

LIST OF NEW DRUGS APPROVED IN YEAR 2018

S.No	Name of drug	Indication	Date of issue
1	Tenofovir Alafenamide Hemifumarate Bulk Emtricitabine 200mg/200mg +Tenofovir Alafenamide 10/25 mg Tablets	In combination with other antiretroviral agents for treatment of Human Immunodeficiency Virus type-1 (HIV-1) infection in adults and adolescents with aged 12 years and older	10.01.2018
2	Clofarabine Bulk & Injection 20 mg/20ml vial	For the treatment of patients 1 to 21 years old with relapsed or refractory acute lymphoblastic leukemia after at least two prior regimens. This indication is based upon response rate	16.01.2018
3	Denaverine Hydrochloride Injection (Vet.)	cattle : Facilitation of parturition in heifers; activation of interrupted parturitions; insufficient opening of the soft birth canal; narrowness of the cervix of first and second degree after correction of uterine torsions; improvement of the conditions for foetotomy; regulation of labour contractions of the utreus Dogs: Activation of Interrupted parturition	16.01.2018
4	Netupitant 300 mg + Palonosetron 0.5 mg Capsule	For the prevention of acute and delayed nausea and vomiting associated with highly emetogenic Cisplatin-based cancer chemotherapy - For the prevention of acute and delayed nausea and vomiting associated with moderate emetogenic cancer chemotherapy in adult	20.02.2018
5	Fipronil 6.1 % m/v + Permethrin 54.5% m/V spot on solution for Dog (Vet.)	In dogs, to be used against infestations with fleas and/or ticks when repellent (anti feeding) activity is necessary against sand-flies and/or mosquitoes	20.02.2018
6	Paziquantel 0.0065 g + Abamectin 0.00025 g tablets for cat (Vet)	In infestation of cats with endoparasites tapeworms (teniae), flukes, roundworms (nematodes); with ectoparasites - lice, fleas, pasture ticks, notedric mange (feline scabies), "walking" dandruff (cheyletiellosis) and other mange, and particularly in cases of complex endo and	20.02.2018

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		ectoparasitic invasion.	
7	Cadexomer Iodine Bulk & Powder 100 % w/w (contain 0.9 % w/v Iodine) or cadexomer Iodine Ointment 500 mg (contains 0.9% w/v iodine)	For the treatment of chronic exuding wounds such as leg ulcers, pressure ulcers and diabetes ulcers infected traumatic and surgical wounds	05.03.2018
8	Dalfampridine Bulk & Film coated extended release tablet 10 mg	For treatment to improve walking in patients with multiple Sclerosis (MS)	12.03.2018
9	Ulipristal Acetate 5 mg tablets	For the pro-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age and intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age	14.03.2018
10	Ulipristal Acetate bulk		02.04.2018
11	Riociguat bulk & 0.5mg/1.0mg/1.5mg/2.0mg/2.5 mg tablet	For the treatment of persistent/ recurrent chronic Thromboembolic pulmonary Hypertension (CTEPH) WHO Group 4) After surgical treatment or imoperable CTEPH to improve exercise capacity and WHO function	16.04.2018
12	Baricitinib 2mg/4mg film coated Tablets	For the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease modification anti-rheumatic drugs. Baricitinib may be used as monotherapy or in combination with methotrexate	07.05.2018
13	Vortioxetine Hydrobromide 5mg/10mg/15mg/20mg	for the treatment of major depressive disorder in adults	14.05.2018

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14	Vardenafil Hydrochloride Trihydrate Bulk and 2.5mg/5mg/10 mg/20 mg tablets	Treatment of erectile dysfunction in adult men	11.06.2018
15	Trientine Hydrochloride Bulk and 250 mg capsule	For the treatment of Wilson's disease (hepatolenticular degeneration) in patients intolerant to Penicillamine. It should be used when continued treatment with Penicillamine is no longer possible because of intolerable or life endangering side effect.	11.06.2018
16	Gadoteridol injection	To visualise lesions with abnormal vascularity in the brain (intracranial lesions), spine and associated tissues in adults and pediatric patients over 2 years of age, lesions in the head and neck in adults.	25.06.2018
17	Fipronil 50mg/134 mg/268mg/402mg spot on solution for cats and dogs	For treatment of flea and tick infestation in cats and dogs (for veterinary use only)	25.06.2018
18	FDC of Emtricitabine 200 mg and Tenofovir Alafenamide 25 mg tablets	In combination with other antiretroviral agents for the treatment of adults and adolescents (aged 12 years and older with body weight atleast 35 kg) infected with Human Immunodeficiency Virus type-1 (HIV-1)	25.06.2018
19	FDC of Azilsartan + chlorthalidone (40 mg + 12.5 mg) and Azilsartan + chlorthalidone (40 mg + 25 mg) tablet	For the treatment of mild to moderate hypertension in adults	09.07.2018
20	FDC of Ceftolozane (1.0 gm) and Tazobactam (0.5 gm) injection	Indicated for the treatment of patients 18 years or older with the following infections caused by designated susceptible microorganisms: <ul style="list-style-type: none"> • Complicated intra-abdominal infections (cIAI) caused by the following Gram-negative and Gram-positive microorganisms: Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, Bacteroides fragilis, Streptococcus anginosus, Streptococcus constellatus, and 	06.08.2018

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		<p>Streptococcus salivarius in combination with metronidazole in ICU setting only.</p> <ul style="list-style-type: none"> • Complicated urinary tract infections (cUTI), including pyelonephritis, caused by the following Gram-negative microorganisms: Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, and Pseudomonas aeruginosa in ICU setting only. 	
21	Olaparib film coated tablets (100mg, 150 mg)	<p>Ovarian cancer:</p> <ul style="list-style-type: none"> • For the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy. • For the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. <p>Breast cancer:</p> <ul style="list-style-type: none"> • In patients with deleterious or suspected deleterious gBRCAm, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer who have previously been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine treatment. 	13.08.2018
22	Ceftazidime 2gm/Avibactam 0.5 gm powder for concentrate for solution for infusion	<p>Complicated Intra-abdominal infections (cIAI)</p> <p>Complicated Urinary tract infections (cUTI), including pyelonephritis</p> <p>Hospital-acquired pneumonia (HAP) including ventilator associated pneumonia</p>	01.10.2018

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		(VAP) with susceptible gram negative microorganisms	
23	Evogliptin Tartrate Bulk and Tablets 5 mg	For treatment of type-2 diabetes mellitus as an adjunct to diet and exercise to improve glycemic control, when used as a monotherapy or in combination with Metformin	22.10.2018
24	Lorcaserin Hydrochloride Bulk and 10 mg tablets	An adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of 30 kg/m ² or greater (obese) or 27 kg/m ² or greater (overweight) in the presence of at one weight related comorbid condition (e.g. Hypertension, dyslipidaemia, type 2 diabetes)	22.10.2018
25	Fimasartan potassium trihydrate bulk drug and Fimasartan film coated tablets 30mg/60mg/120mg	For the treatment of mild hypertension	22.11.2018
26	Sacubitril/Valsartan (as sodium salt complex) and FDC of Sacubitril + Valartan 50 (24+26)/100 (49+51)/200 (97+103) mg film coated tablets	To reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction	24.12.2018