



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: MARCH 2026

'Pharmacovigilance - Passive Surveillance'

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TERMINOLOGY OF ADR

Adverse Drug Reaction: A Response to a medicine that is noxious and which occurs at doses normally used in man.

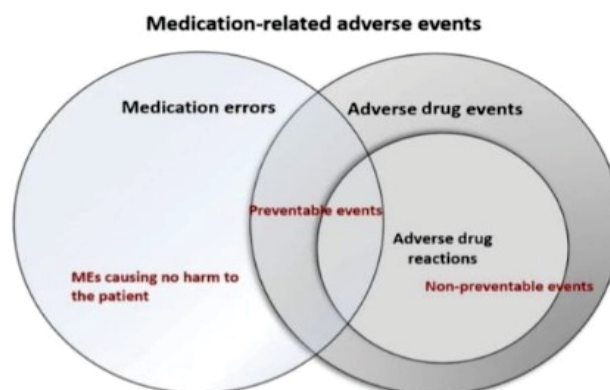
Adverse Drug Event: Any untoward medical occurrence that may present during the treatment with a medicine, but which does not necessarily have a causal relationship with this treatment.

Side Effects: An unpleasant effect of a drug that happens in addition to the main effect.

Benefit and risk analysis: Examination of favourable (benefit) & Unfavorable result of undertaking a special cause of action.

Adverse Case Report: A case report in ADR is a notification relating to a patient with an adverse effect or laboratory test abnormality suspected to be induced by a medicinal product

Serious Adverse Event (SAE): A medical incident that results in death, is life-threatening, requires a hospital stay, or causes a birth defect or disability.



Spontaneous Report: An unplanned, voluntary "heads up" from a doctor or patient about a side effect that wasn't part of a formal study.

Stimulated Reporting: When reporting increases due to a reminder, such as a news article or a letter from the manufacturer about a specific drug.

REFERENCES

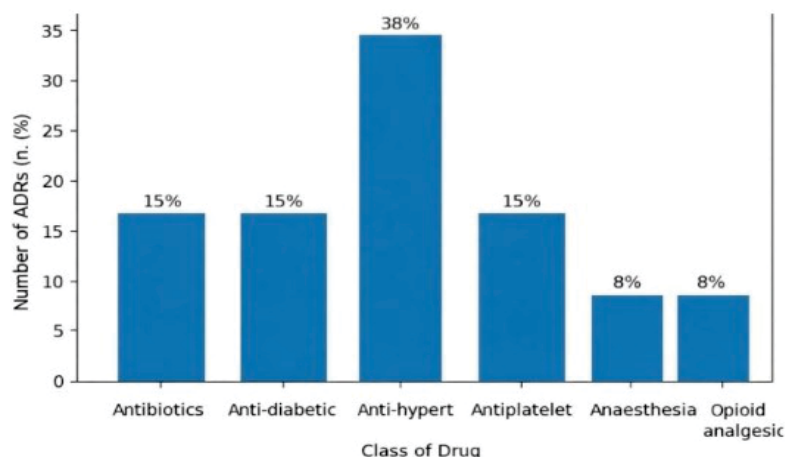
1. Tommy E. Adverse Drug Events/Reactions. Available from: https://www.sapc.za.org/Media/Default/Documents/Pharmacy%20Month/230905_PV%20for%20Pharmacy%20Week_final.pdf?hl=en-IN. [Cited 2026 March 27].
2. https://www.researchgate.net/figure/Classification-of-adverse-events-Adverse-events-include-all-harmful-events-occurring_fig1_321957213?hl=en-IN [Cited 2026 March 27].

VMCH ADR SUMMARY

Total ADR : 13
Most Common Types : Anti Hypertensive drugs (38%)
Serious Cases : NIL

ADRs INVOLVED:

Anti-Hypertensive drugs -38%, Antibiotics -15%,
 Antiplatelet drug -15%, Anti-diabetic drug - 15%,
 Anesthesia -8%, Opioid analgesic - 8%



IF ANY ADR, SCAN AND REPORT HERE



Email Id: vmchadr@gmail.com

FDA ADR INFORMATION

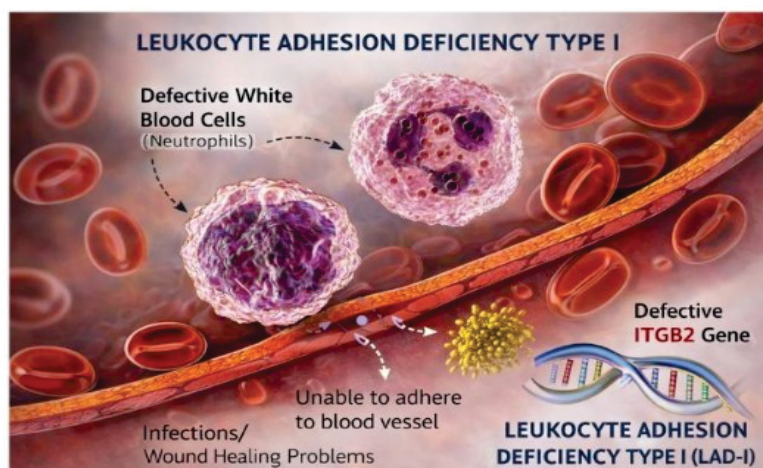


FDA Adverse Event Look-Up Tool (AEMS): The FDA has launched a centralized, real-time database that consolidates adverse event reporting for drugs, biologics, and medical devices. This new tool replaces quarterly data updates with immediate access to safety reports, allowing healthcare providers and the public to identify potential risks and safety signals more quickly. The initiative modernizes postmarket surveillance and improves transparency in monitoring product safety.

REFERENCES

1. The FDA Adverse Event Reporting System (FAERS) Public Dashboard – PRAIS 2.0. 2020. Available from: <https://share.google/dO9AhOkYMKu46pEo5>. [Cited 2026 March 27]
2. <https://www.fda.gov/drugs/fda-adverse-event-monitoring-system-aems/fda-adverse-event-monitoring-system-aems-public-dashboard> [Cited 2026 March 27].

FDA DRUG INFORMATION



The U.S. Food and Drug Administration approved **Kresladi**, the first gene therapy for **severe Leukocyte Adhesion Deficiency type I (LAD-I)**, a rare genetic immune disorder. In LAD-I, white blood cells cannot reach infection sites, causing life-threatening infections. Kresladi works by modifying a patient's own stem cells using a viral vector to insert a functional gene, restoring immune function. This one-time therapy offers a new option for children who previously depended on risky stem-cell transplants. The approval was based on improved **immune markers**, giving hope for better survival in this otherwise often fatal childhood disease.

The U.S. Food and Drug Administration approved **Avlayah (tvidenofusp alfa)** to treat neurologic manifestations of **Hunter syndrome**, a rare genetic disorder. In this condition, harmful sugar molecules accumulate in cells due to enzyme deficiency, leading to brain and organ damage. Avlayah is the first therapy designed to cross the blood-brain barrier, allowing it to treat neurological symptoms in children. It is given as a **weekly IV** infusion and received accelerated approval based on reduced disease biomarkers. This marks a breakthrough, as earlier treatments could not address brain involvement.



REFERENCES

1. Office of the Commissioner. Press Announcements. U.S. Food and Drug Administration. 2019. Available from: <https://www.fda.gov/news-events/fda-newsroom/press-announcements> [cited 2026 March 27].
2. Denali's Avlayah Approved as First Agent for Hunter Syndrome Neurologic Symptoms | Pharmaceutical Technology <https://share.google/n71XJq190xbNHMxby> [cited 2026 March 27].

SHORT COMMUNICATION

Mucormycosis is an uncommon but potentially fatal opportunistic fungal illness that mostly affects immunocompromised people, particularly those with uncontrolled diabetes. It is caused by fungi belonging to the order Mucorales.



SUMMARY

This case highlights the rapid progression and high morbidity of mucormycosis in diabetic patients. Early diagnosis, aggressive antifungal therapy, surgical intervention, and multidisciplinary care including active clinical pharmacist involvement are crucial for improving outcomes.

CASE REPORT

A 62-year-old man with hypertension and newly diagnosed type 2 diabetes developed maxillary sinus mucormycosis presenting with facial swelling, orbital involvement, dental pain, and difficulty opening the mouth. Imaging showed sinusitis and orbital cellulitis, while histopathology confirmed mucormycosis (broad, aseptate, right-angled fungal hyphae).

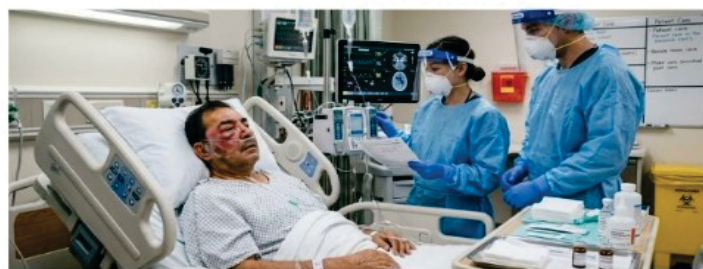
He was treated with antifungal therapy (liposomal amphotericin B and posaconazole) along with planned surgical management (complete maxillectomy). During treatment, he developed electrolyte imbalances (hypokalemia and hypomagnesemia), which were corrected.

Pharmacist interventions included patient counselling, medication optimisation, and ensuring proper drug

By

Abinaya.S, Abitha.M

V-Pharm D





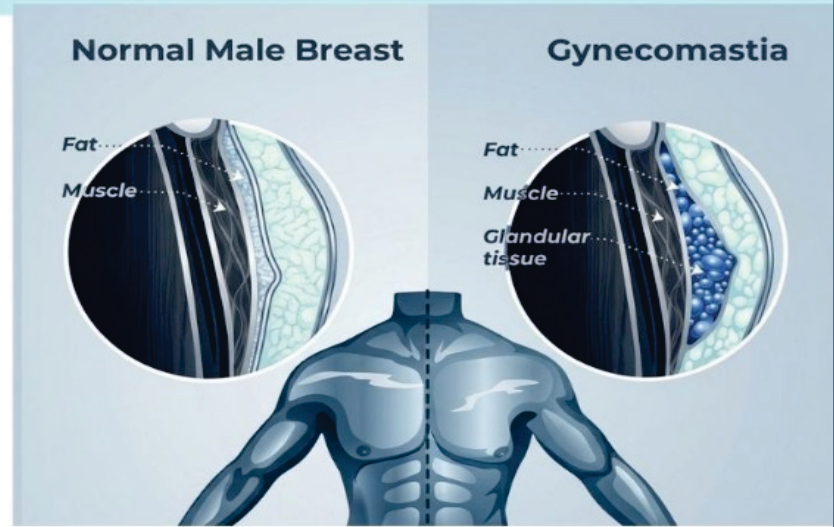
ADR CASE

SPIRONOLACTONE INDUCED GYNECOMASTIA



PATIENT DETAILS

AGE & SEX : 58 YR / MALE
DIAGNOSIS : CAD / ACUTE
KIDNEY INJURY
DOA : 16/03/2026



OUTCOME



RECOVERING



DESCRIPTION OF ADR

SUSPECTED DRUG : SPIRONOLACTONE
(TABLET)
THERAPY DATE : 16/03/2026
DOSE/FREQ/ROA : 50MG /PO/ 1/2-0-0
INDICATION : ACUTE KIDNEY
INJURY



MANAGEMENT

SUSPECTED DRUG WAS
WITHDRAWN AND
TORSEMIDE (TABLET)
10 MG 1-0-1 WAS GIVEN



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
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