

File No. P.17019/03/2026-DSA

Date: 27th July, 2026

The analysis of Adverse Drug Reactions (ADRs) from the PvPI database revealed the following suspected drugs are associated with the ADRs as given below;

S. No.	Issue Date	Suspected drugs	Indication(s)	Adverse Drug Reactions
1	Mar-16	Phenytoin	Used for the treatment of Generalised tonic clonic seizure, partial seizure, status epilepticus	Angioedema
2		Phenytoin		Osteoporosis
3		Nicorandil	Used for the treatment of Angina pectoris, Vasodilator	Risk of ulcer complication
4		Olanzapine	Used for the treatment of Schizophrenia, acute mania episodes in bipolar disorder	Hyponatraemia
5		Crizotinib	Used for the treatment of locally advanced or metastatic Non- Small Cell Lung Cancer (NSCLC) that is Anaplastic Lymphoma Kinase (ALK)	Risk of cardiac failure
6	Apr-16	Roflumilast	Reduce the risk of chronic obstructive pulmonary disease exacerbation	Gynecomastia
7		Clozapine	Used for the management of schizophrenic patients	Neutropenia
8		Disulfiram	Used for Alcohol – abuse deterrent	Erythroderma
9	May-16	Peginterferon alpha – 2a	Used for the treatment of Chronic active Hepatitis B & C	Vasculitis
10		Piperacillin + Tazobactam	Used for the treatment of lower RTI / UTI / intra-abdominal infection, skin and skin structure infection, bacterial septicaemia polymicrobial infection	Vision abnormal
11		Mometasone furoate, topical	Used for Steroid responsive dermatitis, eczema, or atopic dermatitis	Hypertrichosis / Hirsutism, Skin depigmentation



12	Jun-16	Ranibizumab	Used for the treatment of Neovascular age related macular degeneration (AMD), Visual impairment due to Diabetic macular edema (DME), Visual impairment due to Choroidal Neovascularization (CNV) secondary to pathologic myopia	Myocardial Infarction
13		Amphotericin B	Used for the treatment of life-threatening fungal infection including histoplasmosis, coccidioidomycosis, paracoccidioidomycosis, blastomycosis, aspergillosis, cryptococcosis, mucormycosis, sporotrichosis, and candidiasis, visceral and mucocutaneous leishmaniasis unresponsive to pentavalent antimony compounds, severe meningitis, Perioral candidiasis	Bone marrow depression
14		Doxorubicin	Used for the treatment of soft tissue and bone sarcomas, Acute leukaemia, Malignant lymphoma, Hodgkin' disease, Breast carcinoma, small cell carcinoma of lungs, AIDS- related Kaposi's sarcoma, Multiple myeloma, Gastrointestinal tract carcinoma, Bladder cancer, Ovarian carcinoma, Acute myeloblastic leukaemia, Thyroid carcinoma, Neuroblastoma	Photosensitivity reaction
15		Crizotinib	Used for the treatment of locally advanced or metastatic Non – Small Cell Lung Cancer (NSCLC) that is Anaplastic Lymphoma Kinase (ALK) positive.	Pneumonitis, Hepatic encephalopathy
16	Jul-16	Febuxostat	Used for treatment of chronic hyperuricemia in conditions where urate deposition has already occurred (Including a history, or presence of tophus and / or gouty arthritis)	Allergic vasculitis



17		Oxcarbamazepine	Monotherapy or adjunctive therapy in the treatment of partial seizure, secondary generalized seizure, substitution for carbamazepine can be made abruptly with an oxcarbamazepine-to-carbamazepine ratio of 300: 200	Syndrome of Inappropriate Antidiuretic Hormone secretion (SIADH)
18		Artemether & Lumefantrine	Used for treatment of uncomplicated falciparum malaria, mixed infection of falciparum and chloroquine resistant vivax malaria.	Steven- Johnson Syndrome / Toxic Epidermal Necrolysis
19		Cefixime	Used for the treatment of otitis media, respiratory tract infection, uncomplicated UTIs, effective against infection caused by Enterobacteriaceae, H. influenza species	Acute Generalized Exanthematous Pustulosis (AGEP)
20		Hepatitis B Immune globulin (human)	Used for active immunization against Hepatitis B virus (HBV) infection in subjects considered at risk of exposure to HBV – positive material	Encephalopathy
21	Aug-16	Cefotaxime	Infection due to sensitive Gram – positive and Gram-negative bacteria such as bacteraemia, cellulitis, Intra-abdominal infection, Gonorrhoea, bone or joint infection, skin and skin structure infection, Urinary tract infection, Septicaemias, surgical prophylaxis, Endometritis, life threatening resistant/ hospital acquired infections, infection in immune –compromised patient, Haemophilus epiglottitis and meningitis	Anaphylactic shock
22		Lacosamide	As an adjunctive treatment of partial onset seizure in patient >17 years of age	Red Man Syndrome
23		Dimethyl fumarate	Used for relapsing remitting multiple sclerosis	Osteonecrosis
24		Sodium citrate +Diphenhydramine hydrochloride+ Ammonium chloride	Used for symptomatic treatment of cough	Myocardial infraction



25	Nov-16	Cabergoline	Used for the treatment of hyperprolactinemia and inhibition of lactation	Steven- Johnson Syndrome
26		Amlodipine	Used for the treatment of Angina, Hypertension, Coronary Artery Disease	Alopecia
27		Nitrofurantoin	Used for the treatment of urinary tract infection, Cystitis	Drug reaction with Eosinophilia and Systemic Symptoms (DRESS syndrome)
28		Cefoperazone + Sulbactam	For treatment of RTI, UTI, (lower & upper), Septicaemia, Meningitis, Skin & Soft tissue infection, Endometritis, Other infection of genital tract, Intra-abdominal infection bone & joint infection	Acute Generalized Exanthematous pustulosis (AGEP)
29	December 2016	Cefixime	Used for the treatment of otitis media, Respiratory tract infection, uncomplicated UTIs, effective against infection caused by Enterobacteriaceae, H. Influenza species	Anal ulcer
30		Atenolol	Used for the treatment of Angina and myocardial infarction, Arrhythmias, Hypertension, Migraine prophylaxis	Dermatitis Lichenoid
31		Olanzapine	Used for the treatment of Schizophrenia and other psychotic disorders, mania/ mixed episode, psychomotor agitation and violent behaviour	Drug Reaction with Eosinophilia and Systemic Symptoms
32		Meropenem	Used for the treatment of Nosocomial infection like Septicaemia, Febrile neutropenia, intra-abdominal and pelvic infection, etc, caused by cephalosporin's resistant bacteria, meningitis cystic fibrosis	Hypokalaemia
33		Montelukast	Prophylaxis of mild to moderate asthma	Tinnitus
34	Jan-17	Cefepime	Used for the treatment of serious CRTI, uncomplicated and complicated UTI, Uncomplicated skin & skin structure, infection acute exacerbation of chronic bronchitis & intra-abdominal infection	Dermatitis Lichenoid



35		Losartan	Congestive Heart Failure, Hypertension (myocardial infarction along with stroke including reduction of stroke risk in hypertension) with left ventricular hypertrophy, Diabetic Nephropathy in type II diabetes	Burning Micturition
36		Amisulpride	For the treatment of acute and chronic schizophrenic disorder, in which positive symptoms, and or negative symptoms are prominent, including patients characterized by predominant negative symptoms	Tinnitus
37		Carbamazepine	For the treatment of Partial seizure with or without secondary generalization, Trigeminal neuralgia, bipolar disorder	Bruxism
38	Feb-17	Clomipramine	Used for the treatment of Obsessive-compulsive disorder, panic disorder	Melasma
39		Glimepiride	Used for the treatment of Type 2 diabetes mellitus	Lichenoid Drug Eruption
40		Metoprolol	Used for the treatment of Supra-ventricular arrhythmia, Angina pectoris, Hypertension, Myocardial infarction, Migraine prophylaxis, Hyperthyroidism, Heart failure	Lichenoid Drug Eruption
41		Levamisole	Used for the treatment of roundworm and hookworm infestations	Skin Exfoliation
42	Mar-17	Deferasirox	Used for the treatment of chronic iron overload in patients with Non – Transfusion Dependent Thalassemia (NTDT) Syndrome	Osteoporosis
43		Ambroxol	Used for the treatment of all forms of tracheobronchitis, Emphysema with bronchitis pneumoconiosis, chronic inflammatory pulmonary conditions, Bronchiectasis, Bronchitis with bronchospasm asthma	Lacrimation
44		Lurasidone	Used for the treatment of patient with schizophrenia	Thrombocytopenia



45		Etoricoxib	Short term use in acute painful condition	Skin hyperpigmentation
46	Apr-17	Dexamethasone	Adjunct in the emergency treatment of anaphylaxis, short term suppression of inflammation in allergic disorders, adrenocortical insufficiency. Ocular inflammation, autoimmune disorder. Rhematic	Hiccups
47		Cabergoline	For the treatment of parkinson's disease, hyperprolactinemia and inhibition of lactation	Skin hyperpigmentation
48		Sodium valproate	Used for the treatment of generalised tonic-clonic seizure, partial seizure, atonic seizure, absence seizure, myoclonic seizure, acute migraine	Psoriasis
49		Amoxycillin	Used for the treatment of urinary tract infection, upper respiratory tract infection, bronchitis, pneumonia, otitis media, dental abscess, osteomyelitis, Lyme disease in children, endocarditis prophylaxis, post – splenectomy prophylaxis, gynaecological infection, gonorrhoea, helicobacter pylori eradication	Eye irritation
50	May-17	Tinidazole	Used for the treatment of amoebiasis, trichomoniasis and giardiasis, anaerobic infection, necrotising ulcerative gingivitis, bacterial vaginosis, H. pylori associated peptic ulcer, abdominal surgery prophylaxis	Hyperpigmentation
51		Amlodipine	Used for the treatment of Angina, Hypertension, Coronary artery disease	Psoriasis
52		Hydroxyzine	Used for management of pruritus due to allergic condition such as chronic urticaria and atopic contact dermatoses, and in histamine – mediated pruritus	Bullous pemphigoid



53		Amitriptyline	Used for the treatment of moderate to severe depression, migraine prophylaxis, tension type headache, neuropathic / chronic pain, fibromyalgia	Gingival discolouration
54	Jun-17	Paracetamol	Used for the treatment of mild to moderate pain including dysmenorrhoeal pain, headache, pain relief in osteoarthritis and soft tissue lesions, pyrexia, acute migraine attack	Baboon syndrome
55		Lamivudine	Used for the treatment of HIV Infection in combination with at least two other antiretroviral drugs	Hearing loss
56		Mebeverine	Used for the treatment of irritable bowel syndrome	Retrosternal pain
57	Jul-17	Clindamycin	Used for the treatment of respiratory tract infection, penicillin resistant staphylococcal infection and many anaerobes such as bacteroides, skin, soft tissue and dental infection	Acute Generalised Exanthematous Pustulosis
58		Triamcinolone	For the treatment of intraarticular, intra synovial, or periarticular use in adults and adolescents for the symptomatic treatment of subacute and chronic inflammatory joint diseases including osteoarthritis and posttraumatic arthritis, rheumatoid arthritis, juvenile idiopathic arthritis, synovitis, tendinitis, bursitis and epicondylitis	Skin peeling



59		Polymyxin B	- For the treatment of Infections of the urinary tract, meninges and blood stream caused by susceptible strains of Pseudomonas aeruginosa. It may also be used as subconjunctival injection in the treatment of infections of the eye caused by susceptible strains of Pseudomonas aeruginosa. - It may be indicated in serious infections caused by susceptible strains of the organisms- Haemophilus influenzae specifically meningial infections, Escherichia coli specifically urinary tract infections, Aerobacter aerogenes specifically bacteremia, Klebsiella pneumoniae specifically bacteremia.	Mottled skin
60		Diclofenac	Used for the treatment of acute musculo-skeletal pain, arthritis, gout, spondylitis, migraine, post-operative pain	Nicolau Syndrome
61	Aug-17	Terbinafine	Used for the treatment of fungal infection.	Acute Generalised Exanthematous Pustulosis
62		Nitrofurantoin	Used for the treatment of urinary tract infection, Cystitis.	Vasculitis
63	Sep-17	Acetazolamide	Adjunct in treatment of chronic open-angle glaucoma, secondary glaucoma, as a part of pre- operative treatment of acute angle-closure glaucoma	Drug hypersensitivity syndrome
64		Linagliptin	Used for the treatment of Type 2 diabetes mellitus	Acute Generalised Exanthematous Pustulosis
65		Diloxanide	Used for the treatment of intestinal amoebiasis.	Glossitis



66	17th October 2017	Amikacin	Short term treatment of serious infection due to susceptible strains of gram- negative bacteria, including pseudomonas species, Escherichia coli species of indole – positive and indole negative proteus, providencia species, Klebsiella, Enterobacter, Serratia species and acinetobacter species	Steven Johnson Syndrome
67		Allopurinol	Prophylaxis of gout prophylaxis of hyperuricaemia associated with cancer chemotherapy	Uveitis
68		Quetiapine	For treatment of schizophrenia and bipolar disorder	Gynaecomastia
69	28th November 2017	Ceftriaxone	Serious infection due to sensitive bacteria, including septicaemia, pneumonia and meningitis, surgical prophylaxis of meningococcal meningitis, gonorrhoea, bone and joint infection	Palpitation
70	27th December 2017	Fluoxetine	Fluoxetine is a SSRI antidepressant which is used in psychological disorders and also in premature ejaculation	Urinary incontinence
71	30th January 2018	Levetiracetam	For treatment of myoclonus – generalised epilepsy with photosensitivity, idiopathic epilepsy – control of generalised tonic – clonic seizure, post anoxic and post – encephalitic myoclonic epilepsy, epileptic encephalopathies, severe myoclonic epilepsy, absence seizure, rolandic epilepsy	Hypokalaemia
72	28th February 2018	Dapsone	For the treatment of leprosy, acne vulgaris, dermatitis, Pneumocystic pneumonia	Erythema Nodosum
73	27th March 2018	Cefixime	For treatment of otitis media, respiratory tract infection, uncomplicated UTIs, effective against infection caused by Enterobacteriaceae, H. influenza species	Skin Hyperpigmentation



74	27th April 2018	Dexamethasone	Adjunct in the emergency treatment of anaphylaxis, short term suppression of inflammation in allergic disorder, adrenocortical insufficiency, ocular inflammation autoimmune disorder, rheumatic disorder, cerebral oedema, unresponsive shock, bacterial meningitis along with antibiotics	Peripheral neuropathy
75	10th July 2018	Fluoxetine	Used for the treatment of Bipolar disorder, Depressive episode	Hypoacusis (Hearing impairment)
76	3rd December 2018	Telmisartan	Used for the treatment of hypertension	Lichenoid keratosis
77	1st January 2019	Miltefosine	Directly Observed Therapy (DOT) of Visceral Leishmaniasis caused by Leishmania donovani	Acute Pancreatitis
78	14th February 2019	Levetiracetam	Anti-epileptic, 1) As monotherapy in partial onset seizures with or without secondary generalisation in patient with 16 years of age with newly diagnosed epilepsy. 2) As adjunctive therapy in myoclonic seizures in adult and adolescent from 12 years of age with juvenile.	Anencephaly
79		Cetirizine	For the treatment of seasonal/perennial allergic rhinitis & chronic idiopathic urticaria in infants & children.	Tachycardia
80	25th March 2019	Dabigatran	For prevention of stroke, systemic embolism and reduction of vascular mortality in adult patient with atrial fibrillation	Alopecia
81		Sertaline	Major depressive disorders, obsessive compulsive disorders (OCD), panic disorders	Maculopathy



82	15 th May 2019	Amiodarone	In the treatment of control of ventricular and supraventricular arrhythmia where other drug cannot be used, arrhythmia associated with Wolf-White Syndrome. For cardiopulmonary resuscitation in the event of cardiac arrest related to ventricular fibrillation resistant to external electric shock.	Acute Pancreatitis
83		Teicoplanin	Glycopeptide antibiotic-use in serious gram +Ve infection, staphylococcal infection in patients sensitive or unresponsive to penicillin and cephalosporin CAPD related peritonitis, prophylaxis in orthopaedic surgery at risk of gram +Ve infection	Red Man Syndrome
84	6th June 2019	Teicoplanin	Glycopeptide antibiotic-use in serious gram +Ve infection, staphylococcal infection in patients sensitive or unresponsive to penicillin and cephalosporin CAPD related peritonitis, prophylaxis in orthopaedic surgery at risk of gram +Ve infection	Toxic Epidermal Necrolysis (TEN)
85	3rd July 2019	Febuxostat	For treatment of chronic hyperuricemia in conditions where urate crystals deposition has already occurred (including a history, or presence of tophus and /or gouty arthritis).	Toxic Epidermal Necrolysis/Steven Johnson Syndrome
86		Netilmicin	Aminoglycoside antibiotic - Indicated in the treatment of septicaemia including neonatal sepsis and other severe systemic infections.	Tetany
87	6th August 2019	Metronidazole	For the treatment of amoebiasis, urogenital trichomoniasis & giardiasis.	Vasculitis
88		Risperidone	Indicated as monotherapy or as adjunctive therapy in lithium or valproate for the maintenance treatment of Bipolar-1 disorder.	Rabbit Syndrome
89	5th September 2019	Teneligliptin	For the treatment of type-2 Diabetes Mellitus as a monotherapy adjunct to diet and exercise	Arthralgia



90		Atorvastatin	As an adjunct to diet to reduce elevated total cholesterol & triglyceride level in patients with primary hypercholesterolemia & mixed dysbetalipoproteinemia (Type IIa & IIb)	Vit-D deficiency
91	30th October 2019	Cetirizine	For the treatment of allergic rhinitis and chronic urticaria.	Acute Generalized Exanthematous Pustulosis
92		Clozapine	Indicated in the management of Schizophrenic patients.	Neural Tube Defects
93	22nd November 2019	Cetirizine	For the treatment of allergic rhinitis and chronic urticaria.	Hiccups
94		Cilostazole	For the treatment of stable intermittent claudication, acting or cramping in legs that occur with walking.	Tinnitus
95	30th December 2019	Levamisole	Indicated in the treatment and control of mature and developing immature infections of haemonchus, ostertagia, trichostrongylus, cooperia, nematodinus, bunostomum, oesophagostomum and dictyocaulus and all forms of liver fluke infection	Steven Johnson Syndrome
96		Cephalosporin	Indicated in the treatment of serious infections due to susceptible organisms-respiratory tract infections, urinary tract infections, skin billiary tract infections, septicaemia, meningitis other infections due to susceptible organisms and in the treatment of infections due to penicillin resistant strains of staphylococci.	Acute Generalized Exanthematous Pustulosis
97	15th January 2020	Disulfiram	Antidotes, Detoxifying Agents & Drugs Used in Substance Dependence.	Skin Hyperpigmentation
98		Fluconazole	For the treatment of systemic candidiasis, mucosal candidiasis, pityriasis versicolor, prevention of fungal infections in patients with malignancy.	Mouth Ulceration



99	12th February 2020	Olanzapine	For the treatment of Schizophrenia.	Hyponatremia
100		Piperacillin+Tazobactam	In the treatment of LRTI/UTI/Intra-abdominal infections, skin and skin structure infections, bacterial septicemic polymicrobial infections	Blurred Vision
101	12th March 2020	Terlipressin	In the treatment of bleeding oesophageal varices.	Atrial Fibrillation
102	1st June 2020	Hydroxychloroquine Sulphate	Off Label drug use as Prophylactic & Treatment of COVID-19 disease	Mouth Ulceration
103	7th July 2020	SGLT-2 Inhibitors	As an adjunct to diet and exercise to improve glycaemic control in adults with type 2 Diabetes Mellitus	Genital Pruritus
104		Fluconazole	For the treatment of systemic candidiasis, mucosal candidiasis, prevention of fungal infections in patients with malignancy.	Symmetrical Drug-Related Intertriginous and Flexural Exanthema (SDRIFE)
105	31st August, 2020	Pramipexole	Indicated for the treatment of sign and symptoms of idiopathic Parkinsons disease.	Photosensitivity Reaction
106	4th September, 2020	Fluvoxamine	Fluvoxamine is a Selective Serotonin Reuptake Inhibitor (SSRI) indicated for the treatment of obsessive-compulsive disorder and depression	Intracranial/Pulmonary Hypertension
107	5th October 2020	Clindamycin	Antibiotic-Indicated in the treatment of gram +ve organism pathogens, staphylococcus & streptococci, pneumococci.	Symmetrical Drug Related Intertriginous and Flexural Exanthema (SDRIFE)
108	4th November 2020	Clarithromycin	For the treatment of mild to moderately severe infections like acute exacerbation of chronic bronchitis community acquired pneumonia including infections due to Chlamydia, Mycoplasma spegiocella acute streptococcal pharyngitis and skin and soft tissue infections.	Acute Generalised Exanthematous Pustulosis (AGEP)
109		Tamsulosin + Deflazacort	For the treatment of sign & symptoms of benign prostate hyperplasia. For Asthma, Rheumatoid Arthritis when Glucocorticosteroid therapy is warranted.	Ear pain



110	30th December 2020	Beta-Blockers (Atenolol, Bisoprolol, Metoprolol)	Anti-arrhythmic agent- Indicated in the treatment of hypertension, angina pectoris, cardiac arrhythmias, Congestive Heart Failure (CHF).	Lichen Planus
111		Omeprazole	Anti-ulcer, short term treatment of duodenal ulcer, gastric ulcer, reflux oesophagitis, management of Zollinger Ellison Syndrome.	Dysuria
112	4th January 2021	Fexofenadine	In the treatment of relief of symptoms associated with seasonal allergic rhinitis and chronic idiopathic urticaria.	Blurred Vision
113		Ambroxol	Anti-tussive - Acute and chronic disease of the respiratory tract associated with abnormal bronchial secretions in particular acute attacks of chronic bronchitis, asthmatic bronchitis and bronchial asthma.	Fixed Drug Eruption
114	1st February 2021	Cefpodoxime	Used for the treatment of acute bronchitis, exacerbations of chronic bronchitis, bronchiolitis pneumonia, sinusitis, recurrent chronic tonsillitis, pharyngitis, acute otitis.	Drug Reaction with Eosinophilia Systemic Symptoms (DRESS) Syndrome
115		Clarithromycin	Used for the treatment of mild to moderately severe infections like acute exacerbation of chronic bronchitis community acquired pneumonia including infections due to chlamydia, mycoplasma spegiocella acute streptococcal pharyngitis and skin and soft tissue infections.	Burning Sensation
116	01st March 2021	Hydroxyzine	For the management of pruritus due to allergic conditions such as chronic urticaria and atopic contact dermatoses, and in histamine - mediated pruritus.	Photosensitivity Reaction
117		Salicylic Acid	For the treatment of acne vulgaris	Photosensitivity Reaction
118	5th April 2021	Zinc (Acetate/Oxide/Sulphate/Gluconate)	In treatment of acute diarrhoea in children as an adjunct to oral rehydration.	Diarrhoea



119		Clobazam	For the treatment of acute and chronic anxiety states and as an adjunctive therapy in patients with refractory epilepsy.	DRESS Syndrome
120		Baclofen	For the symptomatic treatment of neuronal spasticity due to multiple sclerosis, spinal cord, pathology & injury.	Encephalopathy
121	28th June, 2021	Rosuvastatin & Ticagrelor Interaction	Rosuvastatin: Risk reduction of MI stroke and arterial revascularisation procedure in patients without clinically evident CHD but with multiple risk factors. Ticagrelor: For the prevention of thrombotic events (cardiovascular death, Myocardial Infarction and stroke) in patients with Acute coronary syndromes (ACS) unstable angina, non-ST Elevation Myocardial Infarction (STEMI) including patients managed medically and those who are managed with Percutaneous Coronary Intervention (PCI) or Coronary Artery Bypass Grafting (CABG).	Rhabdomyolysis
122		Etoricoxib	For the treatment of pain, swelling & inflammatory conditions due to arthritis.	Acute Generalized Exanthematous Pustulosis (AGEP)
123		Torsemide	For the treatment of oedema associated with congestive heart failure & hypertension.	DRESS Syndrome





124	28th July 2021	Quetiapine & Valproic Acid Interaction	Quetiapine: - For the management of the manifestation of psychotic disorders (schizophrenia). - For the additional indication "acute manic episode associated with bipolar disorder". Valproic Acid: - As monotherapy and adjunctive therapy in the treatment of patients with complex partial seizures that occur either in isolation or in association with other types of seizure. - As monotherapy or adjunctive therapy in the treatment of patients with complex partial seizure and manic episodes associated with bipolar disorder.	Neuropsychiatric Adverse Events (Depressed level of consciousness/Com a & Disorientation)
125	31 st August 2021	Sofosbuvir	Used in combination with other medicinal products for the treatment of chronic hepatitis C in adults.	Steven-Johnson Syndrome
126	30th September, 2021	Dimethyl Fumarate	Used for Relapsing remitting multiple sclerosis	Alopecia
127		Cefazolin	Cephalosporin antibiotic-indicated in the treatment of serious infections due to susceptible organisms – respiratory tract infections, urinary tract infections, skin & skin structure infection, biliary tract infections, septicaemia	Acute Generalised Exanthematous Pustulosis
128	30th November, 2021	Diclofenac	For the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, gout, painful post-operative pain following dental surgery, migraine attack and post-operative inflammation in patients who have undergone cataract operation.	Skin hyperpigmentation
129	28th December, 2021	Remdesivir	Broad spectrum antiviral medication. Restricted emergency use for treatment of patients with severe COVID-19	Sinus Bradycardia



130	18 th January, 2022	Ibuprofen	For the treatment of chronic arthritic disorders and painful musculoskeletal conditions.	Fixed Drug Eruption
131	28 th February, 2022	Losartan	For the treatment of hypertension	Muscle Spasm
132	17 th March, 2022	Cephalosporin Class	Cephalosporins are beta-lactam antimicrobials used to manage a wide range of infections from Gram-positive and Gram-negative bacteria	Fixed Drug Eruption
133	28 th April, 2022	Cefuroxime	• Antibiotic- Indicated for lower & upper respiratory tract infection, UTI, gynaecological infection, skin or soft tissue infection etc. • Antibiotic- Indicated in the treatment of respiratory tract infections, UTI, ENT soft tissue infections etc.	Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)
134	30 th May, 2022	Itraconazole	• Systemic aspergillosis and candidiasis, cryptococcosis, sporotrichosis, Paracoccidioidomycosis, blastomycosis and other rarely occurring systemic or tropical mycoses. • Empiric therapy of febrile neutropenic patients with suspected fungal infections	Symmetrical Drug Related- Intertriginous and Flexural Exanthema (SDRIFE)
135	17 th June, 2022	Trimetazidine	• Ischaemic heart disease, angina pectoris, sequelae of infarction. • Cardiac drug indicated in the treatment of angina pectoris and intermittent claudication.	Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)





136	15th July, 2022	Tacrolimus	• For prophylaxis of transplant rejection in adult kidney or liver allograft rejection. • Prophylaxis of transplant rejection in kidney, liver or heart allograft recipient. • For prophylaxis of transplant rejection in liver, pancreas, lung, heart and kidney allograft recipients and treatment of allograft rejection resistant to treatment with other immuno- suppressive medicinal products. • By nephrologists only- for the prophylaxis of organ rejection in patients receiving allogenic kidney transplant. • For dermatologists-for treatment of patients with moderate to severe atopic dermatitis in whom the use of alternative conventional therapy is advisable.	Gingival Hypertrophy
137	23rd August, 2022	Cefoperazone	Urinary infections, biliary infections, respiratory infections, infections of skin tissues, meningitis, septicaemia, Pseudomonas, Salmonella typhi & B. fragilis infections.	Coagulopathy
138	26th September, 2022	Piroxicam	• In the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, cervical spondylitis and other musculoskeletal disorder. • Anti-inflammatory agent- Indicated in the treatment of rheumatoid arthritis, ankylosing spondylitis and other musculoskeletal disorders • Indicated in the treatment of musculoskeletal disorders, acute gout, pain after operative intervention following acute trauma and in primary dysmenorrhoea (12 years age or older)	Fixed Drug Eruption





139	17th October, 2022	Amoxicillin	For treatment of urinary tract infections, upper respiratory-tract infections, bronchitis, pneumonia, otitis media, dental abscess, osteomyelitis, Lyme diseases in children, endocarditis prophylaxis, post-splenectomy prophylaxis, gynaecological infections, gonorrhoea, helicobacter pylori eradication enteric fever.	Fixed Drug Eruption
140	28th November, 2022	Norfloxacin	1. Antibacterial- Indicated in the treatment of acute uncomplicated/complicated chronic, recurrent urinary tract infections, including pyelonephritis, cystitis, urethritis & gonococcal infections. 2. Wide variety of infections caused by susceptible Gram +ve and Gram -ve organism including mixed infection in poultry.	Skin Hyperpigmentation
141	26th December 2022	Minoxidil	For the treatment of alopecia (male pattern baldness in men).	Folliculitis
142	31st January 2023	Amphotericin B (Liposomal)	1. Febrile Neutropenia in cancer patients. 2. For invasive fungal infection in patients who are refractory to or intolerant of conventional amphotericin B therapy. 3. By RMP- for the treatment of invasive fungal infection in patients who are refractory to or intolerant of conventional amphotericin-B therapy. 4. Indicated for the treatment of visceral leishmaniasis.	Hearing disorders
143				Tachycardia
144	20th February 2023	Cephalosporins	Cephalosporins are beta-lactam antimicrobials used to manage a wide range of infections from Gram-positive and Gram-negative bacteria.	Purpura
145		Amikacin	Indicated in the treatment of serious infections due to amikacin sensitive organisms.	Vision blurred



146	29th March 2023	Metoprolol	For the treatment of essential hypertension in adults, functional heart disorders, migraine prophylaxis, cardiac arrhythmias, prevention of cardiac death and reinfarction after the acute phase of myocardial infarction, stable symptomatic CHF	Hyponatraemia
147		Nebivolol	For the treatment of essential hypertension	Hyperkalaemia
148		Olmesartan	Use as an Anti-hypertensive	Muscle Spasm
149				Taste Disorder
150	24th April 2023	Sulfasalazine	Use for the treatment of severe rheumatoid arthritis, ulcerative colitis; Crohn's diseases.	Visual Impairment
151		Ziprasidone	1. Use for the treatment of schizophrenia. 2. Use for rapid control of agitation in psychotic patients.	DRESS Syndrome
152	31st May 2023	Ceftriaxone	For the treatment of urinary tract infections, lower respiratory tract infections, bacteraemia, septicaemia, meningitis, abdominal infections and infections caused by pseudomonas species.	Electrocardiogram QT prolonged
153		Levosulpiride	- Use for the treatment of depression and schizophrenia in adults. - For the treatment of different G.I. problems like functional dyspepsia, nausea, vomiting and diabetic gastroparesis.	Restless Legs Syndrome (RLS)
154	22nd June 2023	Teneligliptin	For the treatment of Type-2 Diabetes Mellitus as a monotherapy adjunct to diet and exercise.	Bullous Pemphigoid
155	28th July 2023	Colistimethate Sodium	For the treatment of some serious infections caused by Gram-negative bacteria, including those of the lower respiratory tract and urinary tract, when more commonly used systemic antibacterial agents may be contraindicated or may be ineffective because of bacterial resistance.	Bartter's like syndrome

भारतीय भेषजसंहिता आयोग

स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार

सैक्टर - 23, राज नगर

गाजियाबाद - 201 002 (उ.प्र.), भारत



INDIAN PHARMACOPOEIA COMMISSION

Ministry of Health & Family Welfare, Government of India

Sector-23, Raj Nagar

Ghaziabad - 201 002 (U.P.) INDIA

156	22nd August 2023	Levonorgestrel	- Used as emergency Contraceptive. - For Control of Fertility. - For the treatment of Contraception, Menorrhagia & Endometrial Hyperplasia during Estrogen replacement therapy in women.	Deep Vein Thrombosis
157	27th September 2023	Esomeprazole	- GERD, erosive reflux esophagitis, prevention of relapse of esophagitis & helps in eradication of H. Pylori associated peptic ulcer. - For the treatment of GERD, gastric and duodenal ulcer, Zollinger-Ellison syndrome.	Hyperprolactinaemia
158	25th October 2023	Co-trimoxazole	Indicated in the treatment of respiratory tract infection, urogenital infections, G.I. tract infections etc.	FDE
159	30th November 2023	Mefenamic Acid	Treatment of rheumatoid arthritis, osteoarthritis, dysmenorrhoea, mild to moderate pain, inflammation, fever, dental pain.	DRESS Syndrome
160	27th March 2024	Cefuroxime	Antibiotic- Indicated for lower & upper respiratory tract infection, Urinary Tract Infection (UTI), gynaecological infection, skin or soft tissue infection etc.	AGEP
161		Dutasteride + Tamsulosin	For the treatment of Benign Prostatic Hyperplasia	Palpitation

INDIAN PHARMACOPOEIA (IP)

Official Book of Drug Standards in India

IP REFERENCE SUBSTANCES (IPRS)

Official Physical Standards for Assessing the Quality of Drugs

NATIONAL FORMULARY OF INDIA (NFI)

Reference Book to Promote Rational Use of Generic Medicines

PHARMACOVIGILANCE PROGRAMME OF INDIA (PVPI)

WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services



Tel. No.: +91-120-2783392, 2783400, 2783401;

E-mail: lab.ipc@gov.in;

Website: www.ipc.gov.in



162		Nimesulide	• Use in Inflammatory condition including joint disorders such as rheumatoid arthritis, post traumatic and post operative painful condition and fever. • Acute pain in Orthopaedic, ENT, Dental and Post Operative condition. • Additional indication; for short treatment of adult patients with inflammation & pain associated with arthritis, soft tissue, ENT condition, trauma, dental pain, Musculo skeletal & gynaecology & obstetric painful condition. • For the treatment of pyrexia and inflammatory conditions in livestock	FDE
163		Beta blockers (Metoprolol, Propranolol, Atenolol)	Metoprolol: For the treatment of essential hypertension in adults, functional heart disorders, migraine prophylaxis, cardiac arrhythmias, prevention of cardiac death and reinfarction after the acute phase of myocardial infarction, stable symptomatic CHF. Propranolol: Cardiac arrhythmias; tachycardia; hypertrophic obstructive cardiac myopathy; pheochromocytoma; thrombosis; management of angina; essential and renal hypertension; prophylaxis of migraine. Atenolol: For the treatment of hypertension, angina pectoris, cardiac arrhythmias	Erectile dysfunction (Reversible)
164	21st May 2024	Meropenem	For treatment of pneumonia, nosocomial pneumonia, UTI, intra-abdominal infection, gynaecological infection, skin & soft tissue infection, meningitis, septicaemia & empiric treatment of presumed infection in adult patients with febrile neutropenia.	Acute Generalized Exanthematous Pustulosis (AGEP)



165		Acetazolamide	As an adjunct in the treatment of chronic open-angle glaucoma; secondary glaucoma; as part of pre-operative treatment of acute- angle closure glaucoma.	Choroidal effusion or Choroidal detachment
166	28th June 2024	Amlodipine	- To reduce fatal coronary heart disease, non-fatal myocardial infarction, risk of stroke and treatment of hypertension. - To reduce the risk of coronary revascularization procedures and the need for hospitalization due to angina in patients with coronary artery diseases	Lichenoid Keratosis
167	18th July 2024	Vancomycin	Treatment of serious infection due to Gram-positive cocci including methicillin-resistant staphylococcal infections, brain abscess, staphylococcal meningitis and septicaemia.	DRESS Syndrome
168	28th August 2024	Metronidazole	For the treatment of amoebiasis, urogenital trichomoniasis & giardiasis.	FDE
169	25th September 2024	Tetracycline	Treatment of Rocky Mountain spotted fever, typhus, Q fever, rickettsial pox, tick fever caused by Rickettsiae, respiratory tract infections caused by Mycoplasma pneumonia, Chlamydia infection, nongonococcal urethritis, chancroid, plague, tularemia, cholera, brucellosis, bartonellosis, granuloma inguinale, haemophilus and klebsella infections, psittacosis.	FDE
170	28th November 2024	Amphotericin B	- Treatment of Febrile Neutropenia in cancer patients. - Treatment for invasive fungal infection in patients, who are refractory to or intolerant of conventional Amphotericin B therapy. - Indicated for the treatment of Visceral Leishmaniasis	Hyperkalaemia



171		Carbimazole	Indicated for the treatment of thyrotoxicosis including thyrotoxicosis crisis	Agranulocytosis
172	26th December 2024	Beta-blockers (Metoprolol, Propranolol, Atenolol)	Metoprolol: For the treatment of essential hypertension in adults, functional heart disorders, migraine prophylaxis, cardiac arrhythmias, prevention of cardiac death and reinfarction after the acute phase of myocardial infarction, stable symptomatic CHF and angina pectoris. Propranolol: For the treatment of cardiac arrhythmias; tachycardia; hypertrophic obstructive cardiac myopathy; pheochromocytoma; thrombosis; management of angina; essential and renal hypertension; prophylaxis of migraine. Atenolol: For the treatment of hypertension, angina pectoris, cardiac arrhythmias.	Hypokalaemia
173	12th March 2025	Metronidazole	For the treatment of amoebiasis, urogenital trichomoniasis & giardiasis.	AGEP
174		Luliconazole	For the treatment of cutaneous mycosis viz. Tinea pedis, Tinea corporis and Tinea cruris	Chloasma/Melasma
175		Dalteparin	For the extended treatment of symptomatic Venous Thromboembolism (VTE) proximal Deep Vein Thrombosis (DVT) and/or Pulmonary Embolism (PE) to reduce the recurrence of VTE in patients with cancer.	Muscle spasms
176		Gliclazide	Indicated for the treatment of all types of maturity onset diabetes, diabetes without or with obesity in adults.	Erythema multiforme
177		Tramadol	For the treatment of severe acute and chronic pain, diagnostic measures and surgical pain	Fixed Drug Eruption



178	13th May, 2025	Sulfamethoxazole + Trimethoprim	For the treatment of Urinary Tract infection; Respiratory-tract infection including Bronchitis, Pneumonia, infections in Cystic Fibrosis, Melioidosis, Listeriosis, Brucellosis, Granuloma Inguinale, Otitis Media, Skin infection, Pneumocystis Carinii Pneumonia	Leukopenia
179	27th June 2025	Beta-blockers (Propranolol, Metoprolol)	Propranolol: For the treatment of cardiac arrhythmias, tachycardia, hypertrophic obstructive cardiac myopathy, pheochromocytoma, thrombosis, management of angina, essential and renal hypertension, prophylaxis of migraine. Metoprolol For the treatment of supraventricular arrhythmia, angina pectoris, hypertension, myocardial infarction, migraine prophylaxis, hyperthyroidism, heart failure.	Psoriasis
180		Beta blockers (Metoprolol, Propranolol, Atenolol, Carvedilol)	Metoprolol: For the treatment of Supraventricular arrhythmia, angina pectoris, hypertension, myocardial infarction, migraine prophylaxis, hyperthyroidism, heart failure. Propranolol: For the treatment of Cardiac arrhythmias, tachycardia, hypertrophic obstructive cardiac myopathy, pheochromocytoma, thrombosis, management of angina, essential and renal hypertension, prophylaxis of migraine. Atenolol: For the treatment of hypertension, angina pectoris, cardiac arrhythmias	Erectile Dysfunction (Reversible)





			Carvedilol • To reduce cardiovascular mortality in clinically stable patients, who have survived the acute phase of a myocardial infarction and have a left ventricular ejection fraction of 40% (with or without symptomatic heart failure). • For the treatment of mild to severe chronic heart failure. • For the treatment of left ventricular dysfunction following myocardial infarction in clinically stable patients • For the treatment of hypertension. • For the treatment of Congestive Heart Failure (CHF)	
181	29th August 2025	Tranexamic Acid	• For the treatment of abnormal bleeding in which local hyperfibrinolysis is considered to be involved (pulmonary, haemorrhage, epistaxis, renal bleeding abnormal bleeding during or after prostate surgery). • Haemorrhage or risk of haemorrhage in increased fibrinolysis of hereditary angioneurotic oedema. • For the treatment of excessive bleeding in patients with haemophilia during & following tooth extraction. • For the treatment of menorrhagia. • For the prevention of oral haemorrhage in anticoagulant treated patients undergoing oral surgery.	Nasal Congestion





182		Metoclopramide	- To restore normal coordination and tone the upper digestive tract and relieve symptoms of gastro-duodenal dysfunction including heart burn, dyspepsia, nausea and vomiting associated with such conditions as reflux oesophagitis, gastritis, duodenitis and hiatus hernia. - For the treatment of nausea and vomiting.	Tachycardia
183	26th September 2025	Erythromycin	Alternative to penicillin in hypersensitive patients; pneumonia; legionnaires' diseases; syphilis; chancroid; chlamydia; non-gonococcal urethritis; prostatitis; lymphogranuloma venereum; campylobacter enteritis; relapsing fever; diphtheria and whooping cough prophylaxis upper respiratory tract infection, acne vulgaris, sycosis, vulgaris.	FDE
184	20th February 2026	Dacarbazine	Chemotherapy of malignant melanoma, Hodgkin's lymphoma and soft tissue sarcomas.	Transient reversible blurred vision
185		Dolutegravir	Use in combination with other antiretroviral agents for the treatment of Human Immunodeficiency Virus Type 1 (HIV 1) infection.	Sexual dysfunction
186	30th March 2026	Polymyxin B	Urinary tract infections caused by P. Aeruginosa and E. Coli, bloodstream infections caused by P. Aeruginosa, E. Aerogenes and K. Pneumoniae, Meningeal infections caused by P. Aeruginosa.	Hypokalaemia
187		Clomipramine	Antidepressant- obsessive compulsive disorders, phobic states and depression (when sedation is required).	Akathisia
188		Famotidine	Indicated in the treatment of duodenal & peptic ulcer, Zollinger-Ellison syndrome	Fixed Drug Eruption
189	27th May 2026	Clonidine	Indicated in the treatment of hypertension.	Hyponatremia

190	30th June 2026	Metoprolol	• Antihypertensive agent- Indicated in the treatment of essential hypertension and angina pectoris. • Adjunct to the treatment of Hyperthyroidism. • Additional indication; i) functional heart disorders, ii) Migraine prophylaxis, iii) Cardiac Arrhythmias, iv) Prevention of cardiac death and reinfarction after the acute phase of myocardial infarction v) Stable symptomatic CHF. Additional indication: For the treatment of myocardial infarction.	Hyperkalemia
191	27th July 2026	Polymyxin B	• For the treatment of Infections of the urinary tract, meninges and blood stream caused by susceptible strains of Pseudomonas aeruginosa. It may also be used as subconjunctival injection in the treatment of infections of the eye caused by susceptible strains of Pseudomonas aeruginosa. • It may be indicated in serious infections caused by susceptible strains of the organisms- Haemophilus influenzae specifically meningeal infections, Escherichia coli specifically urinary tract infections, Aerobacter aerogenes specifically bacteraemia, Klebsiella pneumoniae specifically bacteraemia.	Hypotension

Healthcare Professionals, Patients/Consumers are advised to closely monitor the possibility of the above ADRs associated with the use of above suspected drugs. If, such reactions are encountered, please report to the NCC-PvPI, IPC by filling of Suspected Adverse Drug Reactions Reporting Form by HCPs, Medicines Side Effect Reporting Form by Consumer (download from <https://www.ipc.gov.in>), PvPI Helpline Number 1800-180-3024, PvPI Mobile App 2.0 (available at Google Play Store) and ADRMS (<https://adrmsipc.in/adrms/index.html>)