INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA):IJPS00]
Journal Homepage: https://www.ijpsjournal.com

OPEN ACCESS

Research Article

Adverse Drug Reaction Reported To Injection Calcium Gluconate

Bibave Kiran H., Tambe Ayush K.*, Gangarde Atharv S., Vyavahare Sakshi S., Bandal Vaishnavi P., Dhas Sushma S.

S.S.P. Shikshan Sanstha's Siddhi College Of Pharmacy, Newale Wasti, Chikhali-411062

ARTICLE INFO

Received: 11 March 2024
Accepted: 15 March 2024
Published: 22 March 2024

Keywords:
Infusion, burning skin, calcium gluconate, hypocalcemia.

DOI:
10.5281/zenodo.10853399

ABSTRACT

In the modern day, adverse drug reactions (ADR) are one of the most important subjects to evaluate. The World Health Organization (WHO) defines an adverse drug reaction (ADR) as any unpleasant and inadvertent reaction to a drug that happens at dosages used in humans for disease prophylaxis, diagnosis, or therapy; or for altering physiological function. This definition intentionally leaves out therapeutic failures, overdoses, drug abuse, noncompliance, and medication errors. Furthermore, it has been considered a noteworthy adverse event that arises from a medical product-related intervention. On the other hand, side effects are typically connected to a drug's therapeutic properties and can be both advantageous and detrimental. Therefore, it is possible to argue that an adverse drug reaction (ADR) is defined as an adverse or undesired reaction that occurs after taking a medication or a combination of medications under normal use circumstances. Nonetheless, a number of ADR types, including type A, type B, and type C adverse responses, have been documented. types of negative drug reactions Adverse reaction types can be categorized under two primary headings: typical adverse drug reactions (ADRs) such as type A and type B reactions, and uncommon ADRs such as type C, D, and E reactions. Adverse reactions of type A have frequently been linked to dosage, which amplifies the drug's typical therapeutic impact. Moreover, type A ADRs have been linked to the pharmacokinetic or pharmacodynamic aspects of the medications. Genetic variations may be responsible for the pharmacokinetic causes of type A reactions, which in turn result in ADRs.

INTRODUCTION

In the modern day, adverse drug reactions (ADR) are one of the most important subjects to evaluate .The World Health Organization (WHO) defines an adverse drug reaction (ADR) as any unpleasant and inadvertent reaction to a drug that happens at dosages used in humans for disease prophylaxis, diagnosis, or therapy; or for altering physiological function. This definition intentionally leaves out therapeutic failures, overdoses, drug abuse, noncompliance, and medication errors. Furthermore, it has been considered a noteworthy

***Corresponding Author:** Tambe Ayush K.
Address: *S.S.P. Shikshan Sanstha's Siddhi College Of Pharmacy, Newale Wasti, Chikhali-411062*
Email ✉: sakshivyavahare25@gmail.com

Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

adverse event that arises from a medical product-related intervention. While side effects are typically connected to a drug's therapeutic actions, adverse effects, Furthermore, it has been considered a noteworthy adverse event that arises from a medical product-related intervention. While side effects are typically associated with a drug's therapeutic activity and can be both useful and harmful, adverse effects are defined as an overstatement of the intended therapeutic impact and constitute a portion of ADR. Therefore, it is possible to argue that an adverse drug reaction (ADR) is defined as an adverse or undesired reaction that occurs after taking a medication or a combination of medications under normal use circumstances. Nonetheless, a number of ADR types, including type A, type B, and type C adverse responses, have been documented .which happen as an overstatement of the intended therapeutic impact, are a component of ADR. types of negative drug reactions Adverse reaction types can be categorized under two primary headings: typical adverse drug reactions (ADRs) such as type A and type B reactions, and uncommon ADRs such as type C, D, and E reactions . Adverse reactions of type A have frequently been linked to dosage, which amplifies the drug's typical therapeutic impact. Moreover, type A ADRs have been linked to the pharmacokinetic or pharmacodynamic aspects of the medications. Genetic variations may be responsible for the pharmacokinetic causes of type A reactions, which in turn result in ADRs. Furthermore, pharmacokinetic abnormalities brought on by hepatic disorders have been shown to result in ADR by altering the distribution and metabolism of medicine. Pharmacokinetic differences have been hypothesized to be caused by the medicines' elevated half lives combined with lower glomerular filtration rates (GFR). Furthermore, side effects have been noted with medications that the kidneys frequently reject. ADRs have also been reported to be brought on by changes in apparent volume of distribution, inadequate renal perfusion, and reduced absorption brought on by mucosal oedema. Therefore, we are doing this study with the aim of understanding the adverse medication reaction by drug. When addressing ADRs in patients, healthcare professionals make judgments about therapy based on an informal assessment of causality. Regulatory bodies review reports of spontaneous adverse drug reactions (ADRs), and causality analysis can support signal detection and risk-benefit calculations for medications. Since algorithms are organized systems created especially to identify an ADR, they ought to be able to decide on causation more objectively. Four fundamental concepts form the foundation of the objective causal assessments: temporal eligibility, challenge and outcome, challenge and outcome again, and confounding circumstances. The Jones algorithm, the Naranjo algorithm, the Yale algorithm, the Karch algorithm, the Begaud algorithm, the Australian ADR advisory committee, the World Health Organization-Uppsala Monitoring Center (WHO-UMC) criteria, and many other algorithms and decision aids have been published. The Jones algorithm, the Naranjo method, the Yale algorithm, the Karch algorithm, the Begaud algorithm, the Australian ADR advisory committee, and the World Health Organization-Uppsala Monitoring Center (WHO-UMC) criteria are only a few of the documented algorithms and decision aids. There are variances and similarities between each of these algorithms. The WHO-UMC method was created as a useful tool for evaluating case reports after consultation with National Centers involved in the Program for International Drug Monitoring. It is essentially a combination evaluation that considers the case history's clinical-pharmacological elements as well as the caliber of the observational record.

Case Report on Adverse Drug Reactions (ADRs)

In pharmacovigilance, a case report is a notification about a patient who may have been exposed to a medication that caused an adverse medical event or abnormal laboratory test results. It is crucial to emphasize that healthcare professionals, even in the absence of all necessary information, should nevertheless report adverse drug reactions (ADRs).

Consumer

An individual who is not a member of the medical community, such as a patient's friend or relative.

Drug Abuse:

Abuse of drugs refers to the deliberate, excessive use of medications, whether it be intermittent or continuous, and it is accompanied by negative health or psychological effects.

Accelerated Reporting:

This refers to the reporting of a significant negative response to the Board as soon as possible, and in no more than seven calendar days.

Drug Abuse:

Abuse of drugs refers to the deliberate, excessive use of medications, whether it be intermittent or continuous, and it is accompanied by negative health or psychological effects.

Accelerated Reporting:

This refers to the reporting of a significant negative response to the Board as soon as possible, and in no more than seven calendar days. Individuals with medical qualifications, such as doctors, dentists, pharmacists, nurses, or community health officers, are referred to as healthcare professionals.

Marketing Authorization Holder:

An entity that may or may not be the product's maker that has been granted permission by the appropriate authorities to market pharmaceuticals, medical supplies, or cosmetics in Sierra Leone or any other nation. A new drug is defined as a chemical or biologically active pharmaceutical ingredient that has never before received a marketing clearance in India to be used as a component of any pharmaceutical product.

Misuse Situations:

These occur when a medication is purposefully and inappropriately utilized in ways that are not permitted by the approved product information.

The National Pharmacovigilance Center is known as NPC.

Exposure at work Exposure:-due to one's professional or non-professional vocation, to a pharmaceutical product Off-label application circumstances in which a medication is purposefully taken for a medical purpose that does not comply with the approved product information.

Overdose:

The administration of a medication in an amount that exceeds the maximum recommended dose as stated in the approved product information, either individually or cumulatively.

MATERIAL AND METHODS:

Title of Study:

Investigation of Adverse Drug Reaction A case report of drug eruption with a positive Dechallenge-Rechallenge test caused by injection of calcium gluconate.

The current investigation was carried out at Manipal Hospital Baner.

Research Framework

Case report:

observational research on a medication's adverse effect.

The population under study's source

A patient admitted to Baner's Manipal Hospital

CASE STYDY

Name/Intials: KT

Age: 69years

Sex: male

Hospital/Clinic: Manipal Hospital Baner-Pune

Suspected Drug Details:

1. **Drug: Calcium Gluconate**

Dose:10%
Route: Intravenous(IV)
Batch No:22062
Expiry Date:31/3/25
Frequency: STAT
Therapy dates-
Date Started:23/10/22
Date stopped:23/10/22

Concomitant Medical Product:-

25% Dextrose

Therapy dates-

Date Started:22/10/22
Date stopped:22/10/22
Suspected Adverse Drug Reaction:
Event /Reaction start date: 23/10/22
Event/Reaction stop date:23/10/22

Adverse Drug Reaction:-

Injection Calcium Gluconate 10% in 100ml NS was prescribed to the patient,administered by infusion pump. After 2min of ongoing administration patient developed a burning skin ,patch around the prick area.
Infusion was stopped.
No Swelling accompanied with burning patch.

Action Taken after reaction :

Medicine was given in vein of another upper limb.
Reaction reappeared after reintroduction of suspected medication :No

Reporter Details:

Name: Dr.Akshay Khirade
Address: Clinical pharmacologist,Manipal Hospital.
Contact:9604020940
Occupation:Clinical Pharmacologist
Date of this Report:25/10/22

On 22/10/22 first Sodium Bicarbonate is Administered to the Patient adverse reaction is occurred so next day 23/10/22 Calcium Gluconate is administered then after 2min developed a burning skin ,patch around the prick area and Infusion was stopped. After that Medicine was given in vein of another upper limb.

Drug and Pharmacology

Calcium Gluconate (Rx, OTC)
Brand and Other Names:Gluconate, Ca
Classes: Antidotes, Other; Calcium Salts

Dosage Forms & Strengths in Adults

Injectable solution

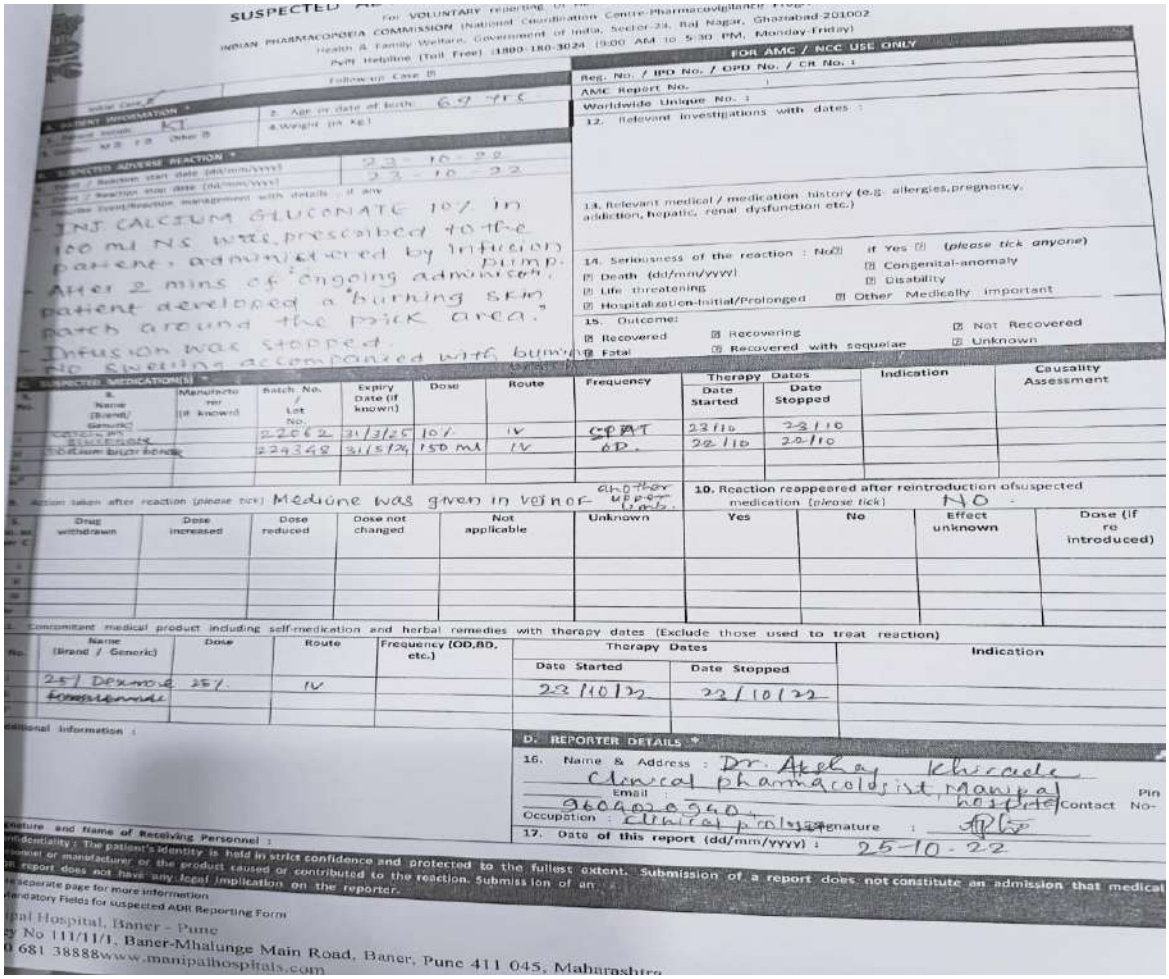
100mg/mL (10%)

Tablet

50mg
500mg
650mg

Capsule

500mg



MECHANISM OF ACTION

Extracellular potassium elevations may result in heart arrhythmias, which may then lead to cardiac arrest and death. Stabilizing cardiac cell membranes is the function of calcium gluconate in the treatment of hyperkalemia. Any patient who presents with hyperkalemia with EKG abnormalities, indicating a hyperkalemic emergency, should receive calcium immediately. By raising the threshold potential of cardiac myocytes, elevated potassium levels destabilize cardiac membranes. The threshold to reestablish the transmembrane voltage gradient is lowered by supplementing with calcium.mild (calcium ionized at 1-1.2 mmol/L)

Handling of non-life-threatening signs and symptoms

IV: 1-2 g over 2 hours; PO: 1-3 g/day in divided doses; oral replacement therapy may be explored and given on an outpatient basis

Severe (ionized calcium <1 mmol/L)

- Without seizure or tetany: 0.5 mg/kg/hr IV; may be increased to 2 mg/kg/hr; not to exceed 3-4 g IV over 4 hours
- Hypocalcemic tetany: 100-300 mg elemental calcium (~3 g calcium gluconate) IV over 5-10 minutes, followed by continuous IV infusion at 0.5 mg/kg/hr (may be increased to 2 mg/kg/hr)
- Monitor serum calcium q4-6hr to maintain serum calcium levels

Adverse Effects

- Frequency Not Defined
- Bradycardia
- Hypotension
- Headache

- Constipation
- Diarrhoea
- Flatulence
- Nausea
- Vomiting
- Hypomagnesemia
- Hypophosphatemia
- Extravasation necrosis

Warnings

Contraindications

- Hypersensitivity
- IM/SC administration
- Ventricular fibrillation during CPR
- Hypercalcemia
- Digoxin poisonings
- Sarcoidosis

Cautions

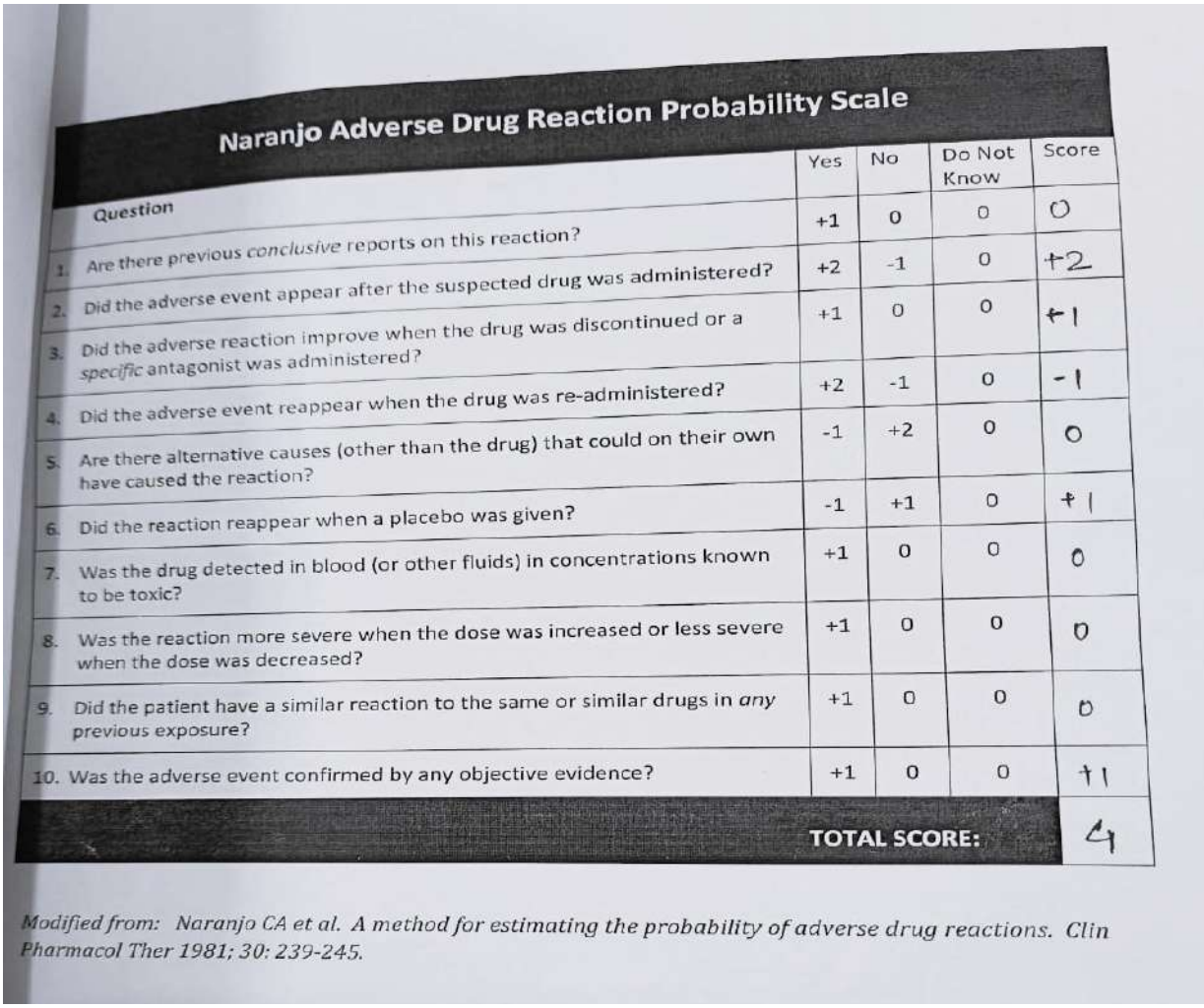
- Hepatic or renal impairment, cardiovascular disease, acidosis, history of renal calculi
- Cardiac arrest may occur
- Calcium gluconate injection contains aluminium, up to 100 mcg per litre
- Constipation, bloating, and gas may occur with oral administration
- Use caution in patients with severe hyperphosphatemia
- Adult and Pediatric Advanced Life Support programs no longer recommend routine calcium for CPR[20].

IMAGE

BRAND	FORM	PILL IMAGE
calcium gluconate intravenous	100 mg/mL (10%) vial	
calcium gluconate intravenous	100 mg/mL (10%) vial	
calcium gluconate intravenous	calcium gluconate intravenous	
calcium gluconate intravenous	100 mg/mL (10%) vial	

RESULT

The study's findings highlighted the necessity of ADR reporting at tertiary care facilities in order to assist in determining the benefit-risk ratio of medications. This investigation led to the conclusion that the adverse medication reaction described in the case study may be of a certain kind. It demonstrates the assessment of causality between a suspected medication and an adverse drug reaction.



Naranjo Adverse Drug Reaction Probability Scale

Question	Yes	No	Do Not Know	Score
1. Are there previous *conclusive* reports on this reaction?	+1	0	0	0
2. Did the adverse event appear after the suspected drug was administered?	+2	-1	0	+2
3. Did the adverse reaction improve when the drug was discontinued or a *specific* antagonist was administered?	+1	0	0	+1
4. Did the adverse event reappear when the drug was re-administered?	+2	-1	0	-1
5. Are there alternative causes (other than the drug) that could on their own have caused the reaction?	-1	+2	0	0
6. Did the reaction reappear when a placebo was given?	-1	+1	0	+1
7. Was the drug detected in blood (or other fluids) in concentrations known to be toxic?	+1	0	0	0
8. Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	0
9. Did the patient have a similar reaction to the same or similar drugs in *any* previous exposure?	+1	0	0	0
10. Was the adverse event confirmed by any objective evidence?	+1	0	0	+1
			TOTAL SCORE:	4

Modified from: Naranjo CA et al. A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther 1981; 30: 239-245.

Scoring for Naranjo algorithm

>9 = definite ADR

5–8 = probable ADR

1–4 = possible ADR

0 = doubtful ADR.

69 year IPD patient prescribed INJ calcium gluconate in 100ml of NS administered by infusion pump after 2min of ongoing administration patient developed burning skin patch around the prick area.

The patient reported and measure naranjo scale and the total score of naranjo scale was 4, that show patient reported with possible adverse drug reaction.

DISCUSSION

This spontaneous case, which was received on October 23, 2022, involved a 69-year-old male patient whose skin began to burn after receiving intravenous calcium gluconate. Commencing on October 23, 2022, and ending on October 23, 2022, was the concurrent drug that included 25% dextrose. In this instance, the infusion was halted after two minutes because the patient's skin and patches were burning [Dechallenge]. Following that, medication was injected into the vein of a different upper limb [Rechallenge].

CONCLUSION

It has been believed that pharmacokinetic and pharmacodynamic differences in drug products are the cause of adverse medication responses. We came to the conclusion in this study that injection calcium gluconate is linked to the adverse drug reaction that is currently being reported. Therefore, in this investigation, the suspected drug was initially decoked and then the medication was reconstituted.

LIMITATION

The current study has some limitations. Firstly, the patient's past medical history was withheld, and the patient's second diagnosis was not disclosed in the ADR form. The third is the lack of an available investigative report on past medication history, allergies, and family history.

ACKNOWLEDGMENT

The authors would like to express their gratitude to all of the cardiology department's specialty doctors as well as the medical staff at our hospital's emergency room for their crucial support and contributions.

REFERENCES

1. WHO. International monitoring of adverse reactions to drugs: adverse reaction terminology. WHO Collaborating Centre for International Drug Monitoring, Uppsala, Sweden, 1992.
2. Zopf Y. Risk factors associated with adverse drug reactions following hospital admission: a prospective analysis of 907 patients in two German university hospitals. Drug Safety 2008; 31: 789-798.
3. Word Health Organization. International drug monitoring: the role of the hospital. Geneva, Switzerland: word health organization;1966. technical report series no.425.
4. Khraenbuhl-Melcher A, Schlienger R, Lampert M, et al. Drug – related problems in hospitals. A review of the recent literature. Drug Safety 2007; 30: 379-407.
5. Stephens MDB. Definitions and classifications of adverse reaction terms in: Stephens MDB, Talbot JCC, Routledge PA, eds. The detection of new adverse reactions, 4th edn. London: Macmillan reference, 1998: 32-44.
6. Edwards IR, Aronson JK. Adverse drug reactions: definitions, diagnosis, and management. Lancet 2000; 356: 1255-259.
7. Nebeker JR, Barach P, Samore MH. Clarifying adverse drug events: a clinican's guide to terminology, documentation, and reporting. An Intern. Med 2004; 140: 795-801.
8. Rawlins M, Thompson W. Mechanisms of adverse drug reactions. In: Davies D, ed. Textbook of adverse drug reaction. Newyork: oxford university press 1977:10.
9. Dr. Ramesh KG, Dr. Parloop AB, Dr. Mahesh DB. Elements of clinical pharmacy, 4th edn:2008-2009, B.S. Shah prakashan; page no-109-114.
10. Pirmohamed M, Park BK. Adverse drug reactions: back to the future. British j Pharmacol 2003; 55: 486-492.
11. Park B, Pirmohamed M, Kitteringham N. idiosyncratic drug reactions: a mechanistic evaluation of risk factors. Br J Clin pharmacol 1992; 34: 377-395
12. Bennett PN, Brown MJ. Clinical Pharmacology. Tenth edition. Churchill Livingstone, Edinburgh, 2008.
13. Tarantino G. Drug-induced liver injury: is it somehow foreseeable? World J Gastroenterol 2009; 15: 2817-2833
14. Elbe D, Savage R. How does this happen?. Part 1: mechanisms of adverse drug reactions associated with psychotropic medications. J Can Aca Child Adol Psychiat 2010; 19: 40-45.
15. Schnyder B, Pichler WJ. Mechanisms of drug-induced allergy. Mayo Clinic Proceedings 2009; 84: 268-272.
16. Roujeau JC. Immune mechanisms in drug allergy. Allergol Int 2006; 55: 27-33.
17. Zaccara G. Idiosyncratic adverse reactions to antiepileptic drugs. Epilepsia 2007; 48: 1223-1244.
18. Beijir HJ, de Blaey CJ. Hospitalisations caused by adverse drug reactions (ADR):

ameta- analysis of observation studies. Pharmworld Sci 2002; 34: 1373-1379.
19. GUIDELINE FOR DETECTING AND REPORTING ADVERSE DRUG REACTIONS Doc No: PBSL/GL/019
20. Calcium gluconate dosing, indications, interactions, adverse effects, and more (medscape.com)

HOW TO CITE: Bibave Kiran H., Tambe Ayush K., Gangarde Atharv S., Vyavahare Sakshi S., Bandal Vaishnavi P., Dhas Sushma S., Adverse Drug Reaction Reported To Injection Calcium Gluconate, Int. J. of Pharm. Sci., 2024, Vol 2, Issue 3, 828-836. https://doi.org/10.5281/zenodo.10853399