Febrile neutropenia in patients treated with chemotherapy | Injection | November 4, 2019 |

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