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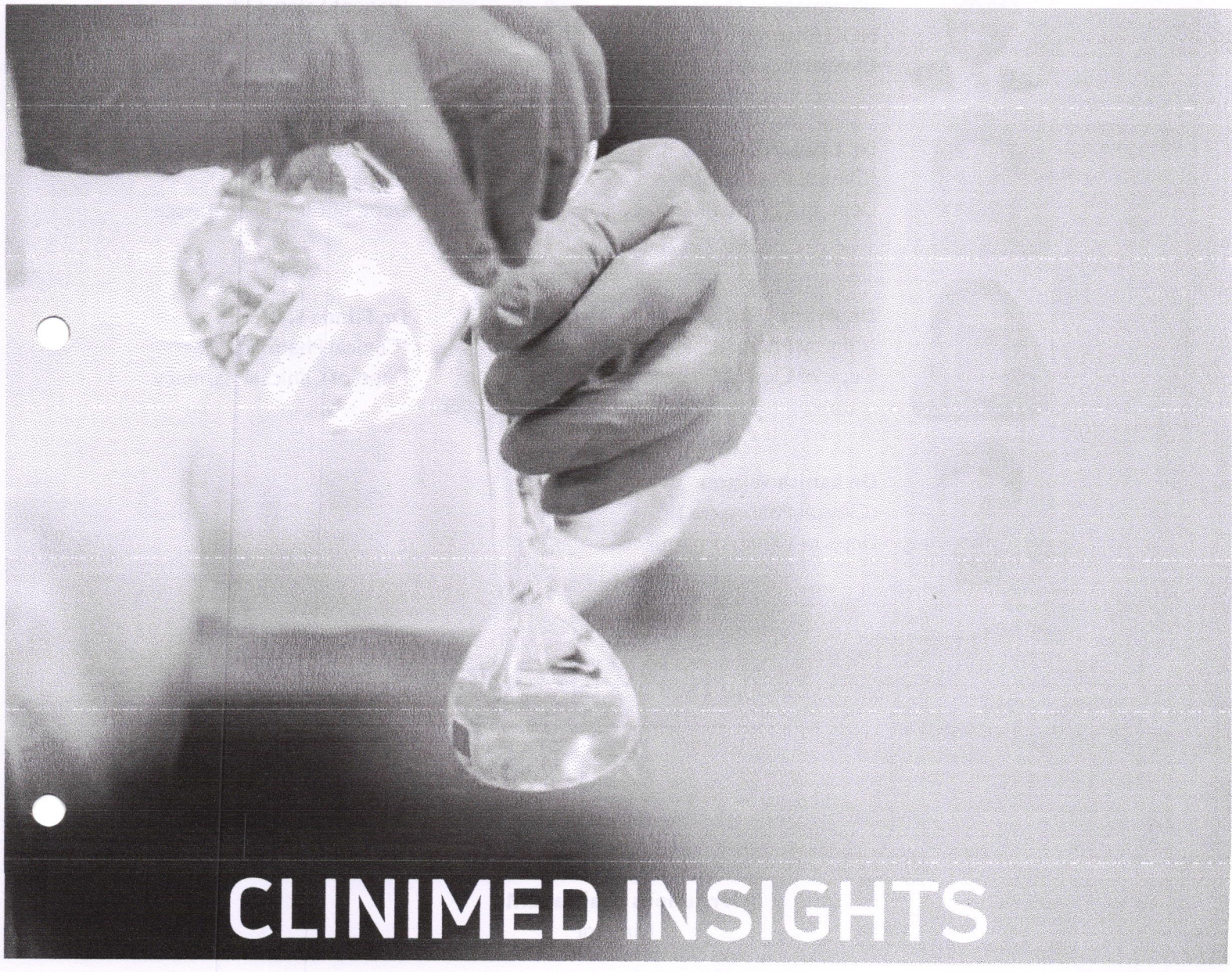
Amala
INSTITUTE OF MEDICAL SCIENCES
NABH & NABL ACCREDITED ISO 9001: 2015

REDEFINING
CARE
everyday
in every way



CLINIMED INSIGHTS

An initiative by,

THE DEPT. OF CLINICAL PHARMACY

Amala Institute of Medical Sciences

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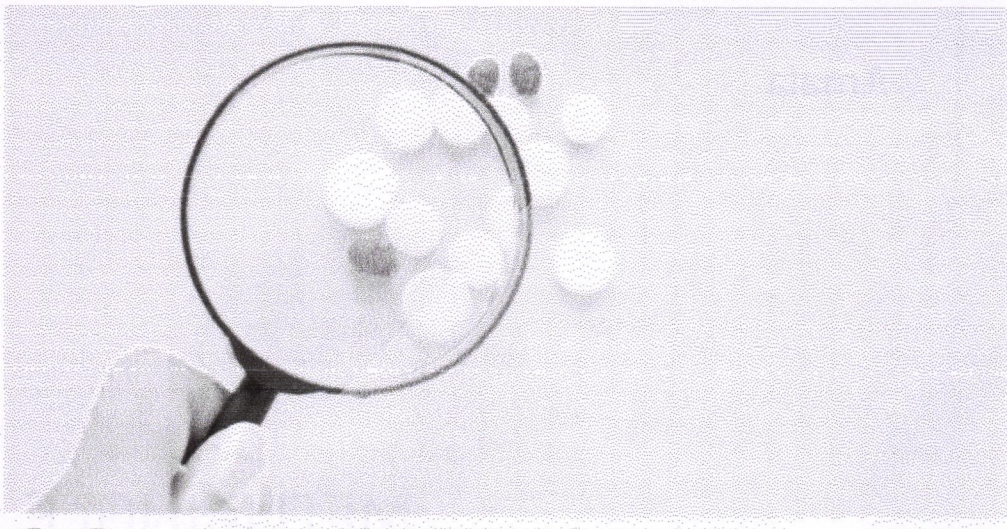
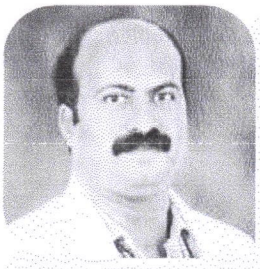


CONTENTS

MED MINGLE

THE MYTH OF NATURAL VERSUS CHEMICAL: A BALANCED PERSPECTIVE



Dr. Dijoe Davis
Dept. of Orthopaedics

In May, a tragic incident occurred where a nurse from Kerala, set to embark on a new life in the UK, accidentally bit into an Arali flower (*Nerium oleander*) and was poisoned to death. This heart-breaking event raises an important question: Is the commonly held belief that natural substances are harmless and only artificial chemicals have side effects true in all situations? Or is our "chemophobia" – the fear of chemicals – based on a false premise?

A study in the UK revealed that many British people believe common salt (sodium chloride) has different compositions when obtained from sea water compared to when it's made in a lab. This highlights the depth of chemophobia in our society. But is there really a division between "natural" and "chemical"? The answer is a resounding "no."

Natural vs. Chemical: A False Dichotomy

In reality, the universe contains only two types of matter: baryonic matter and dark matter. Baryonic matter includes everything we are familiar with, both natural and man-made. Dark matter, still largely unknown, is hypothesized to explain certain cosmic phenomena. Therefore, the distinction between "natural" and "chemical" is artificial; both are made of the same fundamental matter.

Are All Chemicals Poisonous ?

Another critical question is whether all chemicals are poisonous. Oxygen, essential for life, can cause seizures, pulmonary edema, and even vision loss in premature children at high concentrations. Bilimbi, a common fruit, can lead to oxalate nephropathy if consumed in excess. Warfarin, a life-saving drug, can also be used as rat poison. These examples illustrate Paracelsus's principle: "The dose makes the poison." No substance is inherently a drug or poison; it depends on the amount.

The Benefits of Chemicals

Chemophobia often leads to the belief that human suffering is caused by chemicals, and that life would be easier without them. Remember the Malthusian principle, which predicted that population growth would outstrip food production, leading to famine and catastrophe? This didn't happen, thanks to Fritz Haber. Plants need nitrogen, which they get from soil bacteria, not directly from the air. As soil bacteria deplete, so does the harvest. Haber's process for producing ammonia, beginning the era of fertilizers, prevented this crisis. Many of us wouldn't be here without it, as it averted the Malthusian catastrophe.

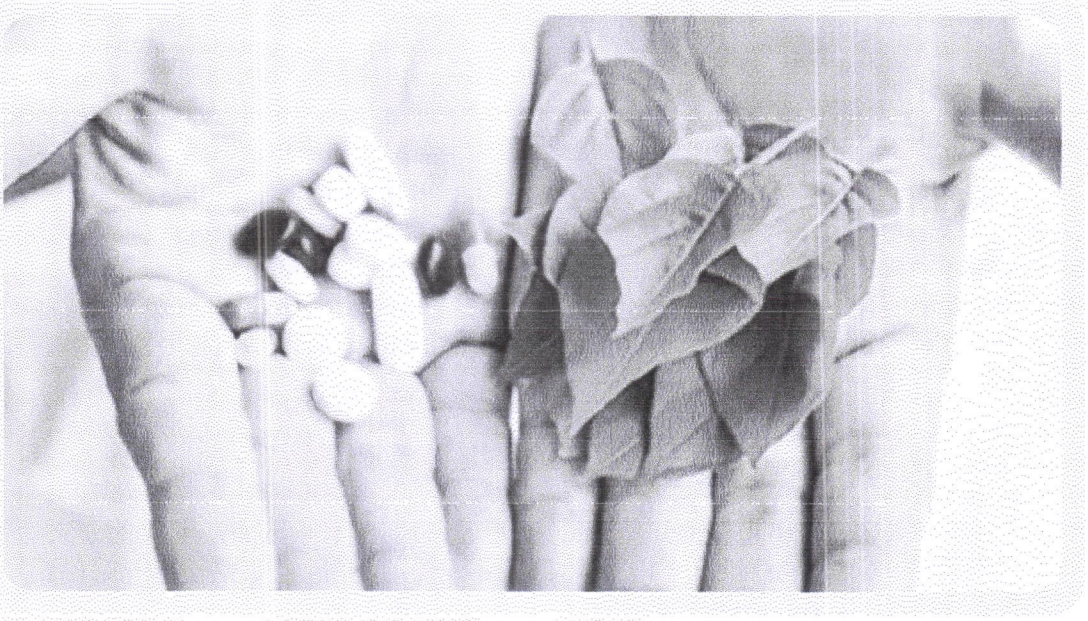
Why the Fear of Artificial Chemicals ?

If both natural and artificial substances have risks and benefits, why are artificial chemicals often associated with side effects? The answer lies in our monitoring systems and brain evolution. Hospitals, like Amala, have Pharmacovigilance units to monitor drug side effects, but there's no equivalent for plants/plant products. Additionally, our brains evolved to remember negative experiences to survive in dangerous environments, a trait that's counterproductive today.

Striking a Balance

Our attitude towards chemicals should be balanced. Whether natural or artificial, anything with an effect can have a side effect. Our goal should be to balance these effects to benefit humanity as a whole. Understanding this helps us make informed decisions and reduces unnecessary fear.

In conclusion, the tragic incident involving the nurse underscores the need for a nuanced understanding of natural versus artificial substances. By fostering a balanced perspective, we can better appreciate the benefits of both and use them wisely for the greater good.



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CDSCO NEW DRUG APPROVALS - 2024

SELPERCATINIB CAPSULES 40 mg, 80mg
Metastatic RET fusion+ve non-small cell lung cancer, advanced or metastatic RET mutant medullary thyroid cancer.

VONOPRAZAN TABLETS 10mg / 20 mg
Treatment of reflux esophagitis, gastric ulcer, duodenal ulcer Adjunct to Helicobacter pylori eradication.

ETIFOXINE HYDROCHLORIDE CAPSULES 50mg
Psychosomatic manifestations of anxiety.

TIRZEPATIDE INJECTION 2.5mg
Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

PLAZOMICIN INJECTION 500mg /10ml
Reserve for use in complicated UTI patients who have limited or no alternative treatment options.

TREPROSTINIL INJECTION 1mg / ml & 10mg/ml
Pulmonary arterial hypertension.

INCLISIRAN INJECTION 284mg / 1.5ml
Adjunct to diet and maximally tolerated statin therapy to reduce LDL cholesterol in patients with primary hyperlipidemia.

ASCIMINIB TABLET 20mg
Chronic myeloid leukemia, chronic phase.

LASMIDITAN TABLET 50mg, 100mg
Acute treatment of migraine with or without aura in adults.

ABROCITINIB TABLETS 50mg, 100mg & 200mg
Atopic dermatitis, refractory, moderate to severe.

DRUG SAFETY ALERT (January To June 2024)

DRUG	ADVERSE EFFECT
Meropenem	Acute Generalized Exanthematous Pustulosis (AGEP)
Cefuroxime	Acute Generalized Exanthematous Pustulosis (AGEP)
Dutasteride +Tamsulosin	Palpitation
Nimesulide	Fixed Drug Eruption (FDE)
Beta blockers (Metoprolol, Propranolol, Atenolol)	Erectile Dysfunction (Reversible)

MEDICAL DEVICE SAFETY ALERT 2023

NCC-MvPI, IPC has observed the following adverse event reports with the use of the following suspected devices which may lead to serious adverse event.

SUSPECTED DEVICE	EVENT DETAILS
Orthopaedic Megaprosthesis (Femoral Stem)	Stem Breakage
Monofilament Synthetic Absorbable Skin Support And Filling Thread Sterile	Atypical Mycobacterial Infection
Transcatheter Pulmonary Valve	*Ralstonia Mannitolilytica Infection*
Intraocular Lens (IOL)	IOL Breakage Post Implantation
Ophthalmic Solution (Pre-Filled Sterile)	Contaminated with Foreign Particles
Blood Administration Set	Contaminated with Fungus, Leaky
Hypodermic Syringe	Poor Quality, Blockage, Plunger Breakage

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NEW MOLECULES @ AMALA

STELARA INJ
USTEKINUMAB
- Crohn's Disease, Ulcerative Colitis, Plaque Psoriasis & Psoriatic Arthritis

LINORMA T3 TAB
LIOTHYRONINE
- Treatment of Hypothyroidism

RAFINLAR CAP
DEBRAFENIB
- Treatment of Malignant Melanoma

VERISET HEMOSTATIC PATCH
- Promote Hemostasis, Prevent Bleeding

MENVEO VACCINE
MENINGOCOCCAL VACCINE
- Prevent Meningococcal infection

OXEMIA TAB
DESIDUSTAT
- Treatment of Anemia due to CKD

LIRAFIT INJ
LIRAGLUTIDE
- Diabetes Mellitus, chronic weight management

ORGONIST TAB
RELUGOLIX
- Treatment of Advanced Prostate Cancer

REVERSEE INJ
SUGAMMADEX
- Reversal of neuro-muscular blockade induced by Rocuroniumor Vecuronium

AXONET TAB
EPALRESTAT
- Treatment of Diabetic Neuropathy

DAYVIGO TAB
LEMBOREXANT
- Treatment of Insomnia

ISUVAZ CAP
ISAVUCONAZOL
- Treatment of Aspergillosis, Mucormycosis

ENHERTU INJ
FAM-TRASTUZUMAB DERUXTECAN
- Breast & Gastric Cancer, Non-Small Cell Lung Cancer, Solid Tumors

MATERIOVIGILANCE

Materiovigilance is the coordinated system of identification, collection, reporting, and analysis of any untoward occurrences associated with the use of medical devices and protection of patient's health by preventing its recurrences.

The fundamental aim of this program is to monitor medical device-associated adverse events (MDAE), create awareness among health-care professionals about the importance of MDAE reporting and generate independent credible evidence-based safety data of medical devices and to share it with the stakeholders.

"Medical device" means any instrument, apparatus, implement, machine, appliance, implant in-vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes of diagnosis, prevention, monitoring, treatment or alleviation of disease.

MEDICAL DEVICE ADVERSE EVENT REPORTING FORM

Materiovigilance Programme of India (MvPI)

This form is intended to collect information on Medical Devices Adverse Event in India. The form is designed to be used voluntarily by Manufacturer/Importer/Distributor of Medical Devices, Healthcare Professionals and anyone with direct/indirect knowledge of Medical Devices Adverse Event.

General Information

1. Date of Report :
2. Type of Report : Initial ☐ Follow up ☐ Final ☐ Trend ☐
3. Reporter Reference for MDMC only: • Centre • Location • Month-Year • Case No.

Reporter Details

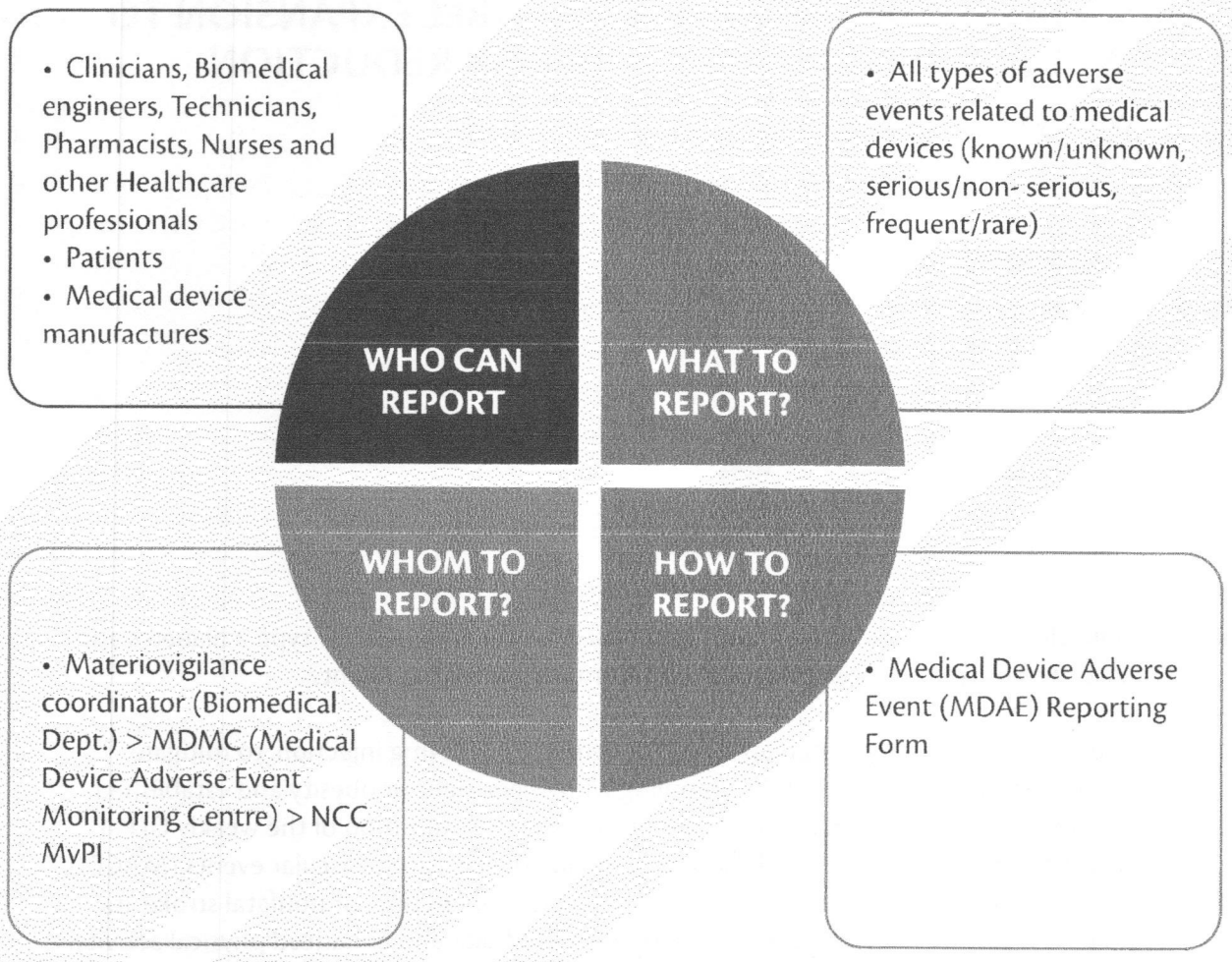
1. Type of Reporter : (a) Manufacturer ☐ (b) Importer ☐ (c) Distributor ☐ (d) Healthcare Professional ☐
   (e) Patient ☐ (f) Others ☐ specify .....
2. In case, where the reporter is not manufacturer, fill the following details:-
   (a) Has the reporter informed the incident to the manufacturer?
   Yes ☐ No ☐
   (b) Is the reporter also submitting the report on behalf of the manufacturer?
   Yes ☐ No ☐
3. Reporter contact information:
   a) Name :
   b) Address :
   c) Tel. /Mobile :
   d) Email :

Device Category

Medical Device	In Vitro Diagnostics (IVD)	Medical Equipments / Machines
I. Therapeutic ☐ Diagnostic ☐ Both ☐ Preventive ☐ Assistive ☐	I. Kits ☐	I. Therapeutic ☐ Diagnostic ☐
II. Implantable device ☐ Non-Implantable device ☐	II. Reagents ☐	II. Therapeutic & Diagnostic ☐
III. Invasive ☐ Non-Invasive ☐	III. Calibrator ☐	III. Preventive ☐
IV. Single use device ☐ Reusable device ☐ Reuse of manufacture marked Single use device ☐	IV. Control Material ☐	IV. Assistive ☐
V. Sterile ☐ Non Sterile ☐	V. Others ☐	V. Imaging ☐
VI. Personal use / Homecare use ☐	VI. IVD electronic reader/ Analyzer ☐	VI. Invasive ☐ Non-Invasive ☐
		VII. Others ☐

Instruction for use Section A-F

- *If Medical Devices/Equipments/Machines : Please fill all the sections i.e. A, B, C, D, E & F*
- *If In Vitro Diagnostics (IVD) : Please fill sections i.e. A (except 6, 7, 8, 13, 14 & 16), B (except 1, 2, 6 & 8), D, E, & F*


• Clinicians, Biomedical engineers, Technicians, Pharmacists, Nurses and other Healthcare professionals
• Patients
• Medical device manufactures
WHO CAN REPORT
WHAT TO REPORT?
• All types of adverse events related to medical devices (known/unknown, serious/non- serious, frequent/rare)
WHOM TO REPORT?
HOW TO REPORT?
• Materiovigilance coordinator (Biomedical Dept.) > MDMC (Medical Device Adverse Event Monitoring Centre) > NCC MvPI
• Medical Device Adverse Event (MDAE) Reporting Form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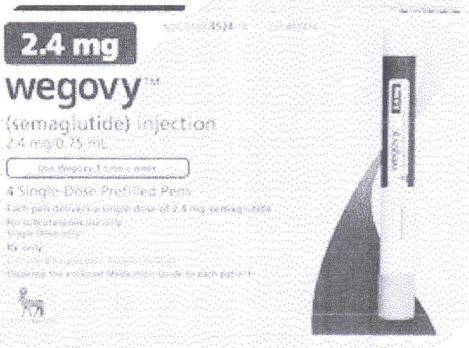
MED MINGLE

FDA APPROVALS

SEMAGLUTIDE RECEIVES FDA LABEL EXPANSION TO INCLUDE CARDIOVASCULAR RISK REDUCTION

WEGOVY (Semaglutide) injection, for subcutaneous use.



Semaglutide is an antidiabetic medication used for the treatment of type 2 diabetes and an anti-obesity medication used for long-term weight management.

The FDA has recently granted approval for Semaglutide 2.4mg injection, to mitigate cardiovascular risk among adults grappling with overweight or obesity and established cardiovascular disease. This label extension permits the utilization of the weekly GLP-1 receptor agonist to lower the likelihood of major adverse cardiovascular events (MACEs), against cardiovascular mortality, nonfatal myocardial infarction, or nonfatal stroke. Its usage is recommended alongside a calorie-restricted diet and enhanced physical activity.

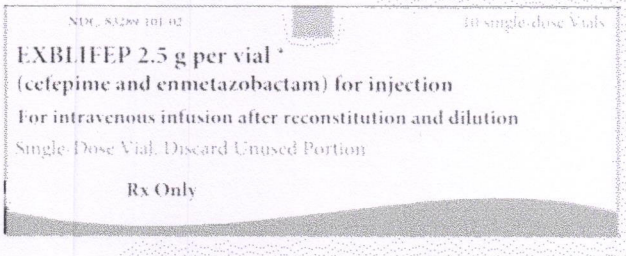
The new indication was granted after a priority review process and was based on results from the SELECT cardiovascular outcomes trial (NCT03574597). Findings from SELECT showed that Semaglutide significantly reduced the risk of major adverse cardiovascular events (MACE)—cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke—by 20% compared with placebo when added to standard of care.
This expanded indication is a major step forward in the treatment of obesity and prevention of its cardiovascular consequences.

MED MINGLE

FDA APPROVALS

ENMETAZOBACTAM FOR COMPLICATED UTIs: BREAKTHROUGH ANTIMICROBIAL THERAPY

EXBLIFEP (Cefepime and Enmetazobactam) injection, for Intravenous use.



Enmetazobactam gains FDA approval for treating patients 18 years and older with complicated urinary tract infections (cUTI) including pyelonephritis caused by designated susceptible microorganisms.

2.5 grams (Cefepime and Enmetazobactam) for injection, is supplied as a sterile powder for reconstitution in single-dose vials containing 2 grams Cefepime and 0.5 grams Enmetazobactam.

The fourth-generation cephalosporin Cefepime and proprietary beta lactamase inhibitor Enmetazobactam combination was developed to fight anti-microbial resistance in Gram-negative bacteria. Enmetazobactam is a beta-lactamase inhibitor that protects Cefepime from degradation by certain serine beta-lactamases.

In the phase 3 trial, 1034 participants were randomized to receive Cefepime 2 g and Enmetazobactam 0.5 g or Piperacillin 4 g and Tazobactam 0.5 g through 2 hours of continuous intravenous infusion every 8 hours. Efficacy was evaluated in patients with a Gram-negative pathogen infection deemed non-resistant to Cefepime-Enmetazobactam and Piperacillin-Tazobactam. Cefepime-Enmetazobactam had a success rate of 79.1%, while Piperacillin-Tazobactam had a success rate of 58.9%.

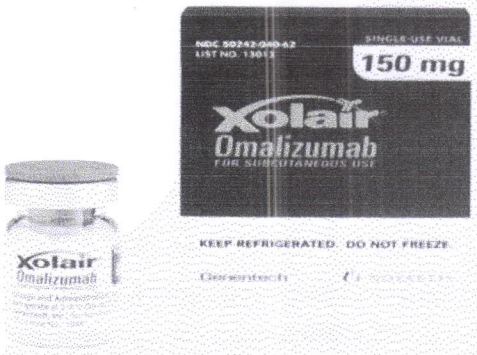
The most frequently reported adverse reactions were increased transaminases, increased bilirubin, headache, and phlebitis/infusion site reactions. With a comparable safety profile to existing treatments and a high success rate in combating cUTIs, Enmetazobactam's FDA approval marks a significant milestone in the fight against antibiotic-resistant infections.

MED MINGLE

FDA APPROVALS

OMALIZUMAB: A NOVEL ANTI IGE - MEDIATED THERAPY FOR MULTIPLE FOOD ALLERGIES.

XOLAIR (Omalizumab) injection, for subcutaneous use.



Omalizumab was greenlit by the Food and Drug Administration (FDA) to help reduce severe allergic reactions like anaphylaxis brought on by accidental exposure to certain foods. It is considered the first medication approved by the FDA that can help protect people against multiple food allergies.

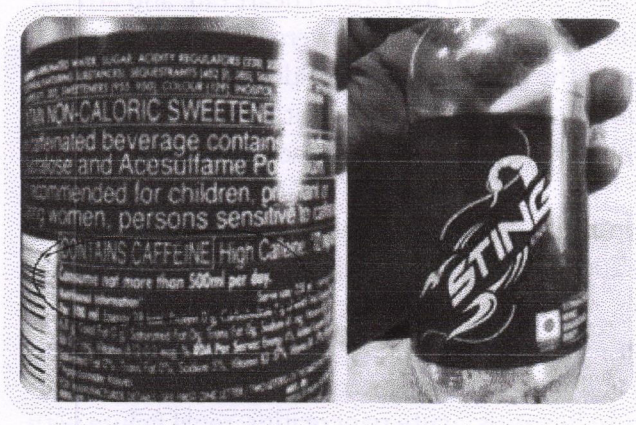
This newly approved use for Omalizumab will provide a treatment option to reduce the risk of harmful allergic reactions among certain patients with IgE-mediated food allergies. In the past, FDA has already approved Omalizumab to treat some cases of persistent asthma triggered by allergies, chronic hives, and chronic inflammatory sinus disease with nasal polyps.

The medication is not intended for use during an allergic reaction. Instead, it is designed to be taken repeatedly every few weeks to help reduce the risk of reactions over time. The FDA said people taking the drug should continue to avoid foods they are allergic too. The most common side effects of Omalizumab observed included injection site reactions and fever.

FDA approval of Omalizumab offers new hope in the battle against the deadliest food allergies.

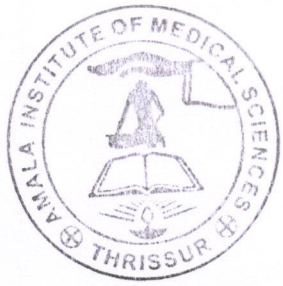
TOX TALK

THE DARKSIDE OF ENERGY DRINKS: HOW SAFE ARE THESE HEAVILY CAFFEINATED DRINKS?



Lately, there have been numerous reports of adverse effects associated with the overconsumption of energy drinks. Recently, it has been reported in Kerala that a young individual experienced an unexplained cardiac arrest after over consuming the energy drink STING. The energy drink Sting contains caffeine (290mg), sugar (50g), taurine (148mg), inositol (21mg), ginseng (9.7mg), vitamin B3 (10.2mg) per 500ml. Research shows that consumption of these highly-caffeinated drinks can lead to a potentially serious heart condition known as Atrial Fibrillation, a type of irregular heartbeat (arrhythmia) occurring in the upper chambers of the heart. If left untreated, it could cause heart palpitations, blood clots, stroke, and even heart failure in extreme cases.

In recent years, the consumption of energy drinks by young adults and athletes has risen significantly, but concerns have been raised about the potential health risks associated with excessive consumption. These concerns include cardiovascular problems, nervous system disorders, followed by gastrointestinal, renal, endocrine, and psychiatric systems and the potential for addiction. The main psychoactive substance in an energy drink is caffeine. They also contain other ingredients that are thought to increase energy and mental alertness, such as taurine, guarana, ginseng, vitamins, and others.



Cardiovascular effect: Several studies have shown an increase in heart rate and arterial blood pressure after energy drink consumption. These findings were attributed to the ergogenic effects of the caffeine content of the energy drink. In addition, significant cardiac manifestations such as ventricular arrhythmias, ST segment elevation and QT prolongation have been documented following energy drink overconsumption.

Neurological & psychological effect: Individuals usually develop symptoms of caffeine intoxication in doses equal to or above 200 mg. Symptoms include anxiety, insomnia, gastrointestinal upset, muscle twitching, restlessness, and periods of inexhaustibility.

Gastrointestinal & Renal System: These drinks can also lead to the development of gastrointestinal and renal disorders. Acute hepatitis, acute pancreatitis, renal failure with acute kidney injury (AKI), rhabdomyolysis, and metabolic acidosis have been described in association with energy drink consumption. As mentioned above, all energy drinks contain high doses of caffeine, taurine, sugar, and vitamins. A megadose of vitamin B3 (niacin) is associated with hepatotoxicity. Hepatotoxicity manifests as a mild elevation of liver enzymes (ALT/AST), hepatic steatosis, hepatic necrosis, and, in rare cases, liver failure.

Most cans of energy drinks (250 mL) contain 50 to 150 mg of caffeine, while the upper safe intake limit for adults is up to 400 mg per day (about 5.7 mg/kg per day for a 70 kg adult), with a single dose not exceeding 200 mg.

While energy drinks can provide a temporary boost in alertness and energy, their potential adverse effects, particularly with excessive or regular consumption, raise significant health concerns. Individuals should be cautious about their intake, especially those with underlying health conditions, children, adolescents, and pregnant women. Increased public education on the potential risks associated with the misuse of energy drinks is warranted to enable individuals to make informed decisions regarding consumption.

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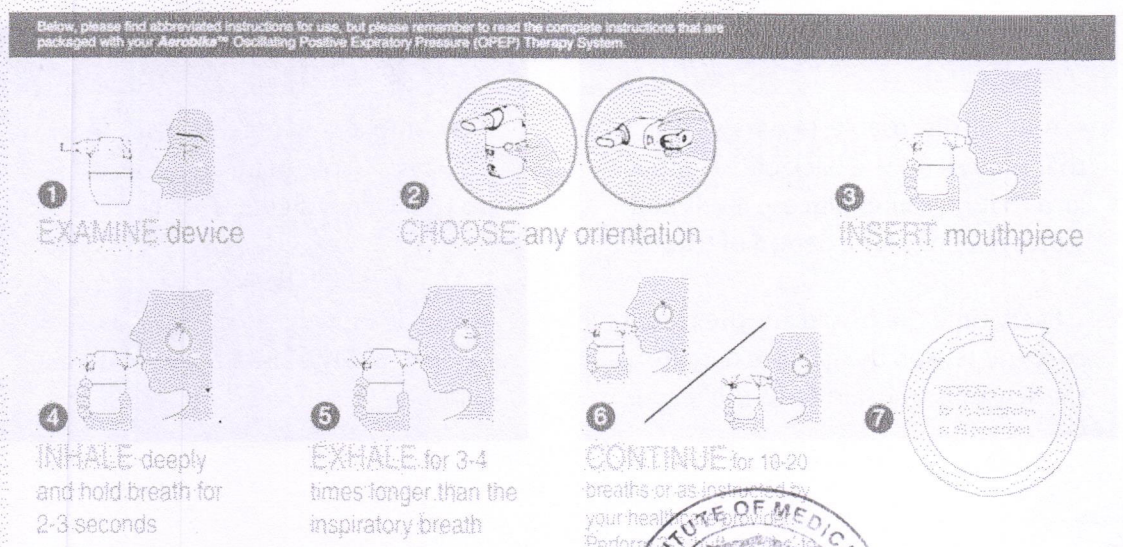
CARING CHRONICLES

AEROBIKA: AN INNOVATION IN DRUG FREE AIRWAY CLEARANCE THERAPY

AEROBIKA is a type of Oscillating Positive Expiratory Pressure (OPEP) device. It is a drug-free and easy to use device that can help clear excess mucus in the airways and improve breathing.

The device has an innovative pressure-oscillation mechanism that creates positive pressure pulses when a patient exhales. This assist with opening weak or collapsed airways. A rocker mechanism in the device causes the air travelling through your lungs to vibrate, which helps loosen secretions from the airway walls. These two things together can help make airway clearance easier and more effective. It can be used to manage respiratory conditions such as COPD, bronchiectasis, and cystic fibrosis.



CARING CHRONICLES

FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM: WHY PRICK WHEN YOU CAN SCAN?

The FREESTYLE LIBRE received FDA approval in 2017 for use in adults with diabetes. It does not require finger-prick blood samples. Instead, this meter reads glucose from interstitial fluids just underneath the skin. It is the first continuous glucose monitoring system that can be used by adult patients to make diabetes treatment decisions without calibration using a blood sample from the fingertip.

FreeStyle Libre system, the world's leading continuous glucose monitoring (CGM) technology, is now available for adults and children (above the age of 4) living with diabetes in India and women with gestational diabetes, offering them the choice to check glucose levels anytime and anywhere, ultimately improving glucose control.

The FreeStyle Libre sensor measures glucose every minute in interstitial fluid through a small (5.5mm long) filament that is inserted just under the skin and held in place with a small adhesive pad. A quick scan of the sensor with a reader provides a real-time glucose reading on demand and a complete picture of a person's glucose levels, without the need of painful, routine fingersticks or daily calibration, enabling meaningful lifestyle and therapy interventions.

FreeStyle Libre sensor

- A small, disposable 14 days sensor that is worn on the back of the upper arm that measures glucose levels and stores readings for a period of 8 hours.
- Every time the user scans the reader over the sensor, the glucose data from the sensor is transferred to the reader.

FreeStyle Libre reader

- A compact, handheld device that displays glucose readings and stores up to 90 days of glucose data.
- When the reader is scanned over the sensor, it shows a current glucose reading and the last 8 hours of data with a trend arrow.

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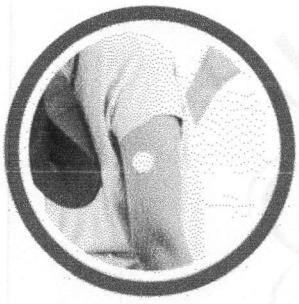
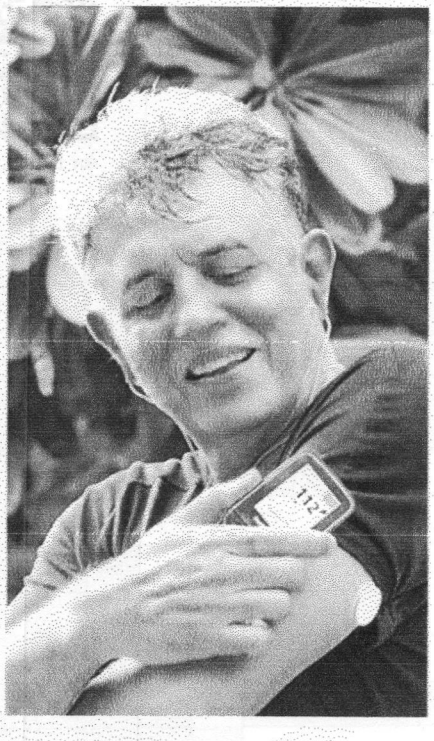


STEP 1
APPLY

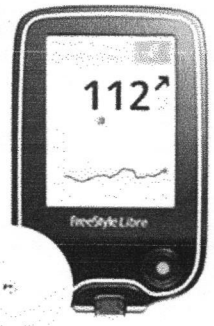
STEP 2
SCAN

STEP 3
READ OUT



Monitoring your glucose is now easy

Why prick, when you can scan?



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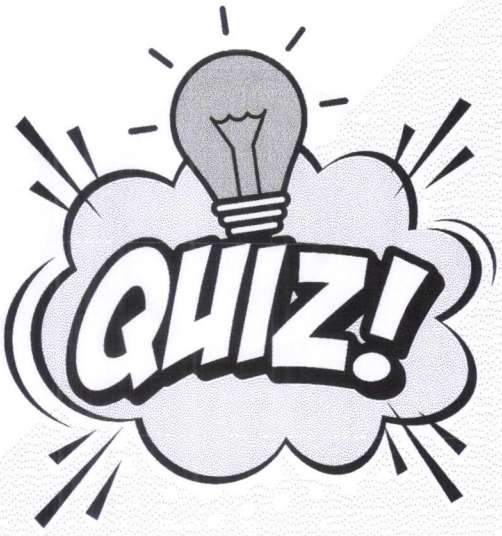
BRAINSTORM



Click on the link for Brainstorm Quiz-2

https://forms.gle/F2i9BiF4MmrRpCFS7

One lucky winner will receive a gift

Last date of participation: **September 10, 2024**

Scan QR Code

for Brainstorm Quiz-2

ANSWER KEY: BRAINSTORM - 1

																		[5]A				
			[4]N					[4]Z										L				
		[5]T	A	K	O	T	S	U	B	O								B				
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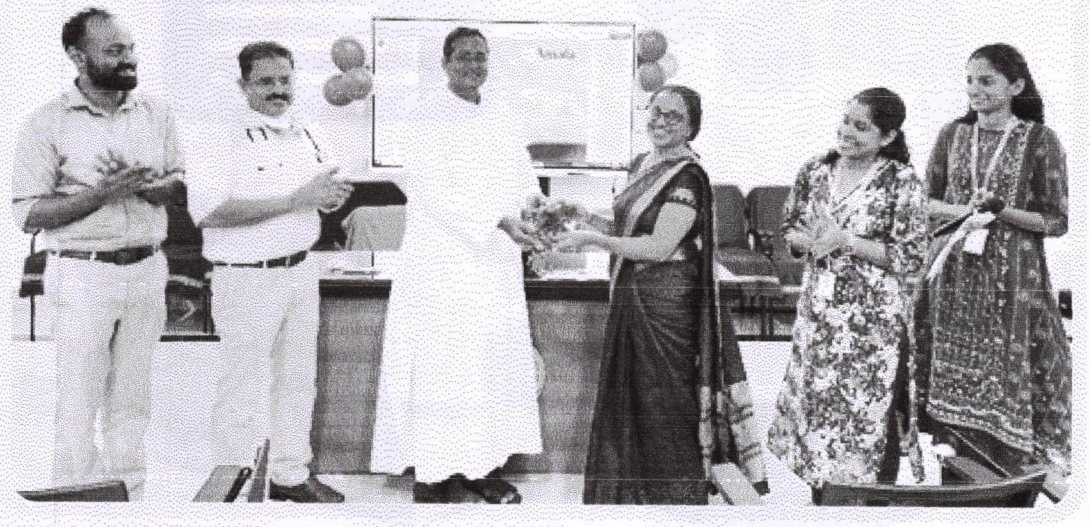
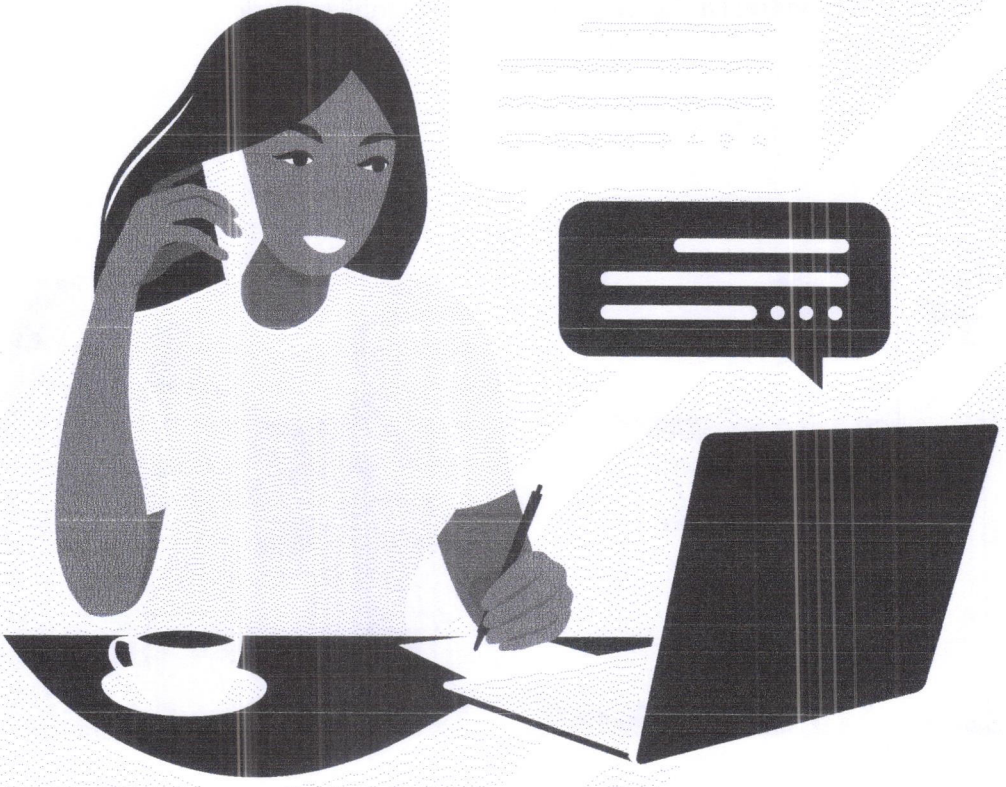
		[5]H	E	L	L	P		O				D					I					
								N									Q					
								[10]C	E	P	H	A	L	G	I	A						

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.

LUCKY WINNER: BRAINSTORM - 1

Hearty congratulations to: Dr. Aparna Gulvadi – Dept. of Paediatrics





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CLINICAL PHARMACY DEPARTMENT

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