

**Medicinal Products Safety Alerts of 2018**

<b>Sl. No</b>	<b>Name of Medicine</b>	<b>Adverse Drug Reaction</b>	<b>Recommendation by ADRAC</b>
01	Benzocaine	Risk of blood disorder (methemoglobinemia) in infants and children	Update the PIL Warning: Methemoglobinemia Contraindication: Infant & Children younger than two years.
02	Fluoropuinolone antibiotics	Risk of hypoglycemia and mental health adverse effects	Update the PIL Box Warning: Increased risk of tendinitis and tendon rupture
03.	Granulocyte-colony stimulating factor (G-CSF) drugs	Risk of large vessel vasculitis	Update the PIL Warning: Allergic reactions, Splenic rupture Alveolar hemorrhage hemoptysis and Sick cell disorders. Contraindication: Patients with known hypersensitivity to E-coli derived proteins.
04.	Metronidazole	Risk of hepatic impairment Severe hepatotoxicity or acute hepatic failure resulting in mortality was reported in patients with cockayne syndrome.	Update the PIL Warning: Chance of severe hepatotoxicity and hepatic failure in patients with cockayne syndrome. Risk of hepatic impairment.
05.	Erythropoietins	Risk of severe cutaneous adverse reactions (SCAR)	Update the PIL Warning: Severe cutaneous adverse reactions (SCAR) & Stevens Johnsons Syndrome.
06.	Desogestrel	Severe psychiatric disorders panic attack, suicidal ideation and self-induced injurious behavior.	Update the PIL Warning: Panic attack, suicidal ideation and self-induced injurious behavior.
07.	Ceftriaxone	Risk of convulsions and involuntary movements	Update the PIL Warning: Risk of convulsions and involuntary movements as Adverse Effects.

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08.	Neuromuscular blocking agents (e.g-suxamethonium, pancuronium, and vecronium)	Prevention of unintended paralysis through medication errors	Update the PIL Warning: To include a warning indicating that the product is a PARALYSING AGENT.
09.	Ulipristal	New measures to minimize risk of liver injury	Update the PIL Contraindication: Ulipristal is not recommended for use in patients with liver disease.
10.	Amlodipine	Alopecia	Update the PIL
11.	Ceftriaxone IV	Serious Convulsion	Update the PIL Warning: To take precaution to push injection slowly
12.	Allopurinol	Toxic Epidermal Necrolysis	Update the PIL
13.	Amiodarone (intravenous)	Potential risk of developing adverse effects in the heart, nervous, system and affect growth & development of foetus and newborns.	Update the PIL
14.	Direct-acting antiviral for hepatitis C	Potential risk of HBV reactivation in patients co infected with both HBV and HCV and Interaction with vitamin k antagonists and changes in INR Value	Update the PIL
15.	Fluoroquinolones	Risk of retinal detachment	Update the PIL
16.	Pioglitazone containing Drug	Risk of Development bladder cancer	Update the PIL
17.	Selective serotonin reuptake inhibitors (SSRIs)	Risk of suicidal thinking and change of behavior	Update the PIL

**Medicinal Products Safety Alerts of 2019**

<b>SI No</b>	<b>Name of Medicine</b>	<b>Indication</b>	<b>Adverse Drug Reaction</b>	<b>Regulatory recommendation taken by other NRAS</b>	<b>ADRAC Decision</b>
01	Carbimazole	Carbimazole is indicated for the treatment of hyperthyroidism, preparation for thyroidectomy, and pre- and post-radioiodine treatment.	Acute Pancreatitis	MHRA announce to update Product information to include risk of Acute Pancreatitis.	Update the PIL
02	Febuxostat	Febuxostat is indicated to treat gout.	increased risk of death	USA The us Food and Drug Administration (FDA) has added a boxed warning for febuxostat (Uloric) indicating and increased risk of death compared to its alternative, allopurinol.	Update the PIL

**Medicinal Products Safety Alerts of 2020**

<b>SI No</b>	<b>Name of Medicine</b>	<b>Indication</b>	<b>Adverse Drug Reaction</b>	<b>Regulatory Action/ recommendation taken by other NRAs</b>	<b>Opinion of TSC</b>
1.	Tofacitinib	Rheumatoid arthritis, psoriatic arthritis and ulcerative colitis	Increased risk of blood clots and death with higher dose	<b>USA.</b> The US FDA has approved a Boxed Warning informing of an increase in the risk of blood clots and death with the 10 mg twice daily dose	Boxed warning can be imposed
2.	Opioid pain medicines	Manage pain when other analgesic treatments cannot be taken or are not able to provide enough pain relief.	Risk of uncontrolled pain and withdrawal symptoms following sudden discontinuation	<b>USA.</b> The US Food and Drug Administration (FDA) has required changes to the prescribing information for opioid pain medicines to warn of serious withdrawal symptoms, uncontrolled pain, psychological distress and suicide following sudden decrease in dose.	To check PIL and incorporate the information is necessary.

**Medicinal Products Safety Alerts of 2021**

No	Name of medicine	Indication	ADR	Regulatory action/ recommendation taken by other NRAs	ADRAC Decision
1.	Clozapine	Schizophrenia	Serious bowel complications (Reference: US FDA, 28 January 2020)	USA: The FDA has strengthened the existing warning that constipation caused by clozapine (Clozaril®, Fazaclo ODT® and Versacloz®) can progress to serious bowel complications.	Update the PIL
2.	Montelukast	Allergic rhinitis	psychiatric effects (Reference: HSA, 10 December 2020)	Singapore. The Health Sciences Authority (HSA) has announced that they are working with the product registrants of montelukast containing products to update the local package inserts to include the risk of neuropsychiatric adverse effects.	Update the PIL
3.	Pirfenidone	Idiopathic pulmonary fibrosis	Serious liver injury (Reference: MHRA, 16 November 2020)	United Kingdom: The MHRA has announced that existing warnings of hepatotoxicity in the product information for pirfenidone (Esbriet®) will be strengthened to include the risk of clinically relevant drug-induced liver injury.	Update the PIL
4.	Carbamazepine	Epilepsy, diabetic neuropathy, trigeminal neuralgia and bipolar disorders	Severe cutaneous adverse reactions. (Reference: HSA, 10 December 2020)	Singapore: The HSA has reminded health-care professionals to verify the HLA-B*1502 status before starting carbamazepine treatment in new patients of Asian ancestry, due to the risk of severe cutaneous adverse reactions such as Stevens-Johnson syndrome and toxic epidermal necrolysis	Update the PIL

No	Name of medicine	Indication	ADR	Regulatory action/ recommendation taken by other NRAs	ADRAC Decision
				(SJS/TEN).	
5.	Ibrutinib	Cancers such as mantle cell lymphoma (MCL) and chronic lymphocytic leukaemia (CLL) particularly for patients with relapsed conditions.	Increased risk of cardiac failure (Reference: SFDA, 2020)	Saudi Arabia: The SFDA has released a new signal communication describing the potential risk of cardiac failure associated with the use of ibrutinib.	Update the PIL

#### Medicinal Products Safety Alerts of 2022

Sl. No	Name of Medicine	Adverse Drug Reaction	Recommendation by ADRAC	Remarks
01	Ceftriaxone	hypersensitivity reactions	Skin test should be done before the use of Injection	14th meeting of ADRAC held on 21 <sup>st</sup> March 2022
02	Ivermectin	Disturbed consciousness and potential encephalopathy	Association/Society of Medical Professionals will be notified	WHO Newsletters, Issue No. 1,2022
03.	Nifedipine	Occurrence of pulmonary edema in pregnant women	A letter will be issued to inform the Gynecologist society	WHO Newsletters, Issue No. 1,2022
04.	Tofacitinib, Baricitinib and Upadacitinib	Serious heart-related events, cancer, blood clots	Printed in the medicine cartoon as a box warning	WHO Newsletters, Issue No. 1,2022

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05.	Tramadol	Urinary Retention	Informed to all health professional organizations including Marketing Authorization Holder, Bangladesh Medical Association	WHO Newsletters, Issue No. 1,2022
06.	Carbamazepine	Erythematous lesion on different parts of body, oral mucosal erosion & fever	A letter will be sent to the Bangladesh Medical Association (BMA) and the Director General of Health Services (DGHS) with a request to issue necessary instructions in this regard that It should be administered only as per the advice of a specialist physicians.	15th meeting of ADRAC held on 16 <sup>th</sup> October 2022
07.	Ketorolac Tromethamine / NSAID	Abdominal pain & vomiting	Should be used with caution in patients with Diabetes Mellitus / Hypertension - Send a letter to the Bangladesh Medical Association (BMA) and Director General, Director General of Health Services (DGHS) with a request to issue necessary instructions in this regard	15th meeting of ADRAC held on 16 <sup>th</sup> October 2022
08.	Rituximab	Shortness of breathing	Should only be administered under the direct supervision of a specialist physician	15th meeting of ADRAC held on 16 <sup>th</sup> October 2022

### Medicinal Products Safety Alerts of 2023

<b>Sl. No</b>	<b>Name of Medicine</b>	<b>Adverse Drug Reaction</b>	<b>Recommendation by ADRAC</b>	<b>Remarks</b>
01	Hydrochlorothiazide	Acute Respiratory Distress Syndrome (ARDS)	Update the PIL	16th meeting of ADRAC held on 21 <sup>st</sup> May 2023
02	Itraconazole	Hypokalaemia	Update the PIL	16th meeting of ADRAC held on 21 <sup>st</sup> May 2023
03.	Steroid Related drugs		Stop selling Without Prescription of Specialist Physicians.	16th meeting of ADRAC held on 21 <sup>st</sup> May 2023

### Medicinal Products Safety Alerts of 2024

<b>Sl. No</b>	<b>Name of Medicine</b>	<b>Adverse Drug Reaction</b>	<b>Recommendation by ADRAC</b>	<b>Remarks</b>
01	Halothane	Cough and respiratory distress leading to respiratory failure and death	Recommendation sent to Drug Control Committee (DCC) to cancel the registration.	17th meeting of ADRAC held on 11 JUN 2024
02	Ciprofloxacin	Tendinitis, tendon rupture, peripheral neuropathy, central nervous system effects and exacerbation of myasthenia gravis	Update the PIL	17th meeting of ADRAC held on 11 JUN 2024

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03.	Fluoroquinolone Antibiotics	Risk of suicidal thoughts and behaviour	Letter sent for the opinion of Associations of Physicians of Bangladesh (APB), Society of Surgeon & Infectious disease specialist	17th meeting of ADRAC held on 11 JUN 2024