

File No. P.17019/03/2024-DSA

Dated: December 26, 2024

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 Reactions |
|-------|------------|-----------------------------|--|---|
| 01 | March 2016 | Phenytoin | Generalised tonic clonic seizure, partial seizure, status epilepticus | Angi oedema |
| 02 | | Phenytoin | Generalised tonic clonic seizure, partial seizure, status epilepticus | Osteoporosis |
| 03 | | Nicorandil | Angina pectoris, Vasodilator | Risk of ulcer complication |
| 04 | | Olanzapine | Schizophrenia, acute mania episodes in bipolar disorder | Hyponatraemia |
| 05 | | Crizotinib | Locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) that is Anaplastic Lymphoma Kinase (ALK) | Risk of cardiac failure |
| 06 | April 2016 | Roflumilast | Reduce the risk of chronic obstructive pulmonary disease exacerbation | Gynecomastia |
| 07 | | Clozapine | Management of schizophrenic patients | Neutropenia |
| 08 | | Disulfiram | Alcohol – abuse deterrent | Erythroderma |
| 09 | May 2016 | Peginterferon alpha – 2a | Chronic active Hepatitis B & C | Vasculitis |
| 10 | | Piperacillin + Tazobactam | In the treatment of lower RTI / UTI / intra-abdominal infection, skin and skin structure infection, bacterial septicaemia polymicrobial infection | Vision abnormal |
| 11 | | Mometasone furoate, topical | Steroid responsive dermatitis, eczema, or atopic dermatitis | Hypertrichosis / Hirsutism, Skin depigmentation |
| 12 | June 2016 | Ranibizumab | Neovascular age related macular degeneration (AMD), Visual impairment due to Diabetic macular edema (DME), Visual impairment due to Choroidal Neovascularization | Myocardial Infarction |

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| | | | (CNV) secondary to pathologic myopia (PM) | |
| 13 | | Amphotericin B | 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 | 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 | Locally advanced or metastatic Non – Small Cell Lung Cancer (NSCLC) that is Anaplastic Lymphoma Kinase (ALK) positive. | Pneumonitis, Hepatic encephalopathy |
| 16 | | Febuxostat | 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 | July 2016 | 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) |



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| 18 | | Artemether & Lumefantrine | For treatment of uncomplicated falciparum malaria, mixed infection of falciparum and chloroquine resistant vivax malaria. | Stevens- Johnson Syndrome / Toxic Epidermal Necrolysis |
| 19 | | Cefixime | 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) | Active immunization against Hepatitis B virus (HBV) infection in subjects considered at risk of exposure to HBV – positive material | Encephalopathy |
| 21 | August 2016 | 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 | For relapsing remitting multiple sclerosis | Osteonecrosis |
| 24 | | Sodium citrate +Diphenhydramine hydrochloride +Ammonium chloride | For symptomatic treatment of cough | Myocardial infraction |
| 25 | November 2016 | Cabergoline | For the treatment of hyperprolactinemia and inhibition of lactation | Steven- Johnson Syndrome |
| 26 | | Amlodipine | Angina, Hypertension, Coronary Artery Disease | Alopecia |

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| 27 | | Nitrofurantoin | 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 | Otitis media, Respiratory tract infection, uncomplicated UTIs, effective against infection caused by Enterobacteriaceae, H. influenza species | Anal ulcer |
| 30 | | Atenolol | Angina and myocardial infarction, Arrhythmias, Hypertension, Migraine prophylaxis | Dermatitis Lichenoid |
| 31 | | Olanzapine | Schizophrenia and other psychotic disorders, mania/ mixed episode, psychomotor agitation and violent behaviour | Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS Syndrome) |
| 32 | | Meropenem | 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 | January 2017 | Cefepime | For 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 | Burning Micturation |



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| | | | left ventricular hypertrophy, Diabetic Nephropathy in type II diabetes | |
| 36 | | Amisulpride | For 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 | Partial seizure with or without secondary generalization, Trigeminal neuralgia, bipolar disorder | Bruxism |
| 38 | February 2017 | Clomipramine | Obsessive –compulsive disorder, panic disorder | Melasma |
| 39 | | Glimepiride | Type 2 diabetes mellitus | Lichenoid Drug Eruption |
| 40 | | Metoprolol | Supra-ventricular arrhythmia, Angina pectoris, Hypertension, Myocardial infarction, Migraine prophylaxis, Hyperthyroidism, Heart failure | Lichenoid Drug Eruption |
| 41 | | Levamisole | For the treatment of roundworm and hookworm infestations | Skin Exfoliation |
| 42 | | Deferasirox | Treatment of chronic iron overload in patients with Non – Transfusion Dependent Thalassemia (NTDT) Syndrome | Osteoporosis |
| 43 | March 2017 | Ambroxol | All forms of tracheobronchitis, Emphysema with bronchitis pneumoconiosis, chronic inflammatory pulmonary conditions, Bronchiectasis, Bronchitis with bronchospasm asthma | Lacrimation |
| 44 | | Lurasidone | Treatment of patient with schizophrenia | Thrombocytopenia |
| 45 | | Etoricoxib | Short term use in acute painful condition | Skin hyperpigmentation |
| 46 | April 2017 | Dexamethasone | Adjunct in the emergency treatment of anaphylaxis, short term suppression of inflammation in allergic disorders, adrenocortical insufficiency. Ocular inflammation, autoimmune disorder. Rhematic | Hiccups |



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| | | | disorder, cerebral oedema, unresponsive shock, bacterial meningitis along with antibiotics | |
| 47 | | Cabergoline | For the treatment of parkinson's disease, hyperprolactinemia and inhibition of lactation | Skin hyperpigmentation |
| 48 | | Sodium valproate | Generalised tonic-clonic seizure, partial seizure, atonic seizure, absence seizure, myoclonic seizure, acute migraine | Psoriasis |
| 49 | | Amoxycillin | 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, gonorrhea, helicobacter pylori eradication | Eye irritation |
| 50 | May 2017 | Tinidazole | Amoebiasis, trichomoniasis and giardiasis, anaerobic infection, necrotising ulcerative gingivitis, bacterial vaginosis, H. pylori associated peptic ulcer, abdominal surgery prophylaxis | Hyperpigmentation |
| 51 | | Amlodipine | Angina, Hypertension, Coronary artery disease | Psoriasis |
| 52 | | Hydroxyzine | 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 | Moderate to severe depression, migraine prophylaxis, tension type headache, neuropathic / chronic pain, fibromyalgia | Gingival discolouration |
| 54 | June 2017 | Paracetamol | Mild to moderate pain including dysmenorrhoeal pain, headache, pain relief in osteoarthritis and soft tissue lesions, pyrexia, acute migraine attack | Baboon syndrome |
| 55 | | Lamivudine | HIV Infection in combination with at least two other antiretroviral drugs | Hearing loss |

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|----|--------------------------------|----------------|--|---|
| 56 | | Mebeverine | For irritable bowel syndrome (IBD) | Retrosternal pain |
| 57 | July 2017 | Clindamycin | Respiratory tract infection, penicillin resistant staphylococcal infection and many anaerobes such as bacteroides, skin, soft tissue and dental infection | Acute Generalised Exanthematous Pustulosis (AGEP) |
| 58 | | Triamcinolone | Corticosteroid | Skin peeling |
| 59 | | Polymyxin B | Other antibiotic | Mottled skin |
| 60 | | Diclofenac | Acute musculo- skeletal pain, arthritis, gout, spondylitis, migraine, post – operative pain | Nicolau Syndrome |
| 61 | August 2017 | Terbinafine | Treatment of fungal infection | Acute Generalised Exanthematous pustulosis (AGEP) |
| 62 | | Nitrofurantoin | Urinary tract infection, Cystitis | Vasculitis |
| 63 | September 2017 | 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 | Type 2 diabetes mellitus | Acute Generalised Exanthematous Pustulosis (AGEP) |
| 65 | | Diloxanide | Amoebiasis | Glossitis |
| 66 | 17 th 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 | Stevens Johnson Syndrome |
| 67 | | Allopurinol | Prophylaxis of gout prophylaxis of hyperuricaemia associated with cancer chemotherapy | Uveitis |
| 68 | 28 th November 2017 | Quetiapine | For treatment of schizophrenia and bipolar disorder | Gynaecomastia |
| 69 | | Ceftriaxone | Serious infection due to sensitive bacteria, including septicaemia, pneumonia and meningitis, surgical prophylaxis of meningococcal meningitis, gonorrhoea, bone and joint infection | Palpitation |



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|----|--------------------------------------|---------------|---|---------------------------------|
| 70 | 27 th December 2017 | Fluoxetine | Fluoxetine is a SSRI antidepressant which is used in psychological disorders and also in premature ejaculation | Urinary incontinence |
| 71 | 30 th 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 | 28 th February 2018 | Dapsone | For the treatment of leprosy, acne vulgaris, dermatitis, Pneumocystic pneumonia | Erythema Nodosum |
| 73 | 27 th 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 | 27 th 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 | 10 th July 2018 | Fluoxetine | Bipolar disorder, Depressive episode | Hypoacusis (Hearing impairment) |
| 76 | 3 rd December 2018 | Telmisartan | Hypertension | Lichenoid keratosis |
| 77 | 1 st January 2019 | Miltefosine | Directly Observed Therapy (DOT) of visceral Leishmaniasis caused by Leishmania donovani | Acute Pancreatitis |
| 78 | 14 th February 2019 | Levetiracetam | Anti-epileptic, 1) As monotherapy in partial onset seizures with or without | Anencephaly |



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| | | | secondary generalisation in patient with 16 year of age with newly diagnosed epilepsy. 2) As adjunctive therapy in myoclonic seizures in adult and adolescent from 12 years of age with juvenile. | |
| 79 | | Cetirizine | For the treatment of seasonal/perennial allergic rhinitis & chronic idiopathic urticaria in infants & children. | Tachycardia |
| 80 | 25 th 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 ortho paedic surgery at risk of gram +Ve infection | Red Man Syndrome |
| 84 | 06 th 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 ortho | Toxic Epidermal Necrolysis (TEN) |

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| | | | paedic surgery at risk of gram +Ve infection | |
| 85 | 03 rd 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/Stevens Johnson Syndrome |
| 86 | | Netilmicin | Aminoglycoside antibiotic - Indicated in the treatment of septicaemia including neonatal sepsis and other severe systemic infections. | Tetany |
| 87 | 6 th 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 | 5 th 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 | 30 th 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 |



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| 93 | 22 nd 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 | 30 th December 2019 | Levamisole | Indicated in the treatment and control of mature and developing immature infections of haemonchus, ostertagia, trichostrongylus, cooperia, nematodinus, bunostomum, oesophagastomum and dictyocaulus and all forms of liver fluke infection | Stevens Johnson Syndrome |
| 96 | | Cephalosporin | Indicated in the treatment of serious infections due to susceptible organisms-respiratory tract infections, urinary tract infections, skin biliary tract infections, septicaemia, meningitis other infections due to susceptible organisms and in the treatment of infections due to penicillin resistant strains of straphylococci. | Acute Generalized Exanthematous Pustulosis |
| 97 | 15 th 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 | 12 th February 2020 | Olanzapine | For the treatment of Schizophrenia. | Hyponatremia |

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| 100 | | Piperacillin+Tazobactam | In the treatment of LRTI/UTI/Intra-abdominal infections, skin and skin structure infections, bacterial septicemic polymicrobial infections. | Blurred Vision |
| 101 | 12 th March 2020 | Terlipressin | In the treatment of bleeding oesophageal varices. | Atrial Fibrillation |
| 102 | 1 st June 2020 | Hydroxychloroquine Sulphate | Off Label drug use as Prophylactic & Treatment of COVID-19 disease | Mouth Ulceration |
| 103 | | SGLT-2 Inhibitors | As an adjunct to diet and exercise to improve glycemic control in adults with type 2 Diabetes Mellitus. | Genital Pruritus |
| 104 | 7 th July 2020 | 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 | 31 st August, 2020 | Pramipexole | Pramipexole is indicated for the treatment of sign and symptoms of idiopathic Parkinsons disease. | Photosensitivity Reaction |
| 106 | 04 th 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 | 05 th 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 | 04 th November 2020 | Clarithromycin | For the treatment of mild to moderately severe infections like acute exacerbation of chronic | Acute Generalised Exanthematous Pustulosis (AGEP) |

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| | | | bronchitis community acquired pneumonia including infections due to Chlamydia, Mycoplasma spegiocella acute streptococcal pharyngitis and skin and soft tissue infections. | |
| 109 | | Tamsulosin + Deflazacort | For the treatment of sign & symptoms of benign prostate hyperplasia. For Asthma, Rheumatoid Arthritis when Glucocorticosteriod therapy is warranted. | Ear pain |
| 110 | 30 th 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 | 04 th 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 | 01 st February 2021 | Cefpodoxime | 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 | Mild to moderately severe infections like acute exacerbation of chronic bronchitis community acquired | Burning Sensation |



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| | | | pneumonia including infections due to chlamydia, mycoplasma spegiocella acute streptococcal pharyngitis and skin and soft tissue infections. | |
| 116 | 01 st 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 | 05 th April 2021 | Zinc (Acetate/Oxide/Sulphate/Gluconate) | In treatment of acute diarrhoea in children as an adjunct to oral rehydration. | Diarrhoea |
| 119 | 28 th June, 2021 | Clobazam | 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 | | 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 | Rhabdomyolysis |

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| | | | Infarction (STEMI) including patients managed medically and those who are managed with Percutaneous Coronary Intervention (PCI) or Coronary Artery Bypass Grafting (CABG). | |
| 122 | 28 th July 2021 | Etoricoxib | For the treatment of pain, swelling & inflammatory conditions due to arthritis. | Acute Generalized Exanthematous Pustulosis (AGEP) |
| 123 | | Torseamide | For the treatment of oedema associated with congestive heart failure & hypertension. | DRESS Syndrome |
| 124 | | Quetiapine & Valproic Acid Interaction | <p>Quetiapine:</p> <ul style="list-style-type: none"> For the management of the manifestation of psychotic disorders (schizophrenia). For the additional indication "acute manic episode associated with bipolar disorder". <p>Valproic Acid:</p> <ul style="list-style-type: none"> 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/Coma & Disorientation) |
| 125 | 31 st August 2021 | Sofosbuvir | In combination with other medicinal products for the treatment of chronic hepatitis C in adults. | Stevens-Johnson Syndrome |

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| 126 | | Dimethyl Fumarate | For Relapsing remitting multiple sclerosis | Alopecia |
| 127 | 30 th September, 2021 | 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 | 30 th 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 | 28 th 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 | <ul style="list-style-type: none"> 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) |

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| 134 | 30 th May, 2022 | Itraconazole | <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> 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 | 15 th July, 2022 | Tacrolimus | <ul style="list-style-type: none"> 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 immunosuppressive 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 |



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| 137 | 23 rd August, 2022 | Cefoperazone | Urinary infections, biliary infections, respiratory infections, infections of skin tissues, meningitis, septicaemia, Pseudomonas, Salmonella typhi & B. fragilis infections. | Coagulopathy |
| 138 | 26 th September, 2022 | Piroxicam | <ul style="list-style-type: none"> 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. 3. 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 | 17 th 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 | 28 th November, 2022 | Norfloxacin | <ol style="list-style-type: none"> Antibacterial- Indicated in the treatment of acute uncomplicated/complicated chronic, recurrent urinary tract infections, including pyelonephritis, cystitis, urethritis & gonococcal infections. Wide variety of infections caused by susceptible Gram +ve and Gram -ve organism including mixed infection in poultry. | Skin Hyperpigmentation |

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| 141 | 26 th December 2022 | Minoxidil | For the treatment of alopecia (male pattern baldness in men). | Folliculitis | |
| 142 | 31 st January 2023 | Amphotericin B (Liposomal) | 1. Febrile Neutropenia in cancer patients. | Hearing disorders | |
| 143 | | | 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. | Tachycardia | |
| | | | 4. Indicated for the treatment of visceral leishmaniasis. | | |
| 144 | 20 th 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 | 29 th 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 |

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|-----|------------------------------|-----------------------|--|--------------------------------|
| 150 | | Sulfasalazine | Use for the treatment of severe rheumatoid arthritis, ulcerative colitis; Crohn's diseases. | Visual Impairment |
| 151 | 24 th April 2023 | Ziprasidone | 1. Use for the treatment of schizophrenia. 2. Use for rapid control of agitation in psychotic patients. | DRESS Syndrome |
| 152 | 31 st 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 | <ul style="list-style-type: none"> 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 | 22 nd June 2023 | Teneligliptin | For the treatment of Type-2 Diabetes Mellitus as a monotherapy adjunct to diet and exercise. | Bullous Pemphigoid |
| 155 | 28 th 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. | Barter's like syndrome |
| 156 | 22 nd August 2023 | Levonorgestrel | <ul style="list-style-type: none"> Used as emergency Contraceptive. For Control of Fertility. For the treatment of Contraception, Menorrhagia & Endometrial Hyperplasia during | Deep Vein Thrombosis |



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| | | | Estrogen replacement therapy in women. | |
| 157 | 27 th September 2023 | Esomeprazole | <ul style="list-style-type: none"> 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 | 25 th October 2023 | Co-trimoxazole | Indicated in the treatment of respiratory tract infection, urogenital infections, G.I. tract infections etc. | FDE |
| 159 | 30 th November 2023 | Mefenamic Acid | Treatment of rheumatoid arthritis, osteoarthritis, dysmenorrhoea, mild to moderate pain, inflammation, fever, dental pain. | DRESS Syndrome |
| 160 | 27 th 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 | In the treatment of Benign Prostatic Hyperplasia | Palpitation |
| 162 | | Nimesulide | <ul style="list-style-type: none"> 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. | FDE |

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| | | | <ul style="list-style-type: none"> For the treatment of pyrexia and inflammatory conditions in livestock | |
| 163 | | Beta blockers (Metoprolol, Propranolol, Atenolol) | <p>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.</p> <p>Propranolol: Cardiac arrhythmias; tachycardia; hypertrophic obstructive cardiac myopathy; pheochromocytoma; thrombosis; management of angina; essential and renal hypertension; prophylaxis of migraine.</p> <p>Atenolol: For the treatment of hypertension, angina pectoris, cardiac arrhythmias</p> | Erectile dysfunction (Reversible) |
| 164 | 21 st 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 | 28 th June 2024 | 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 | | Amlodipine | <ul style="list-style-type: none"> To reduce fatal coronary heart disease, non-fatal myocardial infarction, risk of stroke and treatment of hypertension. | Lichenoid Keratosis |



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| | | | <ul style="list-style-type: none"> To reduce the risk of coronary revascularization procedures and the need for hospitalization due to angina in patients with coronary artery diseases | |
| 167 | 18 th 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 | 28 th August 2024 | Metronidazole | For the treatment of amoebiasis, urogenital trichomoniasis & giardiasis. | FDE |
| 169 | 25 th 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 | 28 th November 2024 | Amphotericin B | <ol style="list-style-type: none"> 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 |

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| 171 | | Carbimazole | Indicated for the treatment of thyrotoxicosis including thyrotoxicosis crisis. | Agranulocytosis |
| 172 | 26 th December 2024 | Beta-blockers (Metoprolol, Propranolol, Atenolol) | <p>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.</p> <p>Propranolol: For the treatment of cardiac arrhythmias; tachycardia; hypertrophic obstructive cardiac myopathy; pheochromocytoma; thrombosis; management of angina; essential and renal hypertension; prophylaxis of migraine.</p> <p>Atenolol: For the treatment of hypertension, angina pectoris, cardiac arrhythmias.</p> | Hypokalaemia |

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/Medicines Side Effect Reporting Form for Consumer (<http://www.ipc.gov.in>), through PvPI Helpline No. 1800-180-3024.