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A REVIEW ON ADVERSE DRUG REACTION OF IBUPROFEN

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ABSTRACT:

Accidental and perhaps dangerous side effects that arise from the inhalation of drugs are known as adverse drug reactions, or ADRs. This extensive study seeks to offer a complete analysis of the several aspects related to adverse drug reactions (ADRs), highlighting the importance of these events in maintaining patient safety and improving healthcare outcomes. In order to distinguish between predictable, dose-dependent effects and unpredictable, idiosyncratic responses, the review classifies ADRs into two categories: Type A and types B reactions. Typical instances of adverse drug reactions (ADRs) in several organ systems are examined, emphasizing the variety of ways that drugs can cause side effects. Reporting and monitoring of ADRs are discussed, emphasizing the crucial role of healthcare professionals in contributing to pharmacovigilance systems. The review underscores the importance of identifying patient-specific risk factors, such as age, gender, genetics, and concomitant diseases, to assess the likelihood of ADR occurrence. **Keywords:** Clinical Pharmacology, Pharmacovigilance, Drug related side effect.

INTRODUCTON:

ADR represent a critical facet of healthcare, encompassing unintended and often undesirable effects resulting from the normal or prescribed use of medications. As pharmaceutical interventions play a pivotal role in managing and treating various health conditions, the occurrence of adverse reactions introduces a complex layer to the delicate balance between therapeutic benefits and potential risks. Having a thorough grasp of ADRs is essential for improving patient care and safety. These responses can take many different forms, from moderate and bearable side effects to serious and sometimes fatal consequences. ADRs are multifaceted, involving elements like patient-specific traits, pharmacological processes, and drug-drug interactions. Pharmacovigilance, a science devoted to the Detection And avoiding of adverse effects linked with pharmaceutical products, includes the identification and treatment of ADRs as essential components. In order to continuously improve the safety profiles of professionals, government agencies, pharmaceuticals and pharmaceutical corporations work together to systematically gather, analyze, and respond to data relating to adverse drug reactions (ADRs). This introduction sets the stage for a deeper exploration of ADRs, delving into their classifications, underlying mechanisms, risk factors, and the evolving landscape of pharmacovigilance. As we navigate the intricate terrain of drug safety, recognizing the significance of ADRs becomes imperative for fostering a healthcare environment that prioritizes patient well-being and optimal therapeutic outcomes^[1]

Defination: -

"ADR" is a phrase used to describe an unwanted and dangerous reaction to a medication when arises at quantities often used for therapeutic purposes. The expression "adverse drug reactions" refers to a broad category of unwanted side effects, ranging in intensity from minor discomfort to serious illnesses. These reactions can be either predictable (Type A reactions), which are usually dose-dependent and connected to the drug's pharmacological activities, or unpredictable (Type B reactions), which are frequently idiosyncratic and unrelated to the drug's known actions.[2] Pharmacovigilance involves the continuing examination and enhancement of medication safety, and two essential components are the reporting and monitoring of adverse drug reactions (ADRs).

pharmacovigilance include:-

- Adverse Drug Reaction (ADR) Monitoring:- the methodical gathering and examination of data on adverse prescription drugs responses, involving their kind, intensity, frequency and prospective risk factors.
- Risk Assessment: determining the risks arising from using drugs, including identifying possible security hazards and assessing risk-benefit ratios.Signal Detection: The identification of new or changing patterns of adverse events that may indicate a previously unrecognized safety issue.
- Risk Management: creating and putting into practice plans to reduce or eliminate hazards connected to drug use that have been identified.
- Post-Marketing Surveillance:-Monitoring the safety of pharmaceutical products after they have been authorized and are available in the market.^[3]
- Regulatory Reporting :-reporting adverse medication reactions to regulatory bodies in a way that is prompt and precise while complying in legislation parameters.
- Communication and Information Dissemination: Providing information to healthcare professionals, patients, and the public about the safe and effective use of medications.
- Collaboration with Healthcare Professionals: Working closely with healthcare providers to enhance the understanding of drug safety issues and to promote safe prescribing practices.
- Global Collaboration: Engaging in international cooperation to share information and improve global drug safety standards^[4]

It involves a multidisciplinary approach, involving healthcare professionals, regulatory agencies, pharmaceutical companies, and, increasingly, patients and the public

Classification Of ADR:-

It can be classified in various ways based on different criteria. One common classification system categorizes ADRs into types A, B, C, D, and E, as follows:

Type A (Augmented) Reactions:

Description: Predictable reactions that are an extension of the drug's pharmacological effects.

Characteristics: Dose-dependent, related to the drug's primary pharmacologic actions.

Examples: Gastrointestinal upset with NSAIDs, bleeding with anticoagulants.

- Type B (Bizarre) Reactions:
 Description: Unpredictable reactions not directly related to the drug's known pharmacological actions.
 Characteristics: Idiosyncratic, often immune-mediated or allergic.
 Examples: Anaphylaxis, Stevens-Johnson syndrome.^[5]
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- Type C (Chronic) Reactions:
 Description: Reactions that occur with prolonged use of a drug.
 Characteristics: Typically associated with cumulative dose or duration of treatment.
 Examples: Osteoporosis with long-term corticosteroid use.
- Type D (Delayed) Reactions: Description: Reactions that manifest after some time from the initiation of therapy. Characteristics: Delayed onset of adverse effects.
 Examples: Carcinogenic effects, teratogenic effects.
 Type E (End-of-Treatment) Reactions:
 - Description: Reactions occurring when the drug is withdrawn or treatment is completed.
 - Characteristics: Often related to sudden discontinuation of the drug.

Examples: Rebound hypertension after stopping antihypertensives.^[6]

Risk Factors: -

Several factors can contribute to an individual's susceptibility to ADR. Identifying these risk factors is crucial for healthcare professionals to assess and manage the potential for adverse reactions. Here are some common risk factors:

- Patient-Related Factors:
 - Age: The very young and the elderly may be more vulnerable to ADRs due to differences in drug metabolism and elimination.
 - Gender: Certain medicines may affect Men and Women differently.
 - **Genetics:** Genetic variations can influence drug metabolism and response, leading to increased susceptibility to ADRs^{.[7]}
 - Underlying Health Conditions: Patients with pre-existing medical conditions may be more prone to ADRs, especially if there are interactions with the drugs used to manage those conditions.
 - > Drug-Related Factors:
 - **Drug Properties:** Certain drugs are inherently more likely to cause adverse reactions due to their pharmacological properties.
 - **Dose and Duration:** Long-term pharmaceutical usage and higher dosages may raise the chance of adverse drug reactions^{.[8]}
 - **Drug Interactions:** Consuming multiple drugs can lead to interactions, potentially causing adverse effects.
 - > External Factors:
 - **Polypharmacy:** Taking multiple medications concurrently increases the risk of interactions and ADRs^{.[10]}

- **Compliance:** Non-compliance with prescribed medication regimens can lead to ADRs, especially if patients self-adjust doses or abruptly stop medications.
- Environmental Factors: Exposure to environmental toxins or substances produce adverse effects.
- **Nutritional Status:** Malnutrition or specific dietary patterns may affect drug metabolism and increase susceptibility to ADRs.

> Psychosocial Factors:

- **Psychological Factors:** Stress, anxiety, and other psychological factors can influence how individuals perceive and react to medications.
- **Health Literacy:** Limited understanding of medication instructions and potential side effects can contribute to ADRs^{.[11]}
- Healthcare-Related Factors:
 - **Prescribing Errors:** Mistakes in drug prescription, such as incorrect dosage or inappropriate drug selection, can lead to ADRs.
 - **Monitoring:** Inadequate monitoring of patients, including routine blood tests or clinical assessments, may result in undetected ADRs^{.[12]}

Regulatory Agencies :-

The safety and effectiveness of the medicine are thoroughly assessed using data from clinical trials as part of this approval procedure.

Post-Marketing Surveillance: After the medicine has been authorized and sold, regulatory bodies use post-marketing surveillance to keep an eye on its safety. This entails gathering and analyzing data on adverse reactions to drugs (ADRs) either patients, healthcare providers, and pharmaceutical corporations report.

Signal Detection: Regulatory agencies use pharmacovigilance data to identify signals or patterns that may indicate potential safety concerns. This involves analysing trends, clustering of specific adverse events, and assessing the overall benefit-risk profile of a drug^[13]

Risk Assessment and Management: Regulatory agencies assess the risks associated with specific drugs and take regulatory actions if necessary. This may include updating drug labels, issuing safety communications, or, in extreme cases, removing a drug from the market.

Information Sharing with Medical Staff and the Public: For the purpose facilitate informed decision-making, regulatory bodies share safety information with doctors and nurses and the general public. This involves providing cautions and safety alerts as well as instructional materials.

Regulatory agencies collaborate internationally to share pharmacovigilance data and best practices. This collaboration ensures a global perspective on drug safety issues and facilitates coordinated regulatory actions^{.[14]}

Labelling and Package Inserts: Regulatory agencies work with pharmaceutical companies to ensure that drug labeling and package inserts accurately reflect the known safety information. This includes providing clear instructions on how to use the medication safely.

Advisory Committees: Regulatory agencies may convene advisory committees, composed of experts in various fields, to provide recommendations on drug safety issues. These committees contribut^[15]

Drug-drug interactions (DDIs):-

It occurs when two or more drugs interact with each other, leading to changes in their effectiveness, toxicity, or both. These interactions can result in an increase or decrease in the therapeutic effects of the drugs involved or cause new and unintended side effects. Understanding drug-drug interactions is crucial for healthcare professionals in prescribing medications and managing patient treatment plans. Here are some key points about drug-drug interactions[16]

Mechanisms of Interaction:Interactions can occur at various levels, including pharmacokinetic (absorption, distribution, metabolism, and excretion) and pharmacodynamic (effect on the body) processes.

- Pharmacokinetic Interactions:
- 1. **Absorption:-** Drugs may interfere with each other's absorption from the digestive tract.
- 2. **Distribution:** -The distribution of therapeutics in blood vessels can be affected through competition for receptors on plasma proteins.
- 3. **Metabolism:-** Inhibition or induction of drug-metabolizing Enzyme can alter the metabolism of drugs.
- 4. **Excretion:** Drugs may compete for renal excretion, affecting their elimination from the body.[17]
- Pharmacodynamic Interactions:

Drugs may interact at the site of action, either enhancing or diminishing their therapeutic effects.

***** Types of Drug-Drug Interactions:

- Additional Effects: The total of the separate effects of two medications is their combined impact.
- Synergistic Effects: The total effect of the various effects is less than the combined effect.
- Antagonistic Effects : One drug diminishes or cancels out the effect of another.
- Common Examples of Drug-Drug Interactions:

Warfarin and Aspirin: Increased risk of bleeding due to both drugs affecting blood clotting.[18]

NSAIDs and Antihypertensive Medications: NSAIDs may reduce the effectiveness of certain antihypertensive drugs.

• Factors Influencing Interactions:

Individual Variability: Genetic factors, age, and underlying health conditions can influence susceptibility to interactions.^[19]

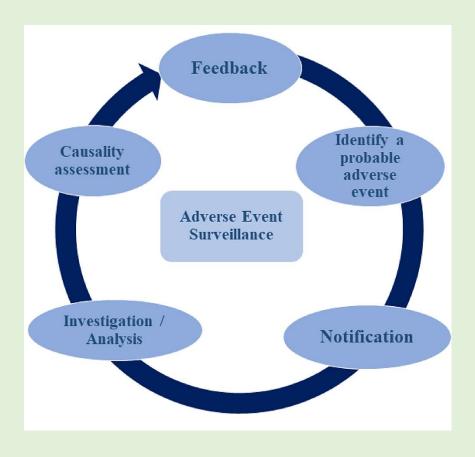
Prevention and Management:

Medication Review: Regularly reviewing a patient's medication list helps identify potential interactions.

Dose Adjustment: Modifying drug doses may help manage interactions timing.

Administration: Staggering the timing of drug administration can minimize interactions.

Monitoring: Regular monitoring for signs of toxicity or reduced efficacy is essential.[20]



Future directions:-

In the field of healthcare and medicine involve ongoing advancements and trends that aim to improve patient outcomes, enhance healthcare delivery, and address emerging challenges. Here are several key areas of focus for future developments:

Precision Medicine: Tailoring medical treatment to individual characteristics, including genetics, lifestyle, and environment, to optimize effectiveness and reduce side effects.

Telemedicine and Remote Patient Monitoring: Increasing access to healthcare, particularly in rural or underserved regions, through the growth of telehealth services and remote monitoring technology. The widespread use of telemedicine during the COVID-19 epidemic has exacerbated this tendency.

Digital Health Technologies: Embracing digital tools such as wearable devices, mobile apps, and health sensors for continuous monitoring, data collection, and management of chronic conditions.

Genomic Medicine: Advancements in understanding the human genome and using genomic information to tailor treatments for various diseases^[21]

Immunotherapy and Gene Therapy: Innovative approaches to treating diseases by enhancing the body's immune response or correcting genetic abnormalities. This includes breakthroughs in cancer immunotherapy and gene editing technologies like CRISPR.

Nanomedicine: Utilizing nanotechnology for targeted drug delivery, diagnostics, and imaging at the molecular and cellular levels.

Patient-Cantered Care Models: Shifting towards patient-centric care that involves shared decision-making, personalized treatment plans, and increased patient involvement in managing their health.

Enhanced Mental Health Services:

Expanding mental health support and services, including digital mental health solutions, to address the growing global burden of mental health disorders. The future of healthcare is dynamic, with interdisciplinary collaboration, technological innovation, and a focus on patient-centric approaches driving transformative changes. Continued research, ethical considerations, and effective implementation strategies are essential to realizing the full potential of these future directions in healthcare.^[22]

A crucial component of contemporary healthcare, patient involvement—also known as patient engagement or patient-centered care—emphasizes the active participation of patients in their own healthcare decisions, treatment regimens, and general well-being. Involving patients in their treatment can result in better health outcomes, happier patients, and a healthcare system that is more effective and cooperative. Key elements of patient participation are as follows:

Together, patients and healthcare professionals decide on treatment options while taking the patient's objectives, values, and preferences into account. This process is known as "shared decision-making."^[23]

Patient education: Giving patients knowledge about their medical issues, available treatments, and self-care techniques enables them to take an active role in their care and make educated decisions.

Communication and Information Sharing: Patients and healthcare professionals may build trust by having open and honest communication that guarantees patients are informed about their condition, available treatments, possible side effects, and advantages.

Care Planning:Collaboratively developing care plans that align with the patient's lifestyle, values, and goals, taking into account their preferences and cultural background.

Health Literacy:Promoting health literacy to ensure that patients understand medical information, instructions, and are able to make informed choices about their health.

Patient Feedback: Actively seeking and valuing patient feedback on their experiences with healthcare services, allowing for continuous improvement in the quality of care provided.

Involvement in Research: Encouraging and facilitating patient participation in research studies and clinical trials, ensuring that research aligns with patient needs and priorities.

Use of Technology:Leveraging digital health tools, patient portals, and mobile apps to enhance patient communication, enable remote monitoring, and facilitate self-management.

Support for Self-Management: Encouraging and supporting patients in actively managing their health through lifestyle changes, adherence to treatment plans, and preventive measures.^[24]

Cultural Competence:Recognizing and respecting the diversity of patients, including their cultural background, beliefs, and values, to provide individualized and culturally sensitive care.

Patient Advocacy:Empowering patients to advocate for themselves and participate in healthcare decision-making processes, as well as advocating for broader improvements in healthcare systems.

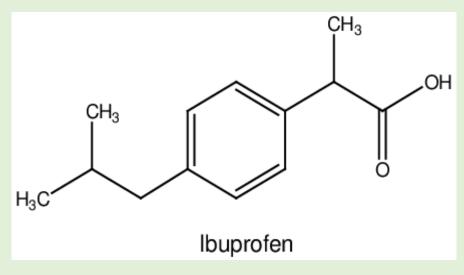
Transition of Care:Involving patients in the planning and coordination of transitions between healthcare settings, ensuring continuity of care and preventing gaps in information.

Patient Support Groups: Facilitating connections between patients with similar health conditions, creating a sense of community and shared experiences that can contribute to emotional support and coping.

In order to provide patient-centered care, which puts the patient at the center of the decisionmaking and delivery of healthcare, patient engagement is essential.

It recognizes patients as partners in their own care and acknowledges the unique perspectives and expertise they bring to the healthcare relationship^{.[26]}

Ibuprofen : -



Molecular Formula:- C13H18O2

NSAID belongs to the class of propionic acid derivatives Its mechanism of action involves inhibiting the synthesis of prostaglandins, substances that play a role in pain, and fever. Commonly used to alleviate conditions such as headaches, muscle aches, menstrual cramps, and various inflammatory disorders, ibuprofen is administered orally in tablet, capsule, or liquid form. While generally considered safe when used as directed. Ibuprofen is often recommended for short-term use, and patients are advised to follow recommended dosages and consult healthcare professionals if experiencing persistent side effects or if considering prolonged use. As with any medication, its use should be approached with consideration of individual health factors, and patients are encouraged to seek medical advice for personalized guidance.

Mechanism of Action of Ibuprofen: -

Nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen work by preventing the enzyme cyclooxygenase (COX) from doing its job. COX plays a pivotal role in the conversion of arachidonic acid into prostaglandins, which are lipid compounds involved in mediating inflammation, pain, and fever. Ibuprofen acts as a non-selective COX inhibitor, affecting both COX-1 and COX-2 isoforms. COX-1 is constitutively expressed and is involved in maintaining normal physiological functions, while COX-2 is induced in response to inflammation. By inhibiting these enzymes, ibuprofen disrupts the synthesis of prostaglandins, which are key signaling molecules in the inflammatory cascade. Prostaglandins sensitize pain receptors, promote vasodilation, and contribute to the development of fever. The reduction in prostaglandin levels achieved through ibuprofen's inhibition of COX leads to a decrease in inflammation, alleviation of pain, and a lowering of fever. While the anti-inflammatory, analgesic, and antipyretic effects of ibuprofen are therapeutically beneficial, its non-selective COX inhibition can also lead to adverse effects, including gastrointestinal irritation, ulceration, and effects on renal function. ^[28]

Contraindications: -

- Hypersensitivity: Ibuprofen and other nonsteroidal anti-inflammatory medication (NSAID) users should refrain from using them if they have a history of hypersensitivity or allergic reaction to them.
- Active gastrointestinal bleeding or ulcers: Ibuprofen may cause irritation to the lining of the stomach, which raises the possibility of gastrointestinal bleeding. As a result, anyone with a history of gastrointestinal bleeding or those who have current peptic ulcers should not use it.
- Ibuprofen has the potential to worsen heart failure by causing fluid retention. People with serious heart failure should not use it.
- Ibuprofen has the potential to impair renal function, especially in those who already have kidney issues. Patients who are at risk of renal failure or who have severe renal impairment should not use it.
- Liver Dysfunction: Those who have a history of severe liver illness or severe liver damage should not use ibuprofen.
- • 3rd Trimester of Pregnancy: Because of the risk of harmful effects on the baby, such as early ductus arteriosus closure, the use of NSAIDs, such as ibuprofen, is often not advised during this time of pregnancy.
- • Past Stroke or Myocardial Infarction (MI): NSAID usage may heighten the risk of cardiovascular events, particularly in people who have previously experienced a stroke or MI.[29]
- • Bypass Surgery (CABG): Because of the elevated risk of cardiovascular events, ibuprofen usage is not advised during the perioperative phase of coronary artery bypass graft (CABG).
- Children Under Certain Ages: Ibuprofen should be used with caution in infants younger than six months and is generally not recommended in infants younger than three months unless specifically advised by a healthcare professional.

Dosage: -

- Chewable pills, capsules, liquid suspensions, and tablets are among the forms of ibuprofen that are available. An individual's age, weight, ailment being treated, and the particular formulation all play a role in determining the right dosage of ibuprofen. Paying attention to the directions on the drug label and those given by the healthcare practitioner is very important. For usual doses, the following general criteria apply:^[30]
- Adults:

For inflammatory conditions (such as arthritis), higher doses may be recommended, ranging from 400 mg to 800 mg every 6 to 8 hours.

• Children:

It's important to use the appropriate pediatric formulation and follow the dosing chart provided by healthcare professionals. The typical range for children is 5 mg to 10 mg per kilogram of body weight, given every 6 to 8 hours, depending on the severity of the condition^{.[31]}

• Special Considerations:

Always use the measuring device provided with the liquid formulation to ensure accurate dosing.

Ibuprofen is usually taken with food or a glass of milk to reduce the risk of stomach upset.

Avoid using more than the suggested amount or length of time without first speaking with a healthcare provider.

Before using ibuprofen, those with certain medical issues or those on other prescriptions should speak with their doctor.

It's critical to remember that each person may react differently to medicine, and dose adjustments may be necessary depending on age, weight, and general health. Furthermore, the information presented here is generic; for individual dose recommendations, see a healthcare provider. Ibuprofen should be taken carefully and under a doctor's supervision, particularly in those who have specific medical problems or are taking other drugs^[32]

Uses:-

- A common nonsteroidal anti-inflammatory medicine (NSAID) for pain relief, ibuprofen also has anti-inflammatory and antipyretic (lowers fever) effects. Some typical applications for ibuprofen include:
- • Pain Relief: Ibuprofen is frequently used to treat mild to moderate pain from a variety of ailments, such as headaches, toothaches, cramping during menstruation, and musculoskeletal injuries.
- Inflammatory Conditions: It works well to reduce inflammation brought on by diseases like osteoarthritis and rheumatoid arthritis. Ibuprofen aids in reducing joint discomfort and swelling.
- Fever Reduction: Ibuprofen is commonly used to lower fever in individuals with febrile conditions such as infections or other illnesses.
- Musculoskeletal Disorders: It is frequently employed to alleviate pain and inflammation related to musculoskeletal disorders, including sprains, strains, and tendonitis.
- Dysmenorrhea (Menstrual Pain):Ibuprofen is a common choice for relieving menstrual pain (dysmenorrhea) due to its ability to reduce prostaglandin levels associated with uterine contractions.
- Headaches and Migraines:For mild to moderate headaches and migraines, ibuprofen is often used to provide relief.
- Dental Pain:buprofen is effective in reducing pain and inflammation associated with dental procedures or conditions such as toothaches.
- Postoperative Pain:After certain surgical procedures, ibuprofen may be prescribed to manage postoperative pain and inflammation.^[33]

Adverse effects of Ibuprofen: -

• Gastrointestinal Effects:

Common: Dyspepsia, heartburn, nausea.

Serious: Gastrointestinal bleeding, peptic ulcers, perforation of the stomach or intestines.

• Mechanism: inhibition of prostaglandin formation, which contributes to the stomach lining's integrity.

• Renal Effects:

Common: Fluid retention, mild renal impairment.

Serious: Acute kidney injury, nephrotic syndrome.

Mechanism: Reduction in renal blood flow due to inhibition of prostaglandin synthesis, especially in individuals with pre-existing renal conditions.

• Cardiovascular Effects:

Common: Increased blood pressure.

Serious: Edema, exacerbation of heart failure.

Mechanism: Fluid retention and sodium retention, leading to increased blood pressure.

• Hematological Effects:

Common: Mild platelet aggregation inhibition.

Serious: Rare cases of thrombocytopenia, leukopenia, and anemia.

Mechanism: Inhibition of prostaglandin synthesis may affect platelet function and interfere with blood clotting.

• Hepatic Effects:

Common: Mild and transient elevation of liver enzymes.

Serious: Rare cases of severe hepatotoxicity.

Mechanism: Idiosyncratic reactions leading to liver damage in some individuals.

• Allergic Reactions:

Common: Rash, itching.

Serious: Anaphylaxis (very rare).

Mechanism: Hypersensitivity reactions can occur, particularly in individuals with a history of allergy to NSAIDs.

• Central Nervous System Effects:

Common: Headache, dizziness.

Serious: Aseptic meningitis (rare).

Mechanism: Some individuals may experience central nervous system-related side effects, but they are generally mild and transient.

• Respiratory Effects:

Common: Bronchospasm in individuals with asthma.

Serious: Severe bronchospasm (rare).

Mechanism: Ibuprofen may exacerbate bronchospasm in susceptible individuals.

It's important for healthcare professionals to consider these potential adverse effects when prescribing ibuprofen and for individuals to promptly report any unusual symptoms to their healthcare provider. Patients should use ibuprofen as directed, follow recommended dosages, and be cautious if they have specific health conditions or are taking other medications. In some cases, healthcare providers may consider alternative treatments or closely monitor patients for adverse effects.

Management for prevention of ADR:-

In order to reduce the risks and guarantee the medication's safe usage, ibuprofen ADR (Adverse Drug Reaction) prevention entails numerous management measures. The following are recommendations for avoiding ibuprofen-related adverse drug reactions (ADRs):

- **Patient Education**:Provide clear and comprehensive information about the proper use of ibuprofen.Emphasize the importance of following the recommended dosage and duration.
- **Dosage Adjustment:** Adjust the dosage based on factors such as age, weight, and renal function, especially in elderly patients or those with renal impairment.
- **Contraindications and Precautions:** Identify and screen patients with contraindications, such as a history of gastrointestinal bleeding, peptic ulcers, or hypersensitivity to NSAIDs.Exercise caution in patients with cardiovascular, renal, or hepatic conditions.
- **Combination Therapy:**Avoid concurrent use of other NSAIDs or medications that may increase the risk of gastrointestinal bleeding.Be cautious with combinations that could lead to drug interactions, such as with anticoagulants or corticosteroids.
- **Monitoring:** Regularly monitor patients for signs of adverse effects, especially gastrointestinal bleeding, renal dysfunction, and cardiovascular events.
- Alternative Therapies: Consider alternative pain management options for patients with a higher risk of ibuprofen-related ADRs. Explore non-pharmacological approaches and alternative medications when appropriate.
- **Topical Formulations**:Consider the use of topical formulations of ibuprofen for localized pain relief to minimize systemic absorption and reduce the risk of systemic side effects.
- **Hydration:Encourage** adequate hydration, especially in patients at risk for renal complications, to reduce the risk of renal toxicity.

Adjust the treatment plan as needed based on the patient's clinical status.

Drug drug interactions: -

• Anticoagulants (Warfarin, Heparin): Taking ibuprofen at the same time as anticoagulant drugs may make bleeding more likely.

- Antiplatelet medications (Aspirin, Clopidogrel): Using ibuprofen and antiplatelet medications at the same time may raise the risk of bleeding in the stomach.
- Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs) and Selective Serotonin Reuptake Inhibitors (SSRIs):
- The risk of gastrointestinal bleeding may rise when ibuprofen is used with SSRIs or SNRIs.
- Angiotensin II receptor blockers (ARBs) and ACE inhibitors: Ibuprofen may lessen the antihypertensive effects of ARBs and ACE inhibitors, which might result in elevated blood pressure.
- Diuretics (Thiazides, Loop Diuretics):The use of diuretics alongside ibuprofen may result in reduced diuretic efficacy and an increased risk of renal impairment.
- Methotrexate:Ibuprofen may increase the blood levels of methotrexate, potentially leading to methotrexate toxicity.
- Corticosteroids:Concurrent use of ibuprofen with corticosteroids may increase the risk of gastrointestinal bleeding and ulcer formation.
- Cyclosporine:Ibuprofen may increase the nephrotoxic effects of cyclosporine, leading to impaired kidney function.
- Lithium: Ibuprofen may increase lithium levels, potentially leading to lithium toxicity.
- Antihypertensive Medications: Ibuprofen can reduce the antihypertensive effects of certain medications used to treat high blood pressure.
- Aspirin:Concurrent use of aspirin with ibuprofen may diminish the cardiovascular protective effects of aspirin.

CONCLUSION :

The gastrointestinal effects, including dyspepsia, heartburn, and the risk of more serious issues such as gastrointestinal bleeding and ulcers, underscore the importance of considering individual gastrointestinal health when prescribing or using ibuprofen. Renal and cardiovascular effects highlight the need for caution, particularly in individuals with preexisting renal conditions or cardiovascular issues. The impact on platelet function and the potential for haematological effects emphasize the importance of monitoring blood clotting and composition during ibuprofen use Hepatic effects, allergic reactions, and central nervous system effects necessitate careful consideration in individuals with liver conditions, a history of NSAID allergies, or susceptibility to central nervous system-related side effects. The list of potential drug interactions emphasizes the need for healthcare professionals to thoroughly review a patient's medication history to avoid adverse effects or reduced efficacy when ibuprofen is used concomitantly with other drugs .Overall, while ibuprofen is a valuable medication for pain relief and inflammation management, its use should be approached with consideration of individual health factors and potential risks

REFERENCES :

1. Aronson JK , Ferner RE . Clarification of terminology in drug safety . Drug Saf 2005 ; 28(5):851-860 .

- 2. Bates DW , Leape LL , Petrycki S . Incidence and preventability of adverse drug events in hospitalized adults . J Gen Intern Med 1993 ; 8(2) : 289 294.
- 3. Lazarou J , Pomeranz BH , Corey PN . Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies . JAMA 1998 ; 279(3) : 1200-1205.
- Pirmohamed M , James S , Meakin S et al . Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients . BMJ 2004 ; 329(5) : 15 9.
- 5. Davies EC, Green CF, Taylor S et al. Adverse drug reactions in hospital in-patients: a prospective analysis of 3695 patientepisodes. PLoS One 2009 ; 4 (1): e4439.
- 6. Wester K , Jönsson AK , Spigset O , Druid H , Hägg S . Incidence of fatal adverse drug reactions: a population based study . Br J Clin Pharmacol 2008 ; 65(7) : 573 9 .
- Rawlins MD , Thompson JW . Pathogenesis of adverse drug reactions . In: Davies DM , ed. Textbook of adverse drug reactions . Oxford : Oxford University Press , 1977 ;5(2): 10 .
- 8. Aronson JK , Ferner RE . Joining the DoTS: new approach to classifying adverse drug reactions . BMJ 2003 ; 327(10): 1222 5.
- 9. Ferner RE , Aronson JK . Preventability of drug-related harms part I: a systematic review . Drug Saf 2010 ; 33(1): 985 994 .
- 10. Coleman JJ , Ferner RE , Evans SJ . Monitoring for adverse drug reactions . Br J Clin Pharmacol 2006 ; 61(3) : 371 378 .
- Rommers MK , Teepe-Twiss IM , Guchelaar HJ . Preventing adverse drug events in hospital practice: an overview . Pharmacoepidemiol Drug Saf 2007 ; 16(40) : 1129 – 1135 .
- 12. Naranjo CA , Busto U , Sellers EM et al . A method for estimating the probability of adverse drug reactions . Clin Pharmacol Ther 1981 ; 30(5) : 239 245.
- Shashi Pratap sigh, Chandra Suresh, Shrivastav Ashish, Asfa Parveen, Yadav Rinki, Pal Yogendra, "Adverse Drug Reaction, monitoring management & diagnosis" World Journal of Pharmaceutical Research 2016;24 (5):51-5 3.
- 14. Claudia Giardina, Paola M. Cutroneo, Eleonora Mocciaro, Giuseppina T. Russo, GiuseppeMandraffino, Giorgio Basile, Franco Rapisarda, Rosarita Ferrara, Edoardo Spina and Vincenzo Arcoraci, "Adverse Drug Reactions inHospitalized Patients: Results of the FORWARD (Facilitation of Reporting Hospital Ward) Study" frontier in pharmacology 2018;11(4):1-4
- 15. H. Khalil, c-Haung "Adverse drug reaction in primary care" A scopine review BMC Health services Rearch 2020;7(8):2-6
- 16. Sharma, c- Dilco, M. Ajmal, P lina mohan ,C.p. jafer, y ahia mohammed, "A prospective study on Adverse drug Reaction of Antibiotics in a tertary care hospital." Saodi pharma2014;7(6) :1-6
- 17. Jamie J coleman, sarahk. Pontefract, "Adverse drug reaction" 2016;6(2):1-3.
- 18. Zipi yan, zhanchan, ziming siao, chaouichen, ganyi wang "The Severity of Adverse Drug Reaction and their influncing Factor based on the ADR" Monitoring centre of human Province scientificreports 2021;7(8):1-5

- 19. Rohila Ankur, Yadav Singhraj,"Adverse drug reaction : An overview" International Journal of Pharmacology Research 2021;5(2):1-4
- 20. Cedric Bousquese, Badisse Dashmna, Sylvie Gailemin Charleshaot, "The Adverse drug Reaction form patient report in social media Project: five major challenges to overcome to operationalize Analysis and efficientily pharmacovigilance process" JMIR Publication 2017;21(3):2-6
- 21. Srivastava Pallavi, Bisht manisha, Dhamija puneet, Kaht Ravi, Adverse Drug Reaction surveillance study in patients visiting a tertiary care Hospital in North India" Research article.2020;7(3): 1-3
- 22. Dhikav Vikas, Singh Anand ks, "Adverse Drug Reaction Monitoring in India" Clinical Pharmacology JIACN2004;5(2):2-6
- 23. Bakal Bijoy, chialiha meghal, "ADR Monitoring in a tertiary care centre in Jorhat" Journal of Pharmacology & Drug research JPADR,2021;4(1):5-8
- 24. Muaed Jamal Alomar, "Factors affecting the development of adverse drug reactions " Saudi Pharmaceutical Journal,2015;24(6):1-7
- 25. In Young Jung, Jung Ju Kim, Se Ju Lee, Jinnam Kim, Hye Seong, Wooyong Jeong, Heun Choi,Su Jin Jeong, Nam Su Ku,Sang Hoon Han, "Antibiotic-Related Adverse Drug Reactions at a Tertiary Care Hospital in South Korea" Hindawi BioMed Research International,2017,6(1):8-12
- 26. Budhrani B. Ashish, MD.Rageeb MD. Usman, Sharma Mrinal, prevesh kumar, "Book of Pharmacy Practice" By pee vee publication2018;5(2):30-34
- 27. Tembhurne V. Sachin, Madgulkar R. Ashwin, Ligade S. Virendra, A Book Of Pharmacy Practice By pee vee publication2020;2(1):3.1-3.6
- 28. Abdullahi Rabiu, Nordin Bin Simbak, Mainul Haque, Adverse Drug Reactions: Predisposing Factors, Modern Classifications and Causality Assessment, Research Journal of Pharmacy and Technology 2014;5(2):1091-1095
- 29. Ayad Raauf, Sura S. Raoof, Nehad Kanaan, Hala Ayad, "Non-Steroidal Antiinflammatory Drugs (NSAIDs): Synthesis of Ibuprofen, Naproxen and Nabumetone" Article in Al Mustansiriyah Journal of Pharmaceutical Sciences2019;8(3):29-33
- 30. Sagar Bashyal, Ibuprofen and its different analytical and manufacturing methods Article in Asian Journal of Pharmaceutical and Clinical Research 2018;5(2):24-27
- 31. Md. Sarowar Jahan, Md. Jahirul Islam, Rehana Begum, Ruhul Kayesh and Asma Rahman, "A Study of Method Development, Validation, and Forced Degradation for Simultaneous Quantification of Paracetamol and Ibuprofen in Pharmaceutical Dosage Form by RP-HPLC Method" Libertas Academica 2015;15(5):75-79
- 32. H. Potthast, J.B. Dressman, H.E. Jungigner, K.K. Midha Biowaiver Monographs for Immediate Release Solid Oral Dosage Forms: Ibuprofen, 2018;4(1):2121-2129.
- 33. Sarfaraz Kazi, Sanjay Bais, Mansi Kore, Review On: Pharmacovigilance ,International journal of pharmacy & herbal technology, 2023;3(1):81-88.