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.



Prof. Dr. M. KARUNANITHI
B.Pharm., M.S., Ph.D., D.Litt.,
CHAIRMAN & SECRETARY

Department of Pharmacy Practice

Presents

ADR PULSE RADAR

(SPOT IT, STOP IT)

VMCH ADR ALERT: SEPTEMBER 2026

'Pharmacovigilance - Passive Surveillance'

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ADR PULSE RADAR : SEPTEMBER 2026

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VMCH ADR MONITORING CENTER: Vol.1, Issue 9

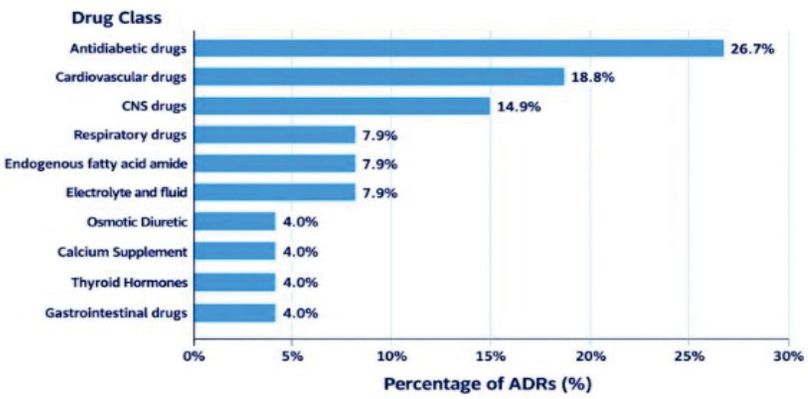
VMCH ADR SUMMARY

TOTAL ADR : 26
MOST COMMON : ANTIDIABETIC DRUGS (27%)

SERIOUS CASES : NIL

ADRs INVOLVED

Antidiabetic drugs (27%), Cardiovascular drugs (19%), CNS drugs (15%), Respiratory drugs (8%), Endogenous fatty acid amide (8%), Electrolyte and fluid (8%), Osmotic diuretic (4%), Calcium supplement (4%), Thyroid hormone (4%), Gastrointestinal drugs (4%).



IF ANY ADR, SCAN AND REPORT HERE

Email Id: vmchadr@gmail.com

FDA ANNOUNCEMENT

FDA Takes Steps to Maintain Newborn Access to Life-Saving Starter Nutrition Products

FDA announced measures to address a potential supply gap of neonatal starter parenteral nutrition (PN), which provides essential nutrients intravenously to premature and critically ill newborns who cannot receive adequate nutrition by mouth or feeding tube.

The FDA issued temporary regulatory and enforcement policies for certain facilities that compound starter PN products to help hospitals maintain access to these critical products while longer-term solutions are identified. FDA will continue to monitor supply needs and take further action if required.

REFERENCES

1.https://nutritioncare.org/

2.https://www.fda.gov/drugs/novel-drug-approvals-fda/novel-drug-approvals-2026.

GOPIKAA SHRI M S
V PHARM D

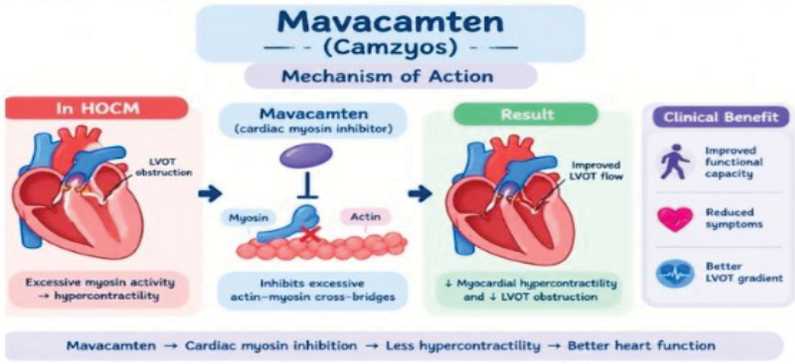
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FDA DRUG INFORMATION

Camzyos- Mavacamten

The U.S. Food and Drug Administration (FDA) has approved Camzyos (mavacamten) capsules for the treatment of adults with symptomatic NYHA class II–III obstructive hypertrophic cardiomyopathy (oHCM) to improve functional capacity and symptoms. Mavacamten is the first-in-class cardiac myosin inhibitor. It reduces excessive actin–myosin cross-bridge formation, thereby decreasing myocardial hypercontractility and improving left ventricular outflow tract obstruction. Clinical trials demonstrated improvements in functional capacity and symptoms compared with placebo. The most important adverse effect is heart failure due to systolic dysfunction, and therefore regular assessment of left ventricular ejection fraction is required. Mavacamten is available under the CAMZYOS REMS because of the risk of heart failure. It also has clinically important interactions with CYP2C19 and CYP3A4 inhibitors and inducers.





- Oral bioavailability: ≥85%
- Tmax: approximately 1 hour
- Protein binding: 97–98%
- Half-life in CYP2C19 normal metabolizers: approximately 6–9 days
- Half-life in CYP2C19 poor metabolizers: approximately 23 days
- Metabolism: primarily CYP2C19, followed by CYP3A4 and CYP2C9.

REFERENCES

1. U.S. Food and Drug Administration. FDA approves new drug to improve heart function in adults with rare heart condition. Silver Spring (MD): U.S. Food and Drug Administration; 2022 Apr 28.
2. U.S. Food and Drug Administration. Drug Trials Snapshots: CAMZYOS (mavacamten). Silver Spring (MD): FDA; 2022.
3. U.S. Food and Drug Administration. CAMZYOS (mavacamten) prescribing information. Silver Spring (MD): FDA.

-LAKSHAYA P - PharmD Intern

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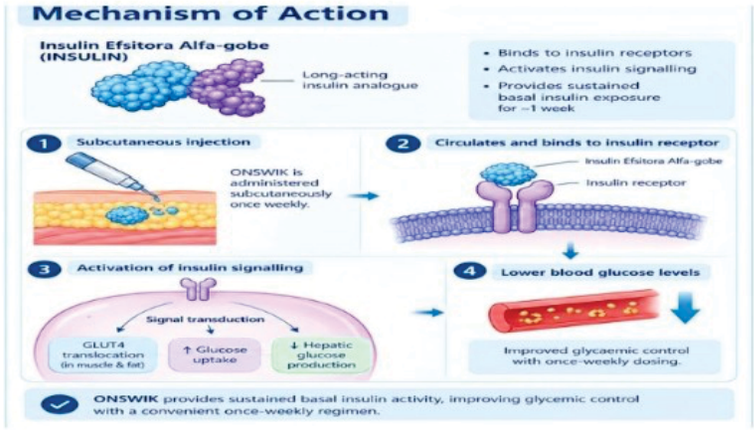
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FDA DRUG INFORMATION

ONSWIK (insulin efsitora alfa-gobe)

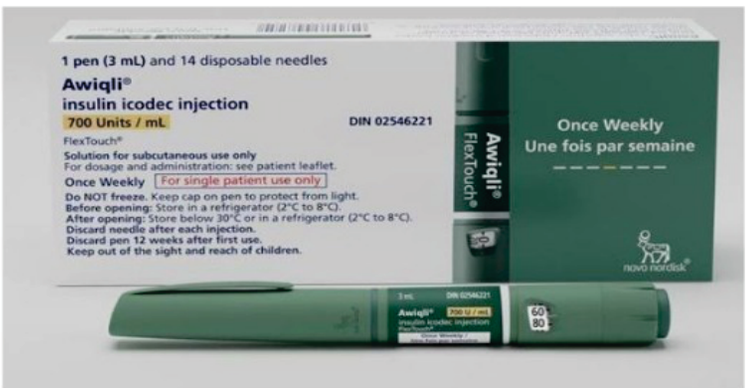
The U.S. Food and Drug Administration (FDA) has approved ONSWIK (insulin efsitora alfa-gobe) injection, a long-acting insulin analogue, as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. ONSWIK is administered by subcutaneous injection once weekly on the same day each week, providing a less frequent alternative to once-daily basal insulin therapy. In clinical trials, ONSWIK produced reductions in HbA1c comparable with once-daily basal insulin comparators. Its prolonged basal insulin activity is designed to provide glycemic control throughout the week. Important safety considerations include hypoglycemia, hypersensitivity reactions, injection-site reactions, lipodystrophy, pruritus, rash, edema, weight gain, and hypokalemia. ONSWIK is not recommended for patients with type 1 diabetes mellitus because of the risk of severe hypoglycemia.



One of the most important points for a presentation is its **prolonged half-life.**

Earlier clinical pharmacology studies reported a mean half-life of approximately **17 days,** with maximum concentration occurring around day 4 after administration. The concentration profile was relatively flat across the weekly interval.

This prolonged exposure is one of the reasons efsitora can be administered once weekly rather than every day.



REFERENCES

1. U.S. Food and Drug Administration. FDA approves once-weekly insulin for type 2 diabetes mellitus. Silver Spring (MD): U.S. Food and Drug Administration; 2026 Sep 24.
2. U.S. Food and Drug Administration. Onswik (insulin efsitora alfa-gobe) injection: BLA 761408 approval letter. Silver Spring (MD): U.S. Food and Drug Administration; 2026 Sep 24.

LAVANYA E -PharmD Intern

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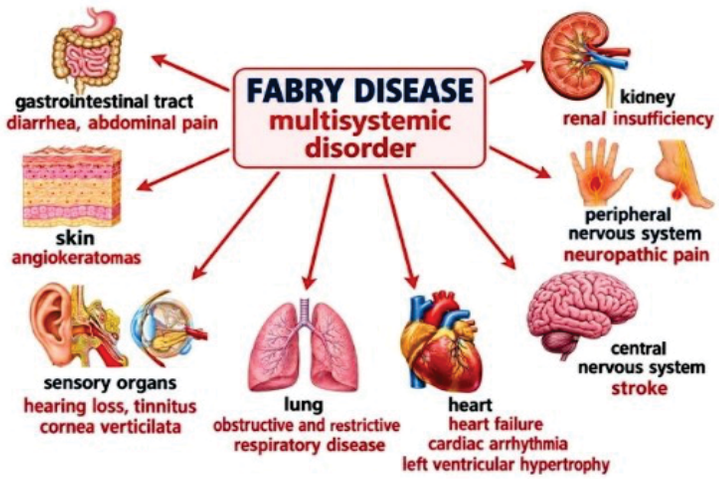
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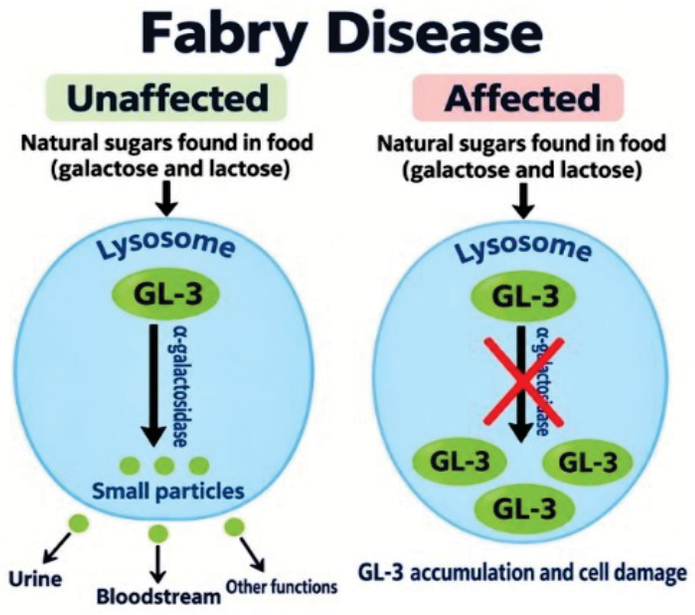
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FABRY DISEASE

SHORT COMMUNICATION



Fabry disease is a rare inherited lysosomal storage disorder caused by mutations in the GLA gene, resulting in deficiency of the enzyme α-galactosidase A and accumulation of glycolipids in various tissues.



CASE REPORT

A 24-year-old male presented with recurrent burning pain in his hands and feet, reduced sweating, fatigue, and multiple small reddish-purple skin lesions since adolescence. Clinical examination revealed characteristic angiokeratomas over the trunk and extremities. Laboratory investigations showed markedly reduced α-galactosidase A enzyme activity, and genetic testing confirmed a pathogenic mutation in the GLA gene. Based on the clinical, biochemical, and genetic findings, the patient was diagnosed with Fabry disease. The patient was managed with enzyme replacement therapy, symptomatic treatment, and regular monitoring of renal, cardiac, and neurological functions. Genetic counselling was provided to the patient and family members. Pharmacist interventions included patient education regarding treatment adherence, monitoring for adverse effects, counselling about enzyme replacement therapy, and ensuring regular follow-up.

SUMMARY

This case highlights the importance of early recognition, appropriate diagnostic testing, genetic counselling, and multidisciplinary management to prevent progressive organ damage and improve the quality of life of patients with Fabry disease.

- B. GOWTHAMI, R. HEMALATHA
V- PHARM. D

ADR CASE

Tab.Palmitoylethanolamide induced DYSPEPSIA IN A PATIENT DIAGNOSED WITH NEUROPATHIC PAIN



PATIENT DETAILS

Age	: 43 Years
Gender	: Male
Suspected Drug	: Tab. Palmitoylethanolamide
Suspected Reaction:	Dyspepsia
Drug Started Date	: 13.05.2026
Date of Reaction	: 22.09.2026
Drug Stopped Date	: 24.09.2026
Causality Assessment:	Probable/Likely (WHO-UMC)

CAUSALITY ASSESSMENT

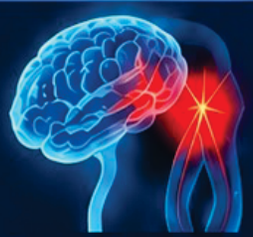
PROBABLE/LIKELY (WHO-UMC)

OUTCOME

RECOVERED

MANAGEMENT

Tab. Palmitoylethanolamide was discontinued.



Generalized Pain



T.Palmitoylethanolamide (Tablet)



Dyspepsia (Indigestion / Stomach upset)



Drug stopped



Symptomatic Treatment

Patient Safety | Rational Drug Use | Pharmacovigilance





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"Vidhya Rathna"

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