



स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग

प्रकाशित मिति: २०८१/११/२५

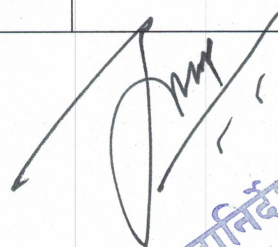
नयाँ औषधि तथा नयाँ समिश्रणहरूको अनुमोदन सम्बन्धि सूचना।

औषधि सल्लाहकार समितिको मिति २०८१/१०/०३ गतेको ५७औं बैठकको निर्णयानुसार निम्न पच्चीस (२५) प्रकारका नयाँ औषधि (New Molecule) साथै औषधिका नयाँ समिश्रणहरू तत्तत रोग एवं रोगको अवस्थामा प्रयोग गर्ने गरि अनुमोदन गरी विभागले अपनाई आएको विधि र प्रकृया पुरा गरी दर्ता गर्न सिफारिस भै आएको व्यहोरा मिति २०८१/११/२५ को विभागीय निर्णयानुसार सम्बन्धित सबैको जानकारीको लागि यो सूचना प्रकाशन गरिएको छ।

S.NO.	Generic Name	Indication(S)
1	Budesonide 0.5 mg and Formoterol Fumarate 20 mcg Respirator Suspension	for regular treatment of asthma, regular long-term treatment of moderate-to-severe COPD, with frequent symptoms and a history of repeated exacerbations in patients aged 6 years and above
2	Budesonide 1.0 mg and Formoterol Fumarate 20 mcg Respirator Suspension	
3	Nepafenac Ophthalmic Suspension 1mg/ml	for the treatment of pain and inflammation associated with cataract surgery in patient aged 10 years and above
4	Itraconazole 130mg Capsules	for the treatment of Blastomycosis (Pulmonary and extrapulmonary), Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis, Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy in patients aged 18 years and above
5	Clofarabine 1mg/ml, 20 ml Vial	for the treatment of Acute lymphoblastic leukaemia (ALL) who have relapsed or are refractory after receiving at least two prior regimens and where there is no other treatment option anticipated to result in a durable response in patients aged 1 to 21 years
6	Pancrelipase delayed release pellets Equivalent to: Lipase 10000 USP units, Protease 37500 USP units, Amylase 33200 USP units	for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions in patients aged 12 years and above
7	Pancrelipase delayed release pellets Equivalent to: Lipase 25000 USP units, Protease 62500 USP units, Amylase 74700 USP units	
8	Trimipiramine Maleate equivalent to Trimipiramine 10mg/25mg tab	for the relief of symptoms of depression
9	Prasugrel HCL equivalent to prasugrel 10mg tab	for the prevention of atherothrombotic events in adult patients with acute coronary syndrome in patient aged 18 years and above
10	Prucalopride 2mg tablets	for symptomatic treatment of chronic constipation in adults in whom laxatives fail to provide adequate relief in adults aged 18 years and above

सहानिर्देशक

11	Nivolumab 40mg, Injection	for treatment of melanoma, adjuvant treatment of melanoma, non-small cell lung cancer (NSCLC), neoadjuvant treatment of NSCLC, Malignant pleural mesothelioma (MPM), Renal cell carcinoma (RCC), Classic Hodgkin lymphoma (CHL), Squamous cell cancer of the head and neck, Urothelial carcinoma, Mismatch repair deficient or microsatellite instability high colorectal cancer, oesophageal squamous cell carcinoma, gastro oesophageal junction or oesophageal adenocarcinoma in adults aged 18 years and above
12	Artesunate powder for injection 60mg	for the treatment of severe malaria caused by Plasmodium falciparum, in adults and children
13	Indacaterol 150mcg (as acetate), glycopyrronium 50mcg, mometasone furoate 160mcg	for maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta 2-agonist and a high dose of an inhaled corticosteroid who experienced one or more asthma exacerbations in the previous year in patients aged 18 years and above
14	Ferric carboxymaltose Injection 500mg/10ml, 100mg/2ml, 1000mg/20ml	for the treatment of iron deficiency in adults when oral iron preparations are ineffective or cannot be used in patient aged 14 years and above
15	L-Glutamine powder for oral solution, 5gm in 8gm sachet	to reduce the acute complication of sickle cell disease in adult and pediatric patient 5 years of age and older
16	Carbetocin 100 mcg/ml Injection	for the prevention of uterine atony and postpartum hemorrhage following cesarean section under epidural or spinal anaesthesia in patients aged 18 years and above
17	Aflibercept Injection 40mg per 1ml Injection	for the treatment of patients with Wet Age-related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), Diabetic Retinopathy (DR), and Retinopathy of Prematurity (ROP) in patients aged 18 years and above
18	Trifarotene 0.005 % cream	for the cutaneous treatment of Acne Vulgaris of the face and/or the trunk in patients from 12 years of age and older
19	Lacosamide Infusion 10mg/ml	as adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy aged 17 years and older
20	Fluticasone Furoate 100mcg & Vilanterol 25mcg powder for inhalation	for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema
21	Desoximetasone 0.05 % cream	for the relief of acute or chronic corticosteroid-responsive dermatoses
22	Ibuprofen Solution for Infusion 400mg/100ml	for the management of mild to moderate pain and the management of moderate to severe pain as an adjunct to opioid analgesics
23	Vortioxetine HCL 5mg/10mg/20mg	for treatment of major depressive episodes including prevention of relapse in adults aged 18 years and above
24	Varenicline Tartarate 0.5mg/1mg	for smoking cessation in adults (tobacco dependence)
25	Dapagliflozin & Metformin (5 mg/ 500 mg, 5 mg/ 1000 mg, 10 mg/ 500 mg & 10 mg/ 1000 mg) Tablet, Extended Release)	For treatment of type 2 diabetes mellitus


महानिदेशक