



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: MAY 2026 'Pharmacovigilance - Passive Surveillance'

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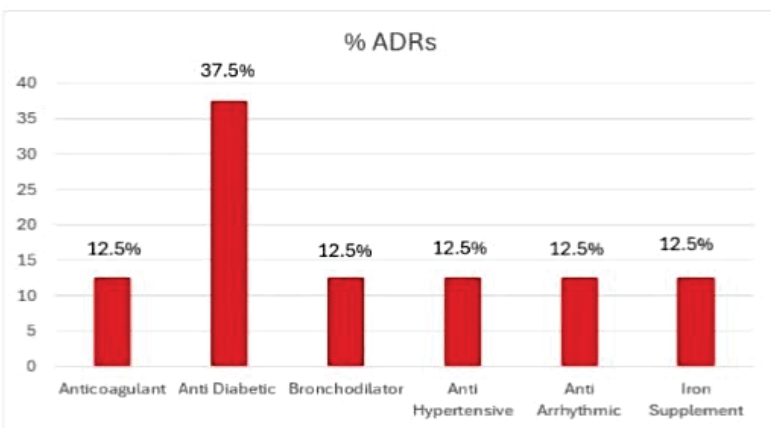
PATRON : PROF. Dr. M. KARUNANITHI, B.PHARM., M.S., PH.D., D.LITT.,

VMCH ADR SUMMARY

Total ADR : 08
Most Common : Anti Diabetic
drugs (37.5%)
Serious Cases : NIL

ADRs INVOLVED

Anti-diabetic drug - 37.5%, Anticoagulant- 12.5%,
Bronchodilator- 12.5%, Anti-Hypertensive drugs
-12.5%, Anti Arrhythmic drug- 12.5%, Iron
Supplement- 12.5%



IF ANY ADR, SCAN AND REPORT HERE



Email Id: vmchadr@gmail.com

FDA ANNOUNCEMENT

FOR IMMEDIATE RELEASE MUMBAI, INDIA and PRINCETON, NJ - **May 13, 2026** – Sun Pharma is voluntarily recalling within the U.S. to the hospital/user level, one batch of DOXOrubicin Hydrochloride Liposome Injection 50mg/25 mL, Lot # HAG2581B, Expiration 05/2027 (675 vials). The single batch of 675 vials is being recalled due to the detection of glass particles in some vials during production.

If glass particles are administered intravenously, they may pose a risk to patient safety including local irritation or swelling in response to the foreign material. More serious potential risks could include blockage of blood vessels and life-threatening blood clot events. To date, Sun Pharma has not received any reports of adverse events related to this batch. Sun Pharma has thoroughly investigated the source of the problem and has taken corrective and preventative actions.

REFERENCE

1. <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sun-pharmaceutical-industries-inc-sun-pharma-initiates-voluntary-us-nationwide-recall-doxorubicin>.

FDA DRUG INFORMATION

HEPCLUDEX [MAY 22, 2026]

The U.S. Food and Drug Administration approved Hepcludex (bulevirtide-gmod) injection to treat chronic hepatitis delta virus (HDV) infection in adults without cirrhosis (advanced liver scarring) or with compensated cirrhosis. **Bulevirtide** is the first FDA-approved treatment for **chronic HDV infection**, a serious and life-threatening condition that can cause rapid development of liver fibrosis (scarring), liver cancer, liver failure, and even death.



Possible side effects associated with Hepcludex include hypersensitivity reactions, including anaphylaxis (severe allergic reactions), injection site reactions, headache, abdominal pain, fatigue, and pruritus (itching). The labeling includes a boxed warning that discontinuation of Hepcludex may result in severe acute exacerbations of HDV and HBV infection.

The U.S. Food and Drug Administration issued a draft guidance to reduce unnecessary animal testing in nonclinical safety assessments for certain cancer drugs.

The guidance will provide recommendations for general toxicology studies, including when animal testing may be unnecessary because there is no binding or pharmacologic activity. In some cases, the guidance recommends using rodent studies only or replacing three-month non-human primate studies with a weight-of-evidence risk assessment.

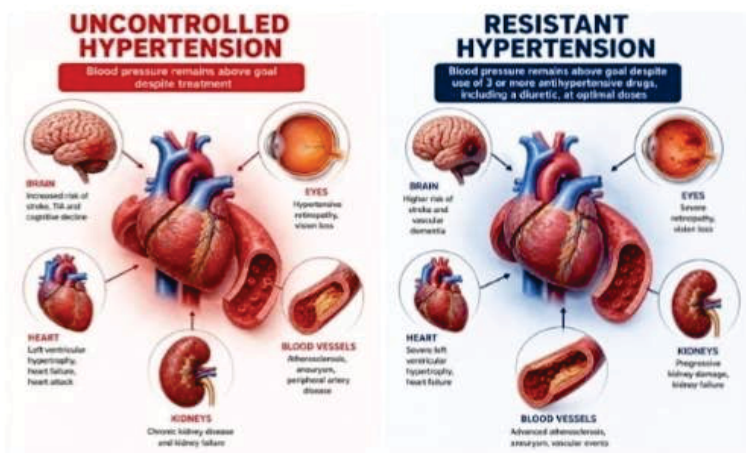


REFERENCES

1. <https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-chronic-hepatitis-delta-virus-hdv-infection>.
2. <https://www.fda.gov/news-events/press-announcements/fda-issues-draft-guidance-cut-unnecessary-animal-testing-cancer-drugs>

FDA DRUG INFORMATION

BAXFENDY (Baxdrostat)



Baxdrostat works by selectively blocking the CYP11B2 (aldosterone synthase) enzyme, helping to reduce excess aldosterone without significantly affecting cortisol production. This mechanism may provide benefit in patients with resistant hypertension who are inadequately controlled with conventional therapies.

The Phase 3 BaxHTN trial demonstrated that baxdrostat significantly reduced systolic blood pressure compared with placebo in patients with resistant hypertension. Researchers highlighted its potential role as a promising future therapy for difficult-to-control hypertension. This update highlights the importance of pharmacovigilance and continued monitoring of investigational cardiovascular therapies to identify potential adverse drug reactions and ensure patient safety during clinical use.

The U.S. Food and Drug Administration is currently evaluating Baxdrostat, a novel drug used in the treatment of resistant and uncontrolled hypertension. Baxdrostat is an aldosterone synthase inhibitor that reduces aldosterone production, thereby lowering blood pressure and decreasing fluid retention.

Clinical studies demonstrated significant reduction in systolic blood pressure in patients receiving Baxdrostat along with standard antihypertensive therapy. Reported adverse reactions included hyperkalemia, dizziness, hypotension, and mild renal function changes. Regular monitoring of serum potassium and renal parameters is recommended during treatment.



REFERENCE

- 1.Center for Drug Evaluation and Research. FDA Update: Agency Approves Baxdrostat to Treat Adults With Hypertension. U.S. Food and Drug Administration. 2026. Available from: American College of Cardiology FDA Update on Baxdrostat.

-Abinaya S, Abitha P, Anupama Sankar
Pharm D Intern

DRESS SYNDROME INDUCED BY PHENYTOIN

SHORT COMMUNICATION

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) syndrome is a rare but severe hypersensitivity reaction associated with several drugs, particularly anticonvulsants such as phenytoin. It is characterized by fever, widespread skin rash, eosinophilia, lymphadenopathy, and involvement of internal organs including liver, kidneys, and lungs. Early recognition and withdrawal of the offending drug are essential to reduce morbidity and mortality.



SUMMARY

This case highlights the importance of early identification of DRESS syndrome associated with phenytoin therapy. Prompt withdrawal of the offending agent, timely medical management, and multidisciplinary care play a vital role in improving patient outcomes and preventing serious complications.

CASE REPORT

A 34-year old female patient with a history of **seizure disorder** was admitted to the hospital with complaints of high-grade fever, diffuse erythematous rash, facial oedema, itching, and generalised weakness for 5 days. The patient had started phenytoin therapy three weeks earlier for newly diagnosed epilepsy.

Laboratory investigations revealed eosinophilia, elevated liver enzymes, and mild renal impairment. Clinical findings along with laboratory parameters confirmed the diagnosis of phenytoin-induced DRESS syndrome. Phenytoin was immediately discontinued, and the patient was treated with systemic corticosteroids, antihistamines, intravenous fluids, and supportive care.

The patient showed gradual clinical improvement within two weeks with reduction in rash, normalisation of eosinophil count, and improvement in liver function tests. Clinical pharmacist interventions included adverse drug reaction monitoring, patient counselling, medication review, and reporting to the pharmacovigilance centre.

-Christy Immaculate. J, Gayathri. M
PHARM. D INTERN



ADR CASE

ORCIPRENALINE INDUCED HYPOKALEMIA



PATIENT DETAILS



Age : 60



Sex : Female



Drug Name : Tab.Orciprenaline



Dose : 10 mg



Route : PO



Frequency : BD



Drug Started On : 18.05.26



Drug Stopped On : 21.05.26



Date of Reaction : 22.05.26

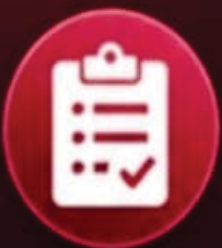


CAUSALITY

WHO-UMC
(PROBABLE/LIKELY)



OUTCOME
RECOVERING



MANAGEMENT

Syp.KCL 15 mL
TDS



DIAGNOSIS
COMPLETE HEART BLOCK



VIVEKANANDHA EDUCATIONAL INSTITUTIONS



"Vidhya Rathna"

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

TIRUCHENGODE CAMPUS

- ★ SWAMY VIVEKANANDHA MEDICAL COLLEGE HOSPITAL AND RESEARCH INSTITUTE
- ★ 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
- ★ VIVEKANANDHA COLLEGE OF ENGINEERING FOR WOMEN (AUTONOMOUS)
- ★ VIVEKANANDHA COLLEGE OF TECHNOLOGY FOR WOMEN
- ★ VIVEKANANDHA INSTITUTE OF INFORMATION AND MANAGEMENT STUDIES
- ★ VIVEKANANDHA COLLEGE OF ARTS AND SCIENCES FOR WOMEN (AUTONOMOUS)
- ★ VIVEKANANDHA COLLEGE FOR WOMEN
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- ★ VIVEKANANDHA VIDHYA BHAVAN MATRIC HIGHER SECONDARY SCHOOL
- ★ VIDYAA VIKAS MATRIC HIGHER SECONDARY SCHOOL (MOREPALAYAM)
- ★ VIVEKANANDHA MEDICAL CARE HOSPITAL (VMCH)

SANKAGIRI CAMPUS

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- ★ VIVEKANANDHA NURSING COLLEGE FOR WOMEN
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