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Indian Pharmacopoeia Commission

National Coordination Centre-Pharmacovigilance Programme of India

(Ministry of Health & Family Welfare, Govt. of India)

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List of Monthly Drug Safety Alerts issued by PvPI from March 2016 to till date

S.No	Issue Date	Suspected drugs	Indication	Adverse Reactions
01	March 2016	Phenytoin	Generalised tonic clonic seizure, partial seizure, status epilepticus	Angioedema
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 (CNV) secondary to pathologic myopia (PM)	Myocardial Infarction
13		Amphotericin B	Life threatening fungal infection including histoplasmosis, coccidioidomycosis, paracoccidioidomycosis,	Bone marrow depression

			blastomycosis, aspergillosis, cryptococcosis, mucormycosis, sporotrichosis, and candidiasis, visceral and mucocutaneous leishmaniasis unresponsive to pentavalent antimony compounds, severe meningitis. Perioral candidiasis	
14		Doxorubicin	Soft tissue and bone sarcomas, Acute leukemia, 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 leukemia, 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	July 2016	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		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	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	August 2016	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		Cefotaxime	Infection due to sensitive gram – positive and gram negative bacteria such as bacteraemia, cellulitis, Intra-	Anaphylactic shock

			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	
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
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), Septicemia, Meningitis, Skin & Soft tissue infection, Endometritis, Other infection of genital tract, Intra abdominal infection bone & joint infection	Acute generalized exanthematouspust ulosis (AGEP)
29		Cefixime	Otitis media, Respiratory tract infection, uncomplicated UTIs, effective against infection caused by Enterobacteriaceae, H. influenza species	Anal ulcer
30	December 2016	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,	Hypokalaemia

			intra-abdominal and pelvic infection, etc., caused by cephalosporin's resistant bacteria, meningitis cystic fibrosis	
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 left ventricular hypertrophy, Diabetic Nephropathy in type II diabetes	Burning Micturation
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	March 2017	Deferasirox	Treatment of chronic iron overload in patients with Non – Transfusion Dependent Thalassemia (NTDT) Syndrome	Osteoporosis
43		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. Rheumatic disorder, cerebral oedema, unresponsive shock, bacterial meningitis along with antibiotics	Hiccups
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		Amoxicillin	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 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
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,	Acute Generalised Exanthematous Pustulosis (AGEP)

			skin, soft tissue and dental infection	
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 exanthematouspust ulosis (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 ExanthematousPust ulosis (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
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 , postanoxic 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 Leishmaniadonovani	Acute Pancreatitis
78	14 th February 2019	Levetiracetam	Anti-epileptic, 1) As monotherapy in partial onset seizures with or without 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.	Anencephaly
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	Acute Pancreatitis

			ventricular fibrillation resistant to external electric shock.	
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	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 orthopaedic surgery at risk of gram +Ve infection	Toxic Epidermal Necrolysis (TEN)
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	Neural Tube

			Schizophrenic patients.	Defects
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, oesophagostomum 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 ExanthematousPust ulosis
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, pityriasisversicolor, prevention of fungal infections in patients with malignancy.	Mouth Ulceration
99	12 th 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 septicemicpolymicrobic infections.	Blurred Vision
101	12 th March 2020	Terlipressin	In the treatment of bleeding oesophagalvarices.	Atrial Fibrillation
102	1 st June 2020	Hydroxychloroquin	Off Label drug use as Prophylactic &	Mouth Ulceration

		e Sulphate	Treatment of COVID-19 disease	
103	7 th July 2020	SGLT-2 Inhibitors	As an adjunct to diet and exercise to improve glycemic 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	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 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 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		Fexofenadine	In the treatment of relief of symptoms associated with seasonal allergic rhinitis and chronic idiopathic urticaria.	Blurred Vision
113	04 th January 2021	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		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	01 st February 2021	Clarithromycin	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	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		Clobazam	Acute and chronic anxiety states and as an adjunctive therapy in patients with refractory epilepsy.	DRESS Syndrome
120	28 th June, 2021	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	Rhabdomyolysis

			<p>patients without clinically evident CHD but with multiple risk factors.</p> <p>Ticagrelor:</p> <p>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).</p>	
122	28 th July 2021	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		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	Stevens-Johnson

			products for the treatment of chronic hepatitis C in adults.	Syndrome
126	30 th September, 2021	Dimethyl Fumarate	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	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