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INSTITUTE OF MEDICAL SCIENCES
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CLINIMED INSIGHTS

AMALA INSTITUTE OF MEDICAL SCIENCES
THRISSUR

An initiative by

THE DEPT. OF CLINICAL PHARMACY

Amala Institute of Medical Sciences

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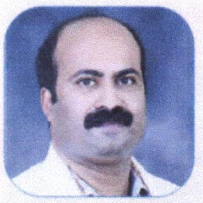

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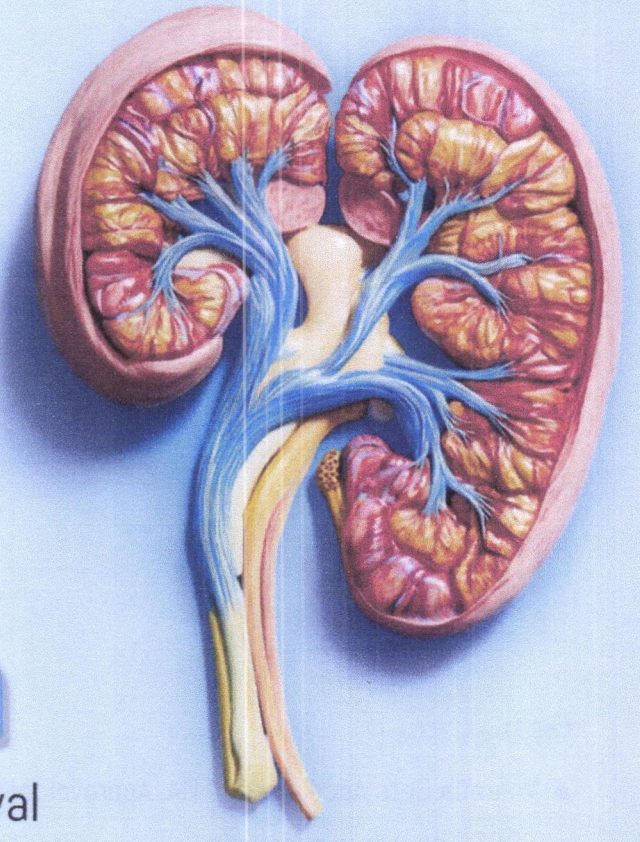


Vanrafia

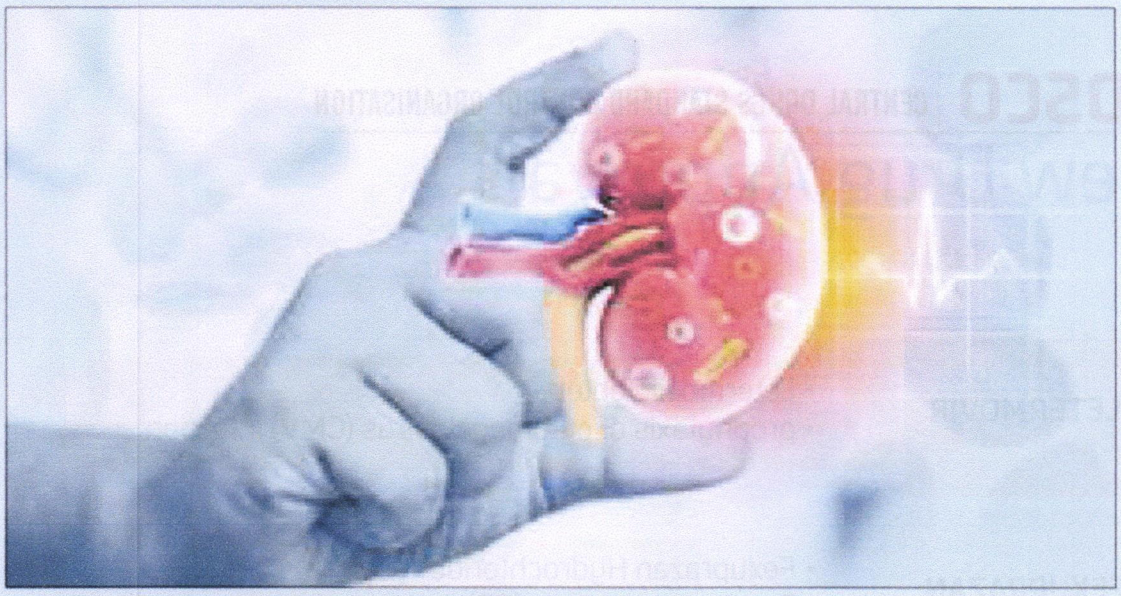
Gets Accelerated FDA Approval for Immunoglobulin A Nephropathy

"A Promising Step Forward in Slowing IgA Nephropathy Progression"

The Food and Drug Administration (FDA) has granted accelerated approval to Vanrafia (atrasentan) to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5g/g.

The pathogenesis of IgAN is believed to be driven by the endothelin (ET)-1 peptide through the ETA receptor. Atrasentan, an endothelin receptor antagonist, is expected to reduce proteinuria in IgAN due to its high selectivity for the ETA receptor compared with the ETB receptor.
Vanrafia is supplied as a 0.75mg tablet. The prescribing information for Vanrafia includes a Boxed Warning for embryo-fetal toxicity; the product is contraindicated for use in pregnant patients. The most common adverse reactions reported with treatment were peripheral edema and anemia.

The accelerated approval of atrasentan was based on the randomized, double-blind, placebo-controlled ALIGN trial (ClinicalTrials.gov Identifier: NCT04573478), which enrolled adults with biopsy-proven primary IgAN, an estimated glomerular filtration rate (eGFR) of at least 30mL/min/1.72m2, and a urine protein of at least 1g/day on a stable dose of maximally tolerated renin angiotensin system (RAS) inhibitor. The study included a main cohort and an exploratory cohort, which included patients taking a stable dose of sodium-glucose cotransporter 2 inhibitor (SGLT2i).



Study participants were randomly assigned 1:1 to receive atrasentan 0.75mg or placebo once daily alongside supportive care (maximum tolerated and stable RAS inhibitor). The primary endpoint was the percent reduction in UPCR (sampled from a 24-hr urine collection) at week 36 compared with baseline.

The efficacy analysis was based on the first 270 patients in the main cohort who reached the 36 week visit. Findings showed treatment with atrasentan reduced UPCR by 38% (95% CI, 32-44) compared with 3% (95% CI, -7, 12) for placebo at week 36 (difference, 36% [95% CI, 26-45]; P <.0001).

The treatment effect on UPCR was consistent across all subgroups including age, sex, race, and baseline disease characteristics, as well as in the exploratory SGLT2i cohort.

CDSCO | CENTRAL DRUGS STANDARD CONTROL ORGANISATION

New Drug Approvals

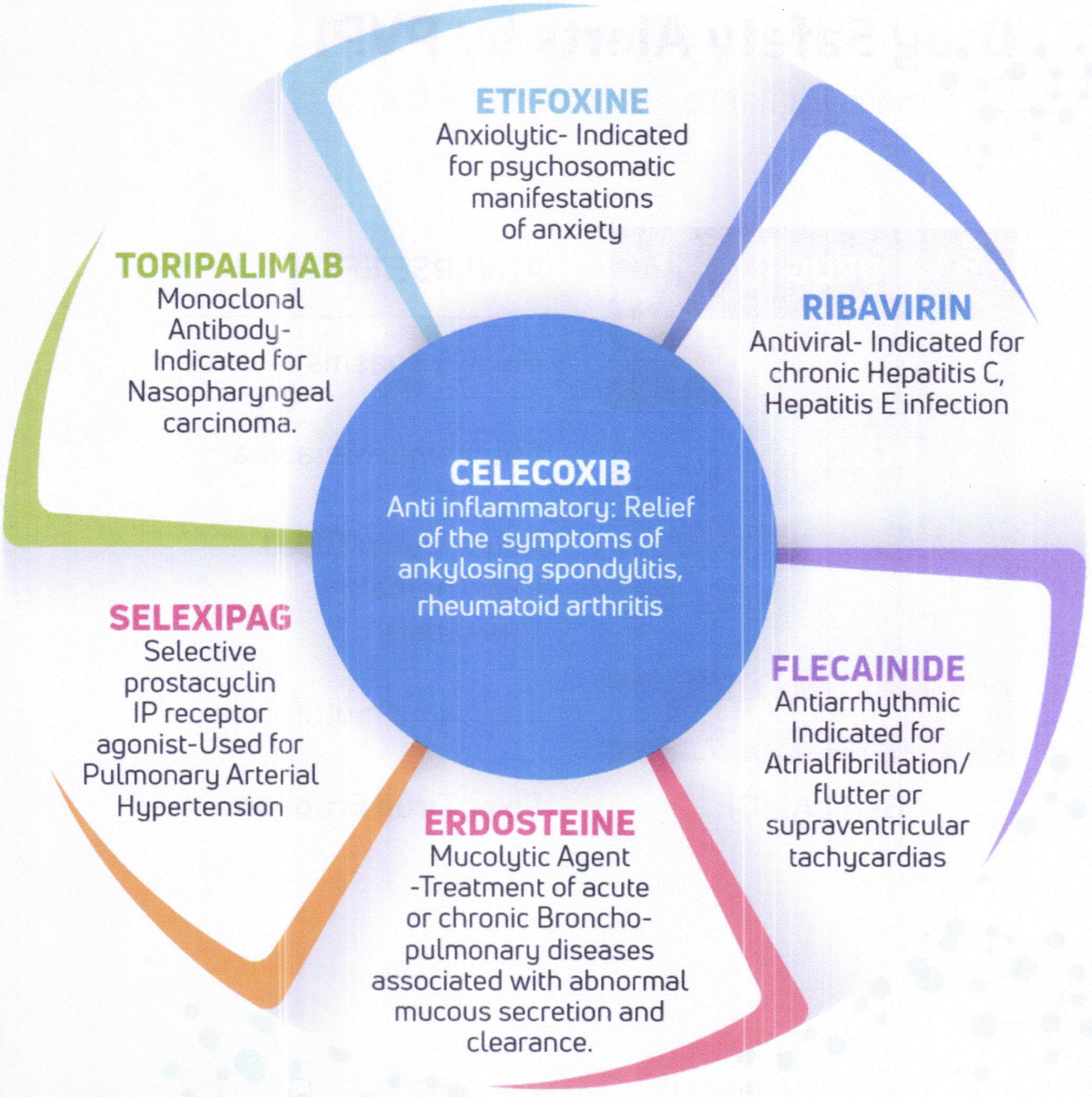
LETERMOVIR	• Letermovir Tablet • prophylaxis of cytomegalovirus (CMV) infection
FEXUPRAZAN	• Fexuprazan Hydrochloride Tablet • Erosive esophagitis (EE)
EDOXABAN	• Edoxaban Tablet • Stroke, Systemic embolism
RIMEGEPANT	• Edoxaban Tablet • Stroke, Systemic embolism
DORAVIRINE	• Rimegepant Oral disintegrating tablet • Migraine
TUCATINIB	• Doravirine Tablet • HIV-1 infection
ZANUBRUTINIB	• Zanubrutinib capsule • Mantle cell lymphoma • Waldenstrom's macrogloubulinemia

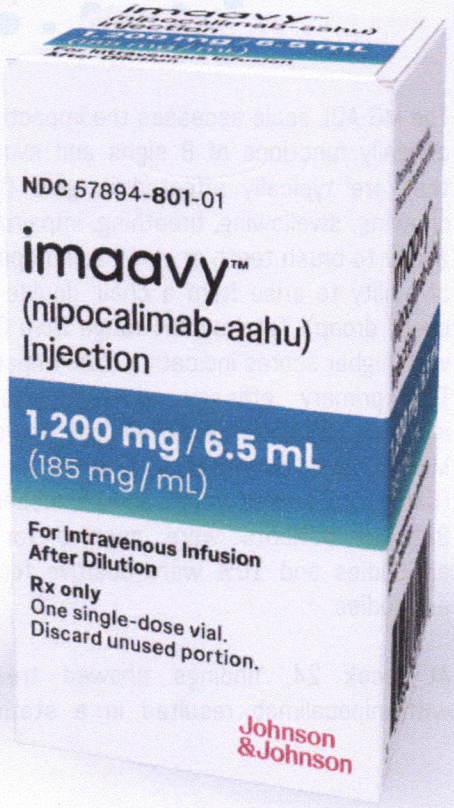
Drug Safety Alerts by PVPI

(Pharmaco Vigilance Programme of India)

DRUG	ADVERSE EFFECT
DALTEPARIN	Muscle spasms
LULICONAZOLE	Chloasma/Melasma
METRONIDAZOLE	Acute Generalised Exanthematous Pusiulosis
GLICLAZIDE	Erythema multiforme
GLICLAZIDE	Fixed Drug Eruption

NEW MOLECULES @ AMALA





Imaavy

Approved for Generalized Myasthenia Gravis

"A NEW SUBCUTANEOUS OPTION FOR ACHR ANTIBODY-POSITIVE GMG PATIENTS"

The Food and Drug Administration (FDA) has approved Imaavy (nipocalimab) for the treatment of generalized myasthenia gravis (gMG) in adult and pediatric patients aged 12 years and older who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

Imaavy is supplied as a 300mg/1.62mL and 1200mg/6.5mL single-dose vial. Prior to beginning treatment, patients should be evaluated for the need to administer-age appropriate vaccines; vaccination with live vaccines during treatment is not recommended.

Treatment is administered every 2 weeks via IV infusion after dilution. The initial dose should be infused over at least 30 minutes; subsequent maintenance doses are infused over at least 15 minutes.

Nipocalimab is a human immunoglobulin G1 (IgG1) monoclonal antibody that binds with high affinity to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG levels. The approval was supported by data from the randomized, double-blind, placebo-controlled phase 3 Vivacity-MG3 study (ClinicalTrials.gov Identifier: NCT04951622), which who had an insufficient response (defined as Myasthenia Gravis – Activities of Daily Living [MG-ADL] score of at least 6) to ongoing standard of care therapy.

Study participants were randomly assigned to receive nipocalimab (n=98) or placebo (n=98) by intravenous (IV) infusion once every 2 weeks. The primary endpoint was the comparison of the mean change from baseline to weeks 22, 23, and 24 between treatment groups in the MG-ADL total score.

The MG-ADL scale assesses the impact of gMG on daily functions of 8 signs and symptoms that are typically affected in gMG (talking, chewing, swallowing, breathing, impairment of ability to brush teeth or comb hair, impairment of ability to arise from a chair, double vision, eyelid droop). Total scores range from 0 to 24 with higher scores indicating more impairment. The primary efficacy analysis population included 153 patients. At baseline, the median MG-ADL and Quantitative Myasthenia Gravis (QMG) total scores were 9 and 15, respectively; 88% of patients were positive for AChR antibodies and 10% were positive for MuSK antibodies.

At week 24, findings showed treatment with nipocalimab resulted in a statistically significant improvement in MG-ADL total score compared with placebo (-4.7 vs -3.3; least squares [LS] mean difference, -1.5 [95% CI, -24, -0.5]; P =.002). Efficacy was also measured using QMG total score (secondary endpoint; range: 0-39, with higher scores indicating more severe impairment). A statistically significant difference favoring nipocalimab was observed in the QMG total score change from baseline (-4.9 vs -2.1; LS mean difference, -2.8 [95% CI, -4.2, -14]; P <.001).

The most common adverse reactions reported with treatment were respiratory tract infections, peripheral edema, and muscle spasms. In clinical trials, infections, hypersensitivity reactions, and infusion-related reactions were observed in patients who received nipocalimab.

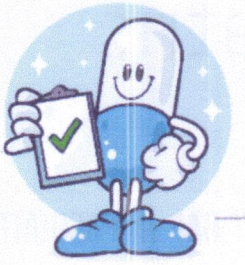
FDA Approves First-Ever **ORAL HYDROCORTISONE SOLUTION** for Paediatric Adrenal Insufficiency

"LIQUID HYDROCORTISONE BRIDGES CRITICAL TREATMENT GAP IN PAEDIATRICS"

The FDA has approved the New Drug Application (NDA) for Khindivi —the first oral hydrocortisone solution approved in the U.S.—for use as replacement therapy in pediatric patients aged 5 years and older with adrenocortical insufficiency.

This ready-to-use 1 mg/mL oral solution eliminates the need to crush or split tablets, offering a convenient and precise dosing option for children. Unlike traditional tablet forms, Khindivi does not require refrigeration, mixing, or shaking, and is especially beneficial for patients with swallowing difficulties or special administration needs.

Dr. Kyriakie Sarafoglou, a pediatric endocrinology expert at the University of Minnesota, highlighted the importance of accurate and flexible dosing in children during key growth phases. "The availability of this FDA-approved oral solution allows physicians to tailor hydrocortisone therapy to the unique needs of each child," she said.



KNOW YOUR DRUG-DRUG INTERACTION

CLARITHROMYCIN
(CYP3A4 inhibitor)
[Macrolide Antibiotic]

SILODOSIN
(Alpha Blocker)

INTERACTION- Increase Serum Silodosin concentration.

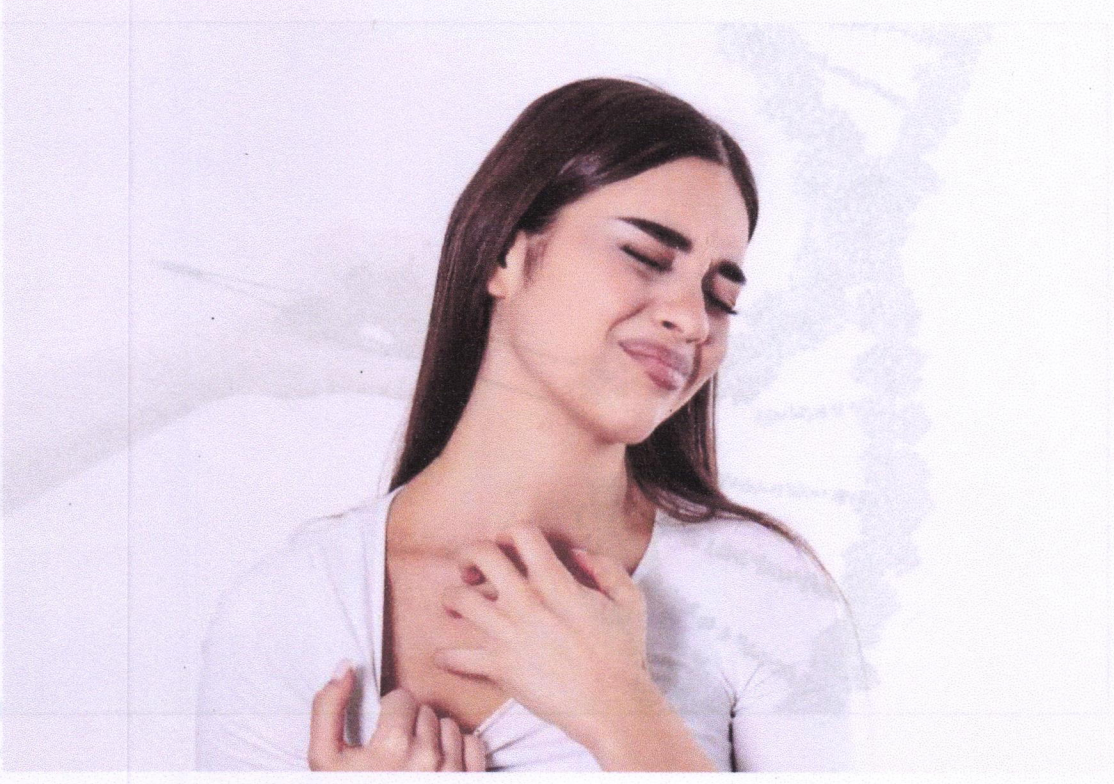
MECHANISM- Inhibition of CYP3A4 mediated metabolism

Use alternative antibiotics that do not inhibit CYP3A4.

FDA SAFETY ALERT:

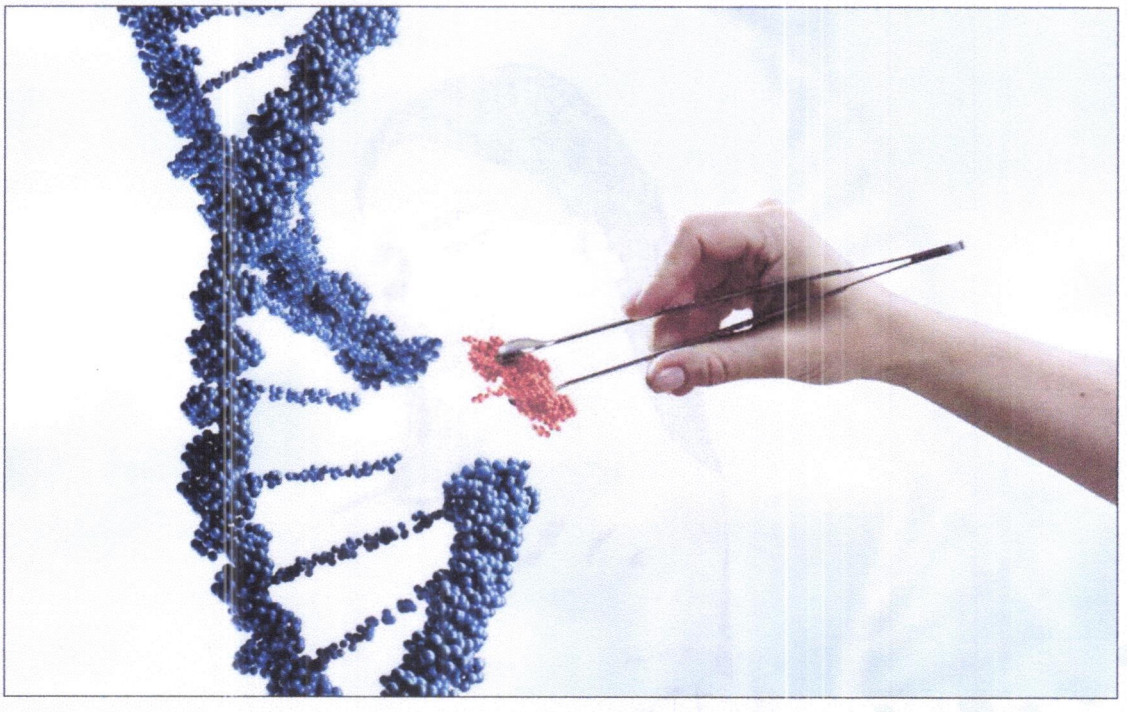
RISK OF SEVERE ITCHING AFTER DISCONTINUING LONG-TERM CETIRIZINE OR LEVOCETIRIZINE

"DISCONTINUATION MAY TRIGGER REBOUND ITCHING IN LONG-TERM USERS"



The U.S. FDA has issued a safety communication warning of rare but severe generalized itching (pruritus) following the discontinuation of long-term use of cetirizine or levocetirizine, commonly used second-generation H1-antihistamines. This distressing symptom, typically beginning within days to weeks after stopping the drug, occurs without visible skin lesions, is not allergic in nature, and may persist for weeks or even months, sometimes prompting patients to restart the medication for relief. In light of post-marketing reports, the FDA now requires updates to prescribing information and patient Medication Guides to reflect this risk. Healthcare professionals are advised to identify patients on long-term therapy, avoid abrupt discontinuation, consider tapering doses, and manage symptoms with supportive care. Patients should be counseled on this potential effect, advised not to stop medication suddenly, and encouraged to consult their provider if itching develops.

CRISPR: A NEW ERA IN CANCER RESEARCH AND TREATMENT



CRISPR, a revolutionary gene-editing technology, is significantly transforming cancer research and treatment. Derived from a natural bacterial immune system, CRISPR enables scientists to make precise changes to DNA. The technology uses a guide RNA to direct the Cas9 enzyme to a specific location in the genome, where it introduces a cut, allowing for the deletion, insertion, or modification of genetic material.

In cancer research, CRISPR is proving indispensable in identifying the genes involved in tumor development and drug resistance. By selectively disabling genes in cancer cells, researchers can better understand which genetic changes drive cancer progression. This insight is leading to the identification of new therapeutic targets and biomarkers, which could result in more effective diagnostics and treatments.

CLINICIAN'S INSIGHTS ON CRISPR

A Perspective by
Dr. Sunu Cyriac
Medical Oncologist and BMT specialist
Amala Institute of Medical Sciences

It basically tries to go into the core of the problem which lies in the DNA and tries to repair that DNA to correct the errors which led to the disease. This is also used in various other fields also, but the most important implications is coming in health care, And CAR-T cell therapy is a form of immunotherapy that has been recently approved for haematological diseases. CAR-T cell therapy is improving every year to increase its effects and reduce its side effects. One of the main ways by which this would be possible soon in the future would be by incorporation or by the marriage of CRISPR technology with CAR-T cells.. So this is really a promising area for patients with haematological malignancies.

CRISPR is also enhancing how scientists model cancer in the lab. Traditional cancer models often fall short in replicating human disease. CRISPR allows researchers to engineer cell lines and animal models with specific mutations found in patients, leading to more accurate studies of tumor biology and drug responses. On the therapeutic front, CRISPR is making major strides, particularly in the field of immunotherapy. Scientists are using the technology to edit immune cells—especially T cells—to improve their ability to recognize and attack cancer. For instance, in CAR-T cell therapy, CRISPR has been used to remove genes that may limit the T cells' effectiveness or to add genes that enhance their cancer-killing abilities.

Early clinical trials using CRISPR-edited immune cells have shown promising results, with edited cells persisting in patients and producing limited side effects. However, challenges remain, including concerns about unintended "off-target" gene edits, potential immune reactions, and ethical considerations—particularly when it comes to editing human embryos or germline cells.

Despite these hurdles, CRISPR continues to evolve. New techniques like base editing and prime editing are being developed to improve precision and safety. As the technology matures, it holds immense potential not only for understanding cancer at a deeper level but also for creating highly personalized, gene-targeted therapies that could revolutionize cancer treatment.

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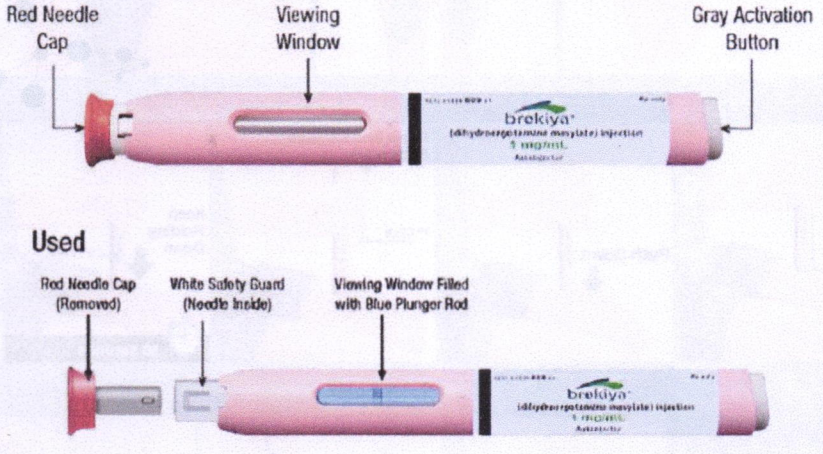
FDA APPROVES BREKIYA:

First Self-Administered DHE Autoinjector for Acute Migraine and Cluster Headache Treatment

"FAST, PORTABLE RELIEF FOR MIGRAINE AND CLUSTER HEADACHE SUFFERERS"

The FDA has approved Brekiya (dihydroergotamine mesylate) injection, developed by Amneal Pharmaceuticals, marking the first and only autoinjector form of DHE for the acute treatment of migraine with or without aura and cluster headaches in adults.

Brekiya delivers a ready-to-use, single-dose subcutaneous injection, offering patients a



convenient, self-administered alternative to hospital or ER-based DHE treatments. Unlike IV formulations commonly used in emergency settings, Brekiya requires no refrigeration, assembly, or priming, making it accessible for use during acute headache attacks.

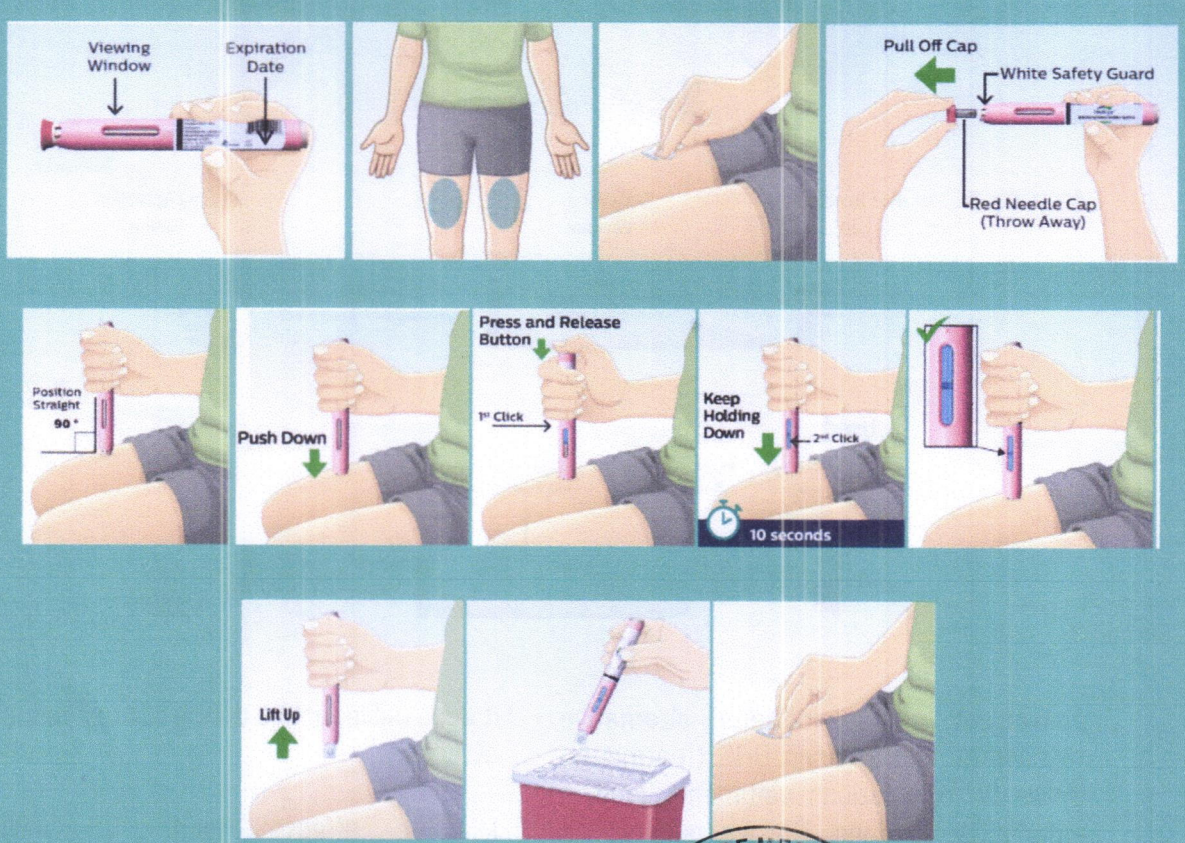
Migraine affects nearly 39 million Americans, and cluster headaches impact

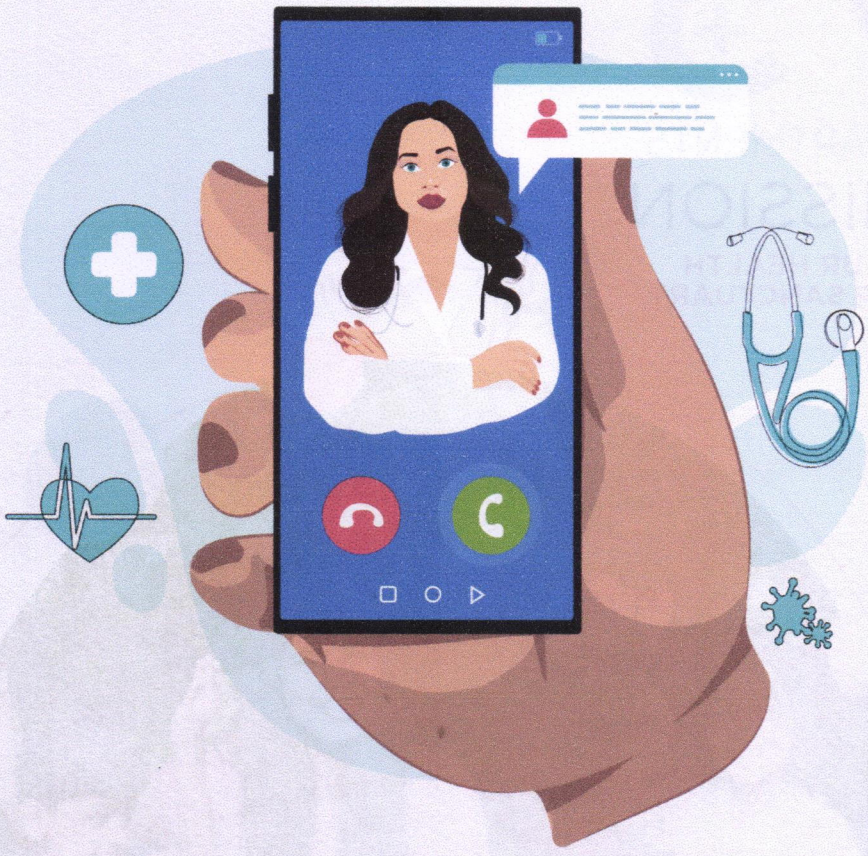
up to 1 million, often resulting in ER visits—where headache is the fourth most common complaint. Brekiya provides a practical option for those who may not respond to oral therapies due to issues such as nausea, vomiting, gastroparesis, or delayed administration.

While Brekiya is a major advancement, it's important to note that it is not indicated for migraine prevention or for types like hemiplegic or basilar migraine, and its safety in pediatric populations has not yet been established.

Brekiya's approval follows another DHE-based innovation: Atzumi, a nasal powder formulation approved in April 2025 for acute migraine treatment in adults. Together, these developments signal a growing focus on portable, user-friendly therapies for managing disabling headache disorders.

Instructions for use





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DEPARTMENT OF CLINICAL PHARMACY

Hot Line No: - 4023

Email: clinicalpharmacy@amalaims.org

Timing: 9:00 am – 5:00 pm

Working days: Monday – Saturday

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in every way

75+
DEPARTMENTS
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