



SWAMY VIVEKANANDHA COLLEGE OF PHARMACY

(Affiliated to the The Tamil Nadu Dr.MGR. Medical University, Chennai,
Approved by PCI, Accredited by NBA, New Delhi)
Elayampalayam, Tiruchengode-637 205, Namakkal (Dt), Tamil Nadu.



Department of Pharmacy Practice

Presents

ADR PULSE RADAR

(SPOT IT, STOP IT)

VMCH ADR ALERT: FEBRUARY 2026
'Pharmacovigilance - Passive
Surveillance'

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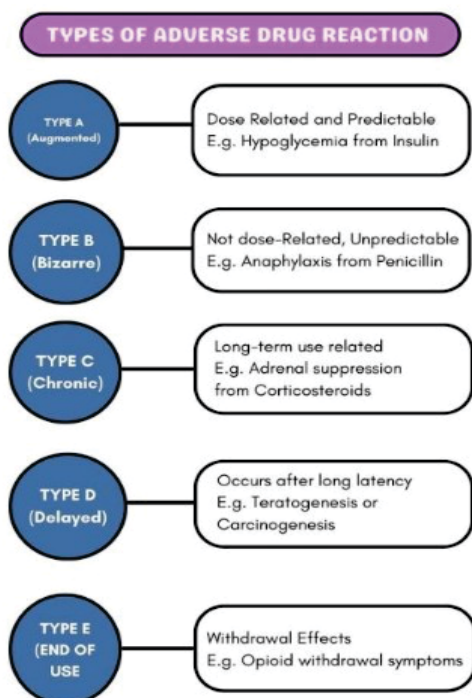
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ADVERSE DRUG REACTION

According to the World Health Organization (WHO), an Adverse Drug Reaction (ADR) is defined as a noxious, unintended, and undesired effect that occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.[1]

TYPES OF ADVERSE DRUG REACTION [2]



ADR ASSESSMENT SCALES

ADR assessment scales are structured tools used to determine the likelihood (causality) and severity of suspected adverse drug reactions. Key scales include the **Naranjo Algorithm** (definite, probable, possible, doubtful), **WHO-UMC criteria** (certain, probable, possible, unlikely), and **Hartwig Severity Scale** (mild, moderate, severe), **Schumock and Thornton Scale** (definitely preventable, probably preventable, not preventable).[3-5]

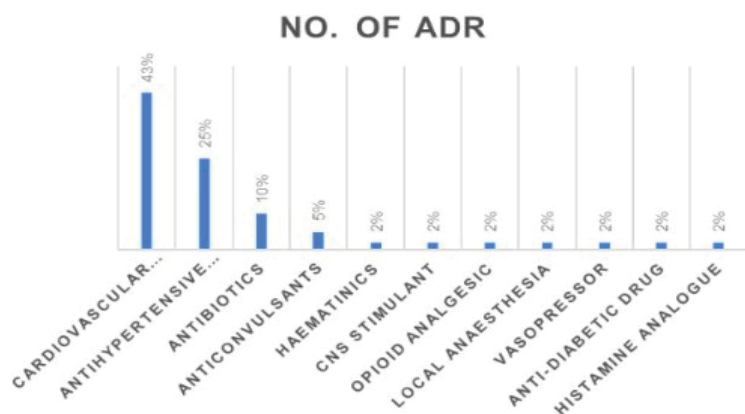
REFERENCES

1. https://www.who.int/docs/default-source/medicines/safety-of-medicines--adverse-drug-reactions-jun18.pdf?sfvrsn=4fc4f40_2
2. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/949130/Guidance_on_adverse_drug_reactions.pdf
3. <https://www.cliniindia.com/naranjo-causality-assessment-scale/>
4. <https://pmc.ncbi.nlm.nih.gov/articles/PMC9959449/>
5. <https://www.cliniindia.com/who-umc-causality-assessment-scale/>

VMCH ADR SUMMARY

Total ADR : 40
Most Common Types : Cardiovascular drugs (43%)
Serious Cases : NIL

ADRs INVOLVED: Cardiovascular drugs (43%), Antihypertensive drug (25%), Antibiotics (10%), Anticonvulsant (5%), Haematinics (2%), CNS Stimulant (2%), Opioid Analgesic (2%), Local Anaesthesia (2%), Vasopressor (2%), Anti-Diabetic drug (2%), Histamine analogue (2%)



IF ANY ADR, SCAN AND REPORT HERE



Email Id: vmchadr@gmail.com

FDA DRUG INFORMATION



Safety labeling update for capecitabine and fluorouracil (5-FU) on risks associated with dihydropyrimidine dehydrogenase (DPD) deficiency

- Boxed Warning:** The Boxed Warning now highlights the risk of serious adverse reactions or death in patients with complete DPD deficiency. It also advises DPYD testing prior to initiating capecitabine or 5-FU, unless immediate treatment is necessary, and recommends avoiding use in patients with certain homozygous or compound heterozygous DYPD variants that result in complete DPD deficiency.FEB 5, 2026[1]

REFERENCE

- <https://www.fda.gov/drugs/resources-information-approved-drugs/safety-labeling-update-capecitabine-and-fluorouracil-5-fu-risks-associated-dihydropyrimidine>



ADR CASE

AMIODARONE INDUCED QT PROLONGATION



PATIENT DETAILS

AGE & SEX : 73 YR / FEMALE
DIAGNOSIS : ATRIAL
FIBRILLATION, LRTI, SHTN
DOA : 16/02/2026



OUTCOME



RECOVERED



DESCRIPTION OF ADR

SUSPECTED DRUG : INJ.AMIODARONE
THERAPY DATE : 16/02/2026
DOSE/FREQ/ROA : 900 MG/STAT/IV
INDICATION : ATRIAL
FIBRILLATION



MANAGEMENT

SUSPECTED DRUG WAS
WITHDRAWN, THE
PATIENT RECOVERED AND
CHANGED FROM
INJECTION AMIODARONE
TO TABLET AMIODARONE
100 MG 1-0-1



CAUSALITY ASSESSMENT

WHO - UMC SCALE
PROPABLE /LIKELY



VIVEKANANDHA EDUCATIONAL INSTITUTIONS



"Vidhya Rathna"

Prof. Dr. M. KARUNANITHI, B.Pharm., M.S., Ph.D., D.Litt.,
Chairman & Secretary

TIRUCHENGODE CAMPUS

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- ★ VIVEKANANDHA DENTAL COLLEGE FOR WOMEN
- ★ SWAMY VIVEKANANDHA COLLEGE OF PHARMACY
- ★ VIVEKANANDHA COLLEGE OF NURSING
- ★ SWAMY VIVEKANANDHA PHYSIOTHERAPY COLLEGE
- ★ VIVEKANANDHA ALLIED HEALTH SCIENCE COLLEGE
- ★ KRISHNA INSTITUTE OF OPTOMETRY & RESEARCH
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