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CLINIMED INSIGHTS

An initiative by

DEPT. OF CLINICAL PHARMACY

Amala Institute of Medical Sciences

AMALA INSTITUTE OF MEDICAL SCIENCES
THRISSUR

Editorial Team

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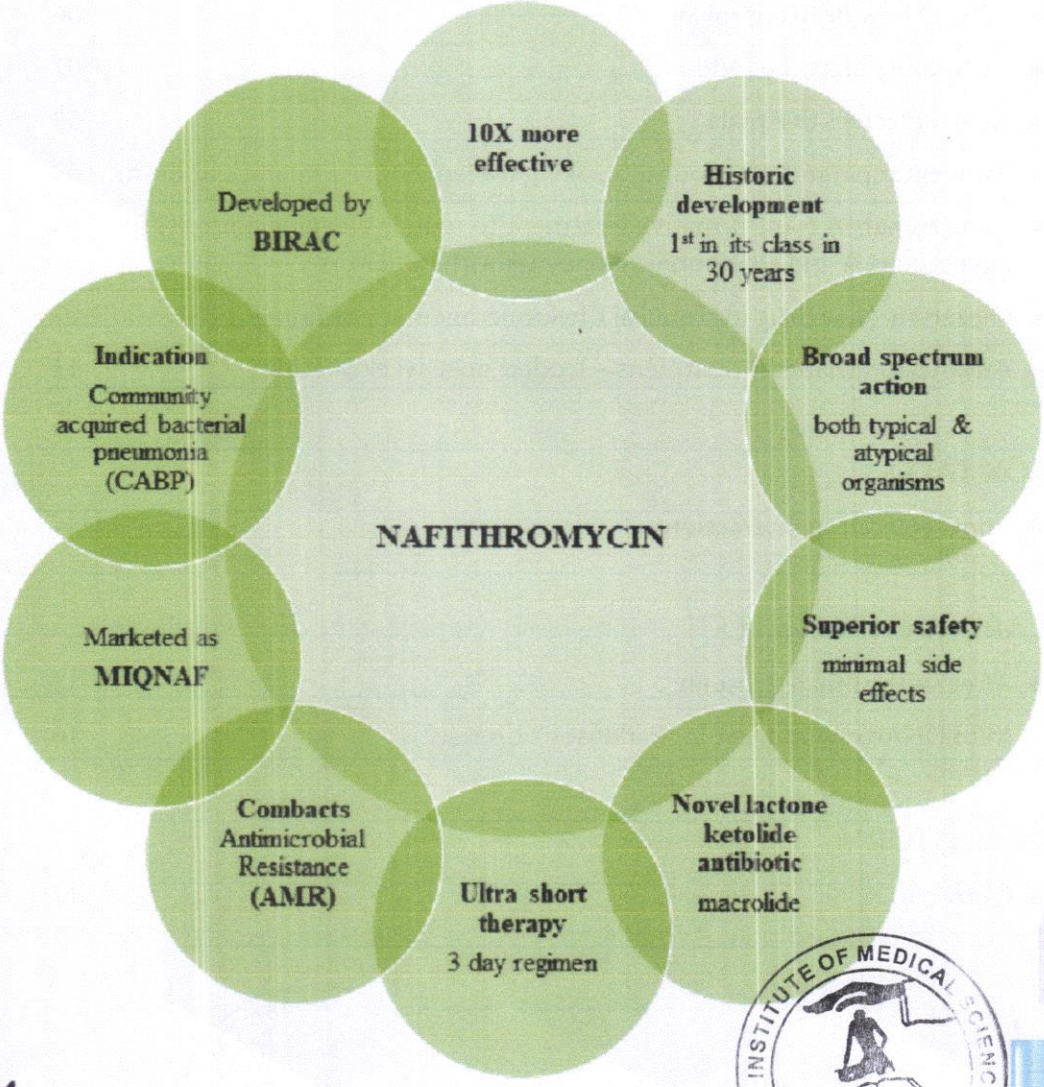
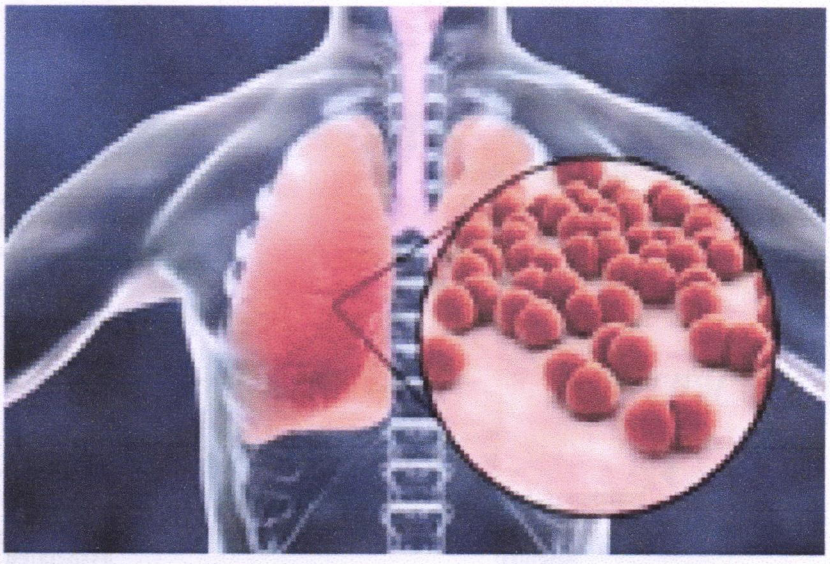
NAFITHROMYCIN:

India's First Indigenous Macrolide Antibiotic

A milestone in combating antimicrobial resistance (AMR)

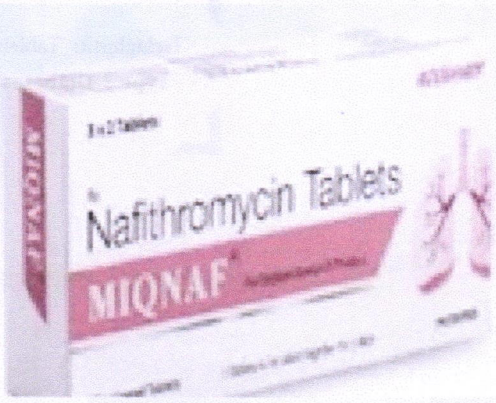


Nafithromycin, developed by Wockhardt with support from the Biotechnology Industry Research Assistance Council (BIRAC), was officially launched on November 20, 2024, by Union Minister Dr. Jitendra Singh. Marketed under the name "Miqnaf," this medication is designed to combat Community-Acquired Bacterial Pneumonia (CABP) caused by drug-resistant bacteria, which particularly affects vulnerable groups, including children, the elderly, and individuals with weakened immune systems.



Nafithromycin is a novel lactone ketolide antibiotic (advanced generation macrolide), which recently entered Phase 3 development in India for the indication of community-acquired bacterial pneumonia (CABP). It overcomes all three of the macrolide resistance mechanisms—Erm, efflux and ribosomal protein mutations in S. pneumoniae. This ground-breaking antibiotic is ten times more effective than current treatments like azithromycin and offers a three-day treatment regimen, significantly shortening the recovery time while improving patient outcomes. Nafithromycin is designed to treat both typical and atypical drug-resistant bacteria, making it a crucial tool in addressing the global health crisis of AMR (Anti-microbial Resistance). It boasts superior safety, minimal side effects, and no significant drug interactions.

Distinctive features of Nafithromycin are ultra-short duration of therapy, oral dosing, high concentration build up in lung i.e. target organ and safety profile. Nafithromycin's development marks a historic milestone as the first new antibiotic in its class to be introduced globally in over 30 years. The drug, which has undergone extensive clinical trials across the U.S., Europe, and India, has been developed with an investment of ₹500 crores and is now awaiting final approval from the Central Drugs Standard Control Organization (CDSCO).



CDSCO (Central Drugs Standard Control Organisation)

NEW DRUG APPROVALS

BRIGATINIB

Brigatinib Tablets

Non-small Cell Lung Cancer

MAVACAMTEN

Mavacamten Capsules

Obstructive Hypertrophic Cardiomyopathy

FERUMOXYTOL

Ferumoxytol Injection

Iron Deficiency Anemia

LUMATEPERONE

Lumateperone Capsules

Depressive episodes associated with Bipolar Disorder

TRELAGLIPTIN

Trelagliptin Tablets

Type 2 Diabetes

BELUMOSUDIL

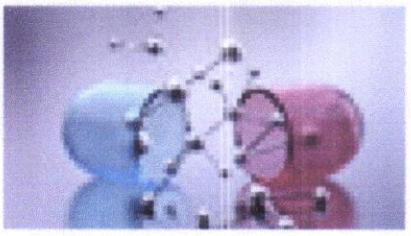
Belumosudil Tablet

Chronic Graft versus Host Disease (cGVHD)

Drug Safety Alerts By PVPI

(Pharmacovigilance Programme of India)

DRUG	ADVERSE EFFECT
Amphotericin B	Hyperkalemia
Carbimazole	Agranulocytosis
Metoprolol, Propranolol, Atenolol	Hypokalemia



New Molecules @ Amala

ABEMACICLIB

- RAMIVEN 150MG TAB
- HR+ and HER2- Advanced/ metastatic breast cancer

AXITINIB

- AXZYB 5MG TAB
- Advanced renal cell carcinoma

APALUTAMIDE

- APNAT 60MG TAB
- Prostate cancer

BRINZOLAMIDE

- BRINOLAR 1% 5ML E/D
- Ocular hypertension/ open-angle glaucoma

DILOXANIDE FUROATE

- AMICLINE 500MG TAB
- Intestinal amebiasis

ELOBIXIBAT

- BIXIBAT 5MG TAB
- Chronic idiopathic constipation

MEPOLIZUMAB

- NUCALA 100MG INJ
- Severe asthma (eosinophilic phenotype), chronic rhinosinusitis with nasal polyps, hypereosinophilic syndrome

PIMAVANSERIN

- PIMAVERSE 34MG TAB
- Hallucinations & delusions associated with Parkinson's disease psychosis

PLECANETIDE

- PLECTIDE 3MG TAB
- Chronic idiopathic constipation, irritable bowel syndrome with constipation

SEMAGLUTIDE

- RYBELSUS 14MG, 7MG, 3MG TAB
- Type 2 diabetes mellitus

TEDIZOLID PHOSPHATE

- STARIZO 200MG TAB
- Acute bacterial skin and skin structure infections

CEFEPIME & ENMETAZOBACTAM

- CIPENAT 2.5G INJ
- Complicated urinary tract infections

ROXOLUTINIB

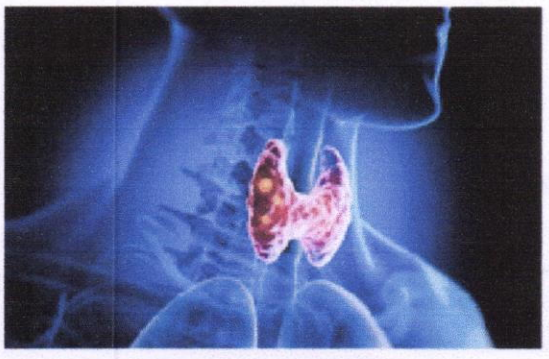
- JAKAVI 5MG TAB
- Myelofibrosis, polycythemia vera, acute graft-versus-host disease

BENRALIZUMAB

- FASENERA 30MG/ML INJ
- Severe asthma with an eosinophilic phenotype

THE FDA AUTHORIZES A GROUNDBREAKING THERAPY FOR HYPOPARATHYROIDISM, A RARE ENDOCRINE DISORDER

YORVIPATH (Palopegteriparatide) injection, Solution for injection in pre-filled pen, for subcutaneous use



The U.S. Food and Drug Administration has approved Yorvipath (Palopegteriparatide), a subcutaneous injection, for the treatment of Hypoparathyroidism in adults. This rare condition, often caused by surgical damage or autoimmune disorders affecting the parathyroid glands, results in insufficient parathyroid hormone (PTH) levels, leading to hypocalcaemia (low blood calcium).

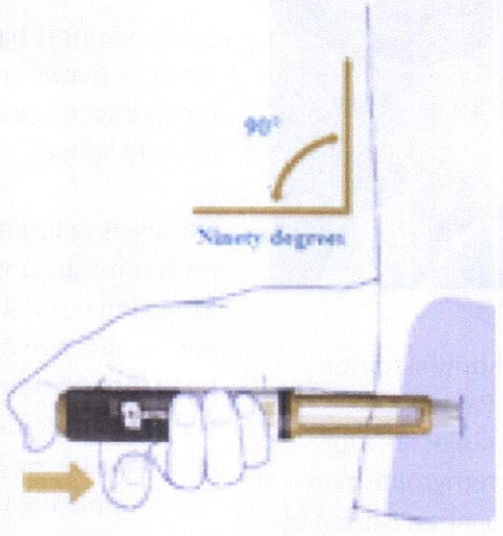
It is a synthetic PTH analog (PTH (1-34)), designed to restore calcium balance. Endogenous PTH maintains extracellular calcium and phosphate homeostasis by increasing serum calcium and decreasing serum phosphate. These effects are mediated by stimulating bone turnover to mobilize calcium and phosphate from bone, promoting renal calcium reabsorption and phosphate excretion, and facilitating active vitamin D synthesis, in turn increasing intestinal absorption of calcium and phosphate.

Dosage is tailored to each patient based on serum calcium levels, with the goal of achieving normal calcium levels using the lowest effective dose. This minimizes the need for additional active vitamin D or calcium supplements, typically limited to less than 600 mg daily. Vitamin D and calcium supplementation should be adjusted before starting and throughout treatment to maintain optimal serum calcium levels.

Palopegteriparatide provides a personalized and effective solution for managing hypoparathyroidism, reducing reliance on supplements and maintaining balanced calcium levels.

THE FDA HAS APPROVED
A TRANSFORMATIVE TREATMENT TO REDUCE BLEEDING EPISODES IN HEMOPHILIA A & HEMOPHILIA B PATIENTS WITH INHIBITORS

ALHEMO (Concizumab-mtci) Injection, single-patient-use prefilled pen, for subcutaneous use



The U.S. Food and Drug Administration has approved Alhemo (Concizumab-mtci) for routine prophylaxis to prevent or reduce bleeding episodes in adults and paediatric patients aged 12 years and older with Hemophilia A (with factor VIII inhibitors) or Hemophilia B (with factor IX inhibitors). Concizumab-mtci, is a humanized IgG4 monoclonal antibody produced by recombinant DNA technology in Chinese Hamster Ovary (CHO) cells. It is a monoclonal antibody antagonist of endogenous Tissue Factor Pathway Inhibitor (TFPI). Through the inhibition of TFPI, Concizumab-mtci acts to enhance FXa production during the initiation phase of coagulation which leads to improved thrombin generation and clot formation with the goal of achieving hemostasis in patients with Hemophilia A or B with inhibitors. It is administered as a daily subcutaneous

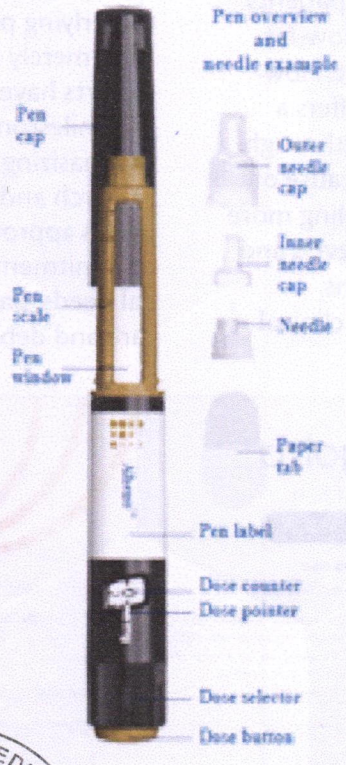
injection, with the following recommended dosing regimen:

- Day 1: Loading dose of 1 mg/kg
- Day 2: Once-daily dose of 0.2 mg/kg until the maintenance dose is individualized.

Hemophilia A and B are rare inherited disorders that result in insufficient clotting factors, causing poor blood clotting. As a result, patients may experience prolonged bleeding after injury or surgery and may also suffer from spontaneous, potentially life-threatening bleeding in muscles, joints, and organs.

Traditional treatment for Hemophilia involves replacing the missing clotting factors; however, over time, some patients develop inhibitors (antibodies) that interfere with the activity of factor VIII or IX, making it more difficult to control bleeding and reducing the effectiveness of factor replacement therapy.

The approval of Concizumab-mtci offers a significant advancement in the management of Hemophilia A and B with inhibitors, providing an effective and convenient treatment option to reduce bleeding episodes and improve patient outcomes.

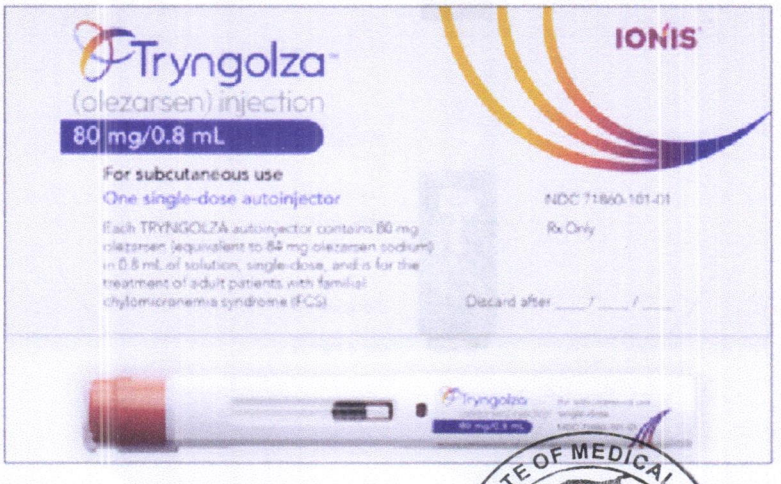


FDA APPROVES NEW DRUG FOR FAMILIAL CHYLOMICRONEMIA SYNDROME (FCS)

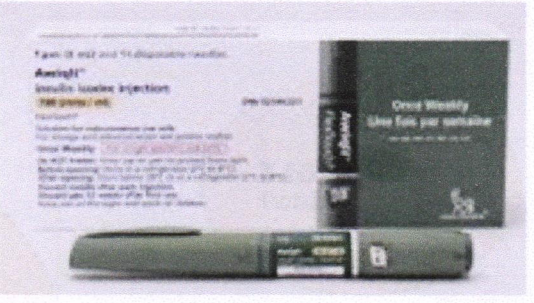
The U.S. Food and Drug Administration has approved Tryngolza (olezarsen), used with diet, to reduce triglycerides (TG) in adults with familial chylomicronemia syndrome (FCS). This is a first-in-class approval, meaning Tryngolza uses a new mechanism of action, or works differently in the body, than other therapies currently used to treat FCS. Tryngolza is injected subcutaneously (under the skin) once per month.

FCS is an ultra-rare condition, affecting approximately 1 in a million individuals. Due to its rarity and complex nature, effective treatment options have been extremely limited, leaving many patients dependent on highly restrictive low-fat diets and symptom management. However, the newly approved drug offers a much-needed therapeutic breakthrough. It is designed to target the root cause of the metabolic dysfunction, enabling more effective control of triglyceride levels and reducing the risk of complications.
The approval is based on robust clinical trial data demonstrating the drug's efficacy and safety in significantly lowering triglyceride levels in patients with FCS. Participants in the trials reported not only biochemical improvements but also relief from the burdensome symptoms of the condition, such as severe abdominal pain and fatigue. This marks a major advancement for the FCS community, offering new hope to patients and their families.

The new drug works by inhibiting a key protein involved in triglyceride production and metabolism, which helps to prevent the excessive build-up of these fats in the bloodstream. Unlike previous approaches, this mechanism directly addresses the underlying pathophysiology of FCS rather than merely managing its symptoms. Experts have welcomed this development as a milestone in rare disease treatment, emphasizing the importance of continued research and innovation in this area. The drug's approval underscores the FDA's commitment to addressing unmet medical needs, particularly for those living with rare and debilitating conditions.



ADVANCES IN DIABETES TREATMENT - ONCE WEEKLY INSULIN



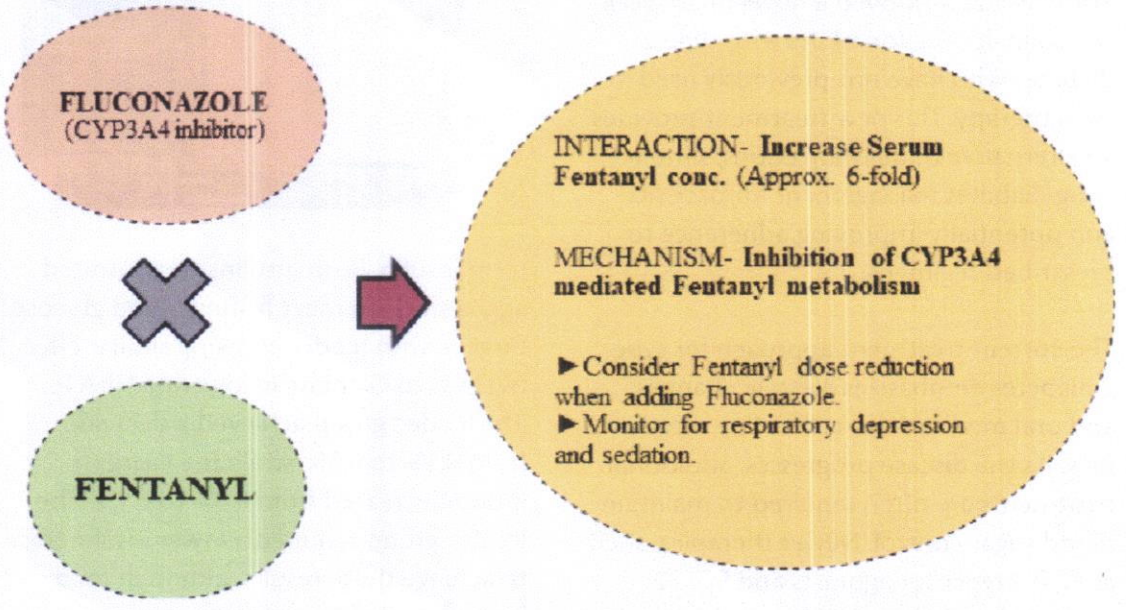
The FDA has approved a novel once-weekly insulin, Icodec for adults with type 2 diabetes who have not previously used insulin therapy. This new treatment provides an alternative to daily injections, simplifying diabetes management for patients and potentially improving adherence to prescribed regimens.

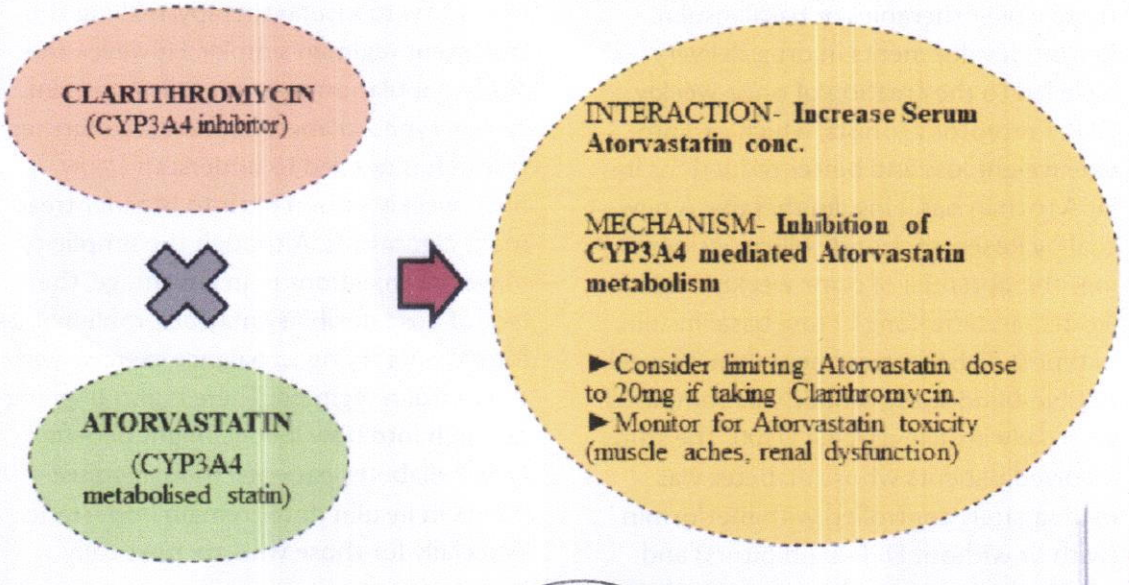
The current treatment approach for type 2 diabetes emphasizes lifestyle changes and oral medications as first-line therapies. As the disease progresses, additional treatments are often required to maintain blood sugar control. Newer therapies, such as GLP-1 receptor agonists and SGLT2 inhibitors, have been introduced earlier in treatment strategies, as they help control blood glucose without causing weight gain and have a low risk of hypoglycaemia. When oral medications become ineffective, patients may be offered options like these newer therapies or basal insulin. Recent developments in drug delivery have led to the creation of once-weekly GLP-1 receptor agonists, which can provide weight loss and better reductions in HbA1c than basal insulin therapy. A new trial by Rosenstock and colleagues examines the potential of once-weekly insulin Icodec, an ultra-long-acting basal insulin, in type 2 diabetes treatment. In a 26-week double-blind study, Icodec was compared with daily insulin glargine U100. The study involved patients whose diabetes was inadequately controlled with metformin (with or without DPP-4 inhibitors) and who had not previously received long-term insulin. Both insulins were titrated aggressively to meet fasting blood glucose targets, with Icodec showing similar effectiveness to Glargine in lowering HbA1c. The Icodec group achieved a decrease from 8.1% to 6.7%, while the Glargine group decreased from 8.0% to 6.9%. The Icodec group required a lower insulin dose to achieve these results, although mild hypoglycaemia was slightly more common in this group, though not statistically significant.

The authors suggest that a once-weekly insulin option could be beneficial for patients new to insulin therapy, making the treatment regimen simpler. However, the study population may not fully represent typical type 2 diabetes patients, so further research is needed to understand how once-weekly insulin fits into broader treatment algorithms. Although the simplicity of weekly injections is an advantage, the lack of dose flexibility may be problematic for patients trying to balance exercise with their insulin regimen. There is also ongoing research into how Icodec might benefit type 1 diabetes patients, though adjustments in insulin doses remain important, especially for those who are physically active.

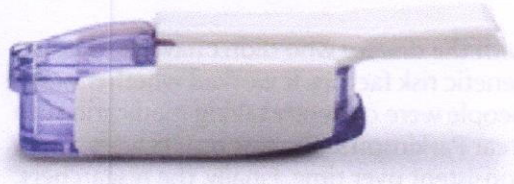
TOX TALK

KNOW YOUR DRUGS...





CARING CHRONICLES
AFREZZA: THE INHALED INSULIN



Afrezza is the only ultra-rapid acting inhaled insulin that starts lowering blood sugars in ~12 minutes for adults living with type 1 or type 2 diabetes. It is a man-made insulin that is breathed-in through your lungs (inhaled) and is used to control high blood sugar in adults with diabetes mellitus. It can be inhaled at the beginning of a meal to start lowering blood sugar levels in as little as 12 minutes without the use of injections. And just as it enters the body quickly, it also leaves the body fast (within 1.5-3 hours, depending on dose).

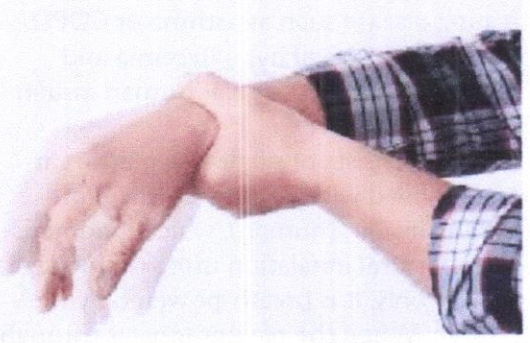
The microparticle used in Afrezza consists of two main components: human insulin in its most basic form, combined with an inactive ingredient. These microparticles are inhaled deeply into the lungs, where they are quickly absorbed into the body. In fact, as Afrezza passes through the lungs, insulin is released into the bloodstream in less than 1 minute. Acute bronchospasm has been observed in Afrezza treated patients with asthma and COPD. Afrezza is contraindicated in patients with chronic lung disease such as asthma or COPD, during episodes of hypoglycemia and hypersensitivity to regular human insulin.

Afrezza consists of single-use plastic cartridges filled with a white powder containing insulin (human), which is administered via oral inhalation using the Afrezza Inhaler only. It is breath-powered by the patient. When the patient inhales through the device, the powder is aerosolized and delivered to the lung. The amount of drug delivered to the lung will depend on individual patient factors.

The cartridges are color-coded, blue for 4 units and green for 8 units. The inhaler is fully assembled with a removable mouthpiece cover. The Afrezza Inhaler can be used for up to 15 days from the date of first use. After 15 days of use, the inhaler must be discarded and replaced with a new inhaler. Inhaler may be stored refrigerated, but should be at room temperature before use. Cipla has obtained regulatory approval from Central Drugs Standard Control Organisation (CDSCO) for the exclusive distribution and marketing of Afrezza® (insulin human) Inhalation Powder in India.

Injected Mealtime Insulin Dose	AFREZZA® Dose	# of **4 unit** (blue) cartridges needed		# of **8 unit** (green) cartridges needed
up to **4** units	**4** units	1		
5-8 units	**8** units			1
9-12 units	**12** units	1	+	1
13-16 units	**16** units			2
17-20 units	**20** units	1	+	2
21-24 units	**24** units			3

A POTENTIAL BLOOD TEST FOR PARKINSON'S DISEASE



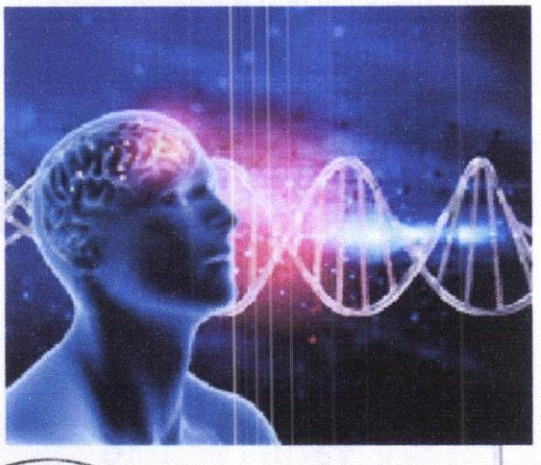
In Parkinson's disease, neurons that produce dopamine start to die in the part of the brain that controls movement. This eventually leads to symptoms such as shaking, stiffness, and difficulty with balance and coordination. Drugs that boost dopamine levels can relieve symptoms for a while, but they don't slow progression of the disease and eventually stop working. New treatments for Parkinson's disease are badly needed.
The lack of early diagnosis before extensive damage occurs, has hampered drug development. One likely cause of Parkinson's disease in some people is damage to neuron's mitochondria. An assay to identify people whose disease is driven by mitochondrial damage would be needed to test drugs that boost mitochondrial function.

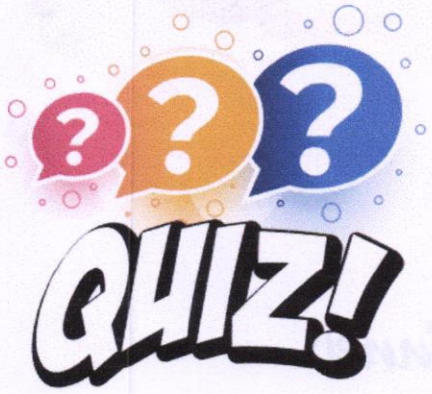
In a new study from Duke University developed a blood test to detect damage to the DNA in mitochondria, called mtDNA. They built their test, which they call Mito DNADX, on polymerase chain reaction (PCR) technology. The test found that mtDNA damage was elevated in cells taken from the blood of people with Parkinson's disease compared with people without the condition.

Mito DNADX detected mtDNA damage both in people with a rare genetic mutation known to cause Parkinson's and in those with the disease who didn't have any known genetic risk factors. It worked whether or not people were currently taking medications to treat Parkinson's. The test results were also consistent over time. Finally, the researchers calculated a cut-off value for mtDNA damage that effectively separated people with Parkinson's disease from healthy volunteers.

Further experiments showed that the abnormal activity of a protein called LRRK2 kinase increased levels of mtDNA damage. Decreasing abnormal LRRK2 activity is currently a target of drug development for Parkinson's disease. Therefore, Mito DNADX might be used to monitor treatment effects in real time.

Further research is needed to validate the test in larger, more diverse populations. Longer-term studies are also needed to see if mtDNA damage changes as Parkinson's disease progresses. In addition, mtDNA damage is not unique to Parkinson's disease. Researchers are working on other ways to diagnose and track Parkinson's disease that may prove to be more specific for the disease.





BRAINSTORM-4

Click QR code for brainstorm quiz-4
https://forms.gle/EfxXSsAGMwJVcEbt7
One lucky winner will receive a **GIFT**
Last date of participation: **April 1st, 2025**

Scan QR Code

for Brainstorm Quiz-4

ANSWER KEY: BRAINSTORM - 3

1. ELOBIXIBAT is used for _____? **Chronic constipation**
2. Name the first EPINEPHRINE product administered nasally for treating anaphylaxis? **NEFFY**
3. Nobel Prize in physiology/medicine 2024 was awarded for the discovery of _____. **Micro RNA**
4. Which one of the following is an Antibiotic? **Tedizolid**
5. Which of the following is NOT TRUE regarding drug Cobenfy? **Target dopamine receptors**
6. Which of the following acts as a vector for dengue? **Aedes mosquito**
7. A method that involves injecting anticancer drugs into the bladder? **Intravesical therapy**
8. ELAGOLIX is indicated for pain associated with which of the following conditions? **Endometriosis**
9. BPaLM regimen is associated with which of the following disease? **MDR –TB**
10. Name India's first indigenous Dengue Vaccine undergoing phase 3 clinical trial? **DengiAll**

Thank you to everyone who tried their luck in the last issue quiz, and commiserations to the others who got all the questions right. We hope you'll give it another try in the next quiz.

5 Stars 1 lucky Winner

1. Dr. Sangeetha Sajeevu- Dept of Emergency medicine
2. Dr. Mithun Raju- Dept. of Anesthesiology
3. Dr. Anish S- Dept. of General medicine
4. Dr. James Joseph- Dept. of General Medicine
5. Lijo K O- Administration (MC)

LUCKY WINNER: BRAINSTORM -3

Hearty congratulations to

LIJI K. O.

Department of Administration
Amala Institute of Medical Sciences

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DEPARTMENT OF CLINICAL PHARMACY

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