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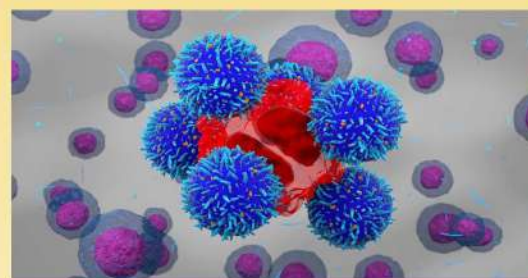
## CAR-T cell therapy: A promise for Indian cancer patients

Cancer is a disease that results from the uncontrolled proliferation and growth of cells. Due to early detection methods, there is a decrease in death rates in many types of cancer. However, among the causes of death worldwide, cancer still ranks second after cardiovascular diseases. Therefore, cancer research has focused mainly on developing more effective treatments to reduce deaths from cancer. With a better understanding of the molecular mechanisms in cancer cells, advances in cancer treatment have evolved and changed. The main priority of research is to develop treatment modalities with the highest response rate and less side effects. In this context, immunotherapies have started a new era in cancer treatments.

In India, cancer is rapidly becoming a much bigger public health problem than it once was. According to the most recent estimates, new cancer diagnoses in the country reached nearly 1.6 million in 2023, up from about 980,000 in 2010. And 800,000 people are estimated to die from cancer each year, a number that is expected to grow substantially in the coming decades. Despite this expanding burden of cancer in India, many new cancer treatments are inaccessible because of their high cost and the general lack of insurance coverage among people in India. In addition, some treatments, including CAR T-cell therapy, can cause severe side effects that must be treated in a hospital, further driving up the costs of treatment and requiring access to a nearby hospital, which isn't the case for many people in the country.

Cancer scientists are using AI, DNA sequencing, precision oncology and other tech to improve treatment and diagnosis of the disease. Here are 6 advances. Breakthroughs include the DNA sequencing of more than 12,000 cancer tumours and a new test for diagnosing cancers are being developed world wide. Current immunotherapy therapeutics include inhibitors of immune checkpoint, monoclonal antibodies (mAbs), mRNA vaccines, and adoptive cell transfer in the form of chimeric antigen receptor (CAR)-T cell therapies. Clinical trials are being conducted in the US for a number of CAR T-cell treatments, a type of immunotherapy in which a person's T cells are altered in a lab to specifically destroy cancer cells.

Additionally, even though CAR T-cell therapies appeared to be potential treatments for blood malignancies such as lymphoma and leukemia, once approved for usage, they were likely to be highly expensive and have serious adverse effects. Presently, more than six CAR T-cell therapies have been approved in United States for multiple cancer conditions.



Representative image of CAR-T cells destroying cancer cell

### Breakthrough in CAR-T cell therapy (developed and approved in India)

Due to lack of advanced facilities, Indian scientist Dr Alka Dwivedi embarked on a collaborative journey with scientists from IIT Bombay, Oncologists from Tata Memorial centre, Mumbai and National Institutes of Health (NIH) Clinical Center in Bethesda, Maryland took up the challenge of designing an effective CAR-T cell therapy, actlycabtagene autoleucl (NexCAR19), that could be manufactured in India, made available at a reasonable cost, and meet the needs of patients in India's health care system.

In October 2023, India's Central Drugs Standard Control Organization, made NexCAR19 India's first approved CAR-T cell therapy. The approval was based on the results of two small clinical trials conducted in IndiaExit Disclaimer in 64 people with advanced lymphoma or leukemia. According to trial results presented in December 2023 at the American Society of Hematology meeting, 67% of patients (36 out of 53) in the two trials had a notable decrease in the extent of their cancer (objective response), with the cancer disappearing altogether in about half (complete response). ImmunoACT, a spin-off company of IIT Bombay, funded the trial and will be manufacturing actlycabtagene autoleucl and bringing it to market.

### INSIDE THIS ISSUE

CONTENTS	Pg. No
CAR-T cell therapy: A promise for Indian Cancer patients	1-2
Case Report: Hypertriglyceridemia induced Pancreatitis after Lenvatinib and Pembrolizumab use	3-4
Drug Profile Zelsuvmi (Berdazimer)	4-5
Event Corner	6-8
Publications from the Department of Pharmacy Practice	9



## Procedure

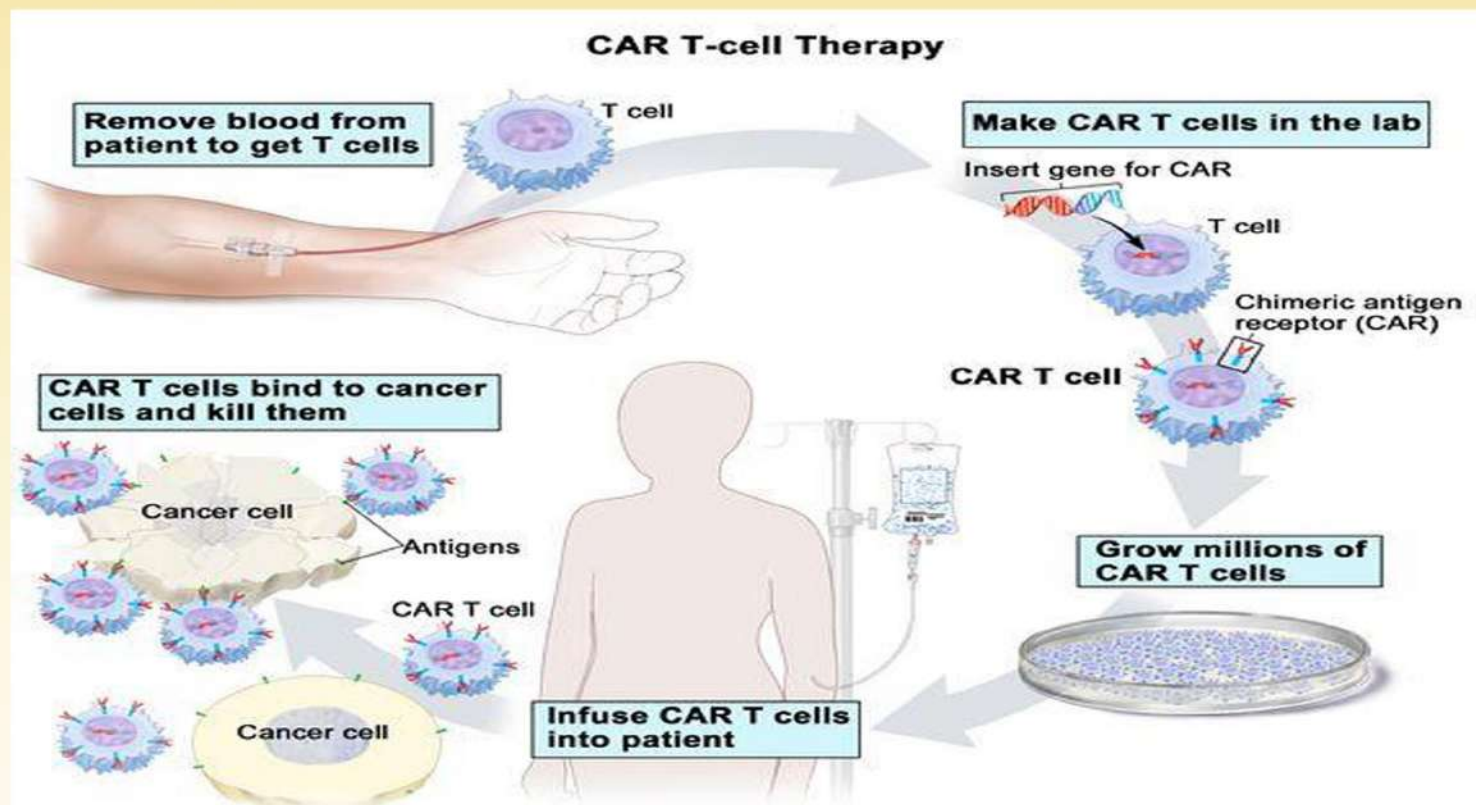
- Isolation: T cells are extracted from the patient's blood through a process called apheresis.
- Modification: In a laboratory, the T cells are engineered to express a chimeric antigen receptor (CAR) on their surface. This CAR is designed to recognize a specific antigen (marker) present in the cancer cells.
- Expansion: The modified T cells, now called CAR-T cells, are multiplied in large numbers in the lab.
- Infusion: The expanded CAR-T cells are infused back into the patient's bloodstream through an intravenous line. Once infused, the CAR-T cells circulate through the body and bind to the specific antigen on the cancer cells. This binding triggers a powerful immune response:
- Activation: The CAR-T cells become activated and release immune molecules that damage and kill the cancer cells.
- Proliferation: Activated CAR-T cells can multiply further within the body, creating an army of cancer-fighting cells.
- Memory: Some CAR-T cells develop memory, enabling them to recognize and attack the cancer cells if they reappear later.

## Patient declared cancer free using Indian-made CAR-T cell therapy

Oncologists from Tata Memorial Hospital, Mumbai declared that first patient as 'Cancer-free' who received CAR-T cell therapy. The patient is Dr (Col) VK Gupta, a Delhi-based gastroenterologist, took this therapy by paying Rs. 42 lakh which would've otherwise cost him Rs 4 crore abroad. Also, the oncologists from Tata Memorial hospital have declared that another two patients are in the verge of declaring 'Cancer-free' status. Despite the challenges, CAR-T cell therapy represents a significant advancement in cancer treatment. Ongoing research is focused on improving its effectiveness, affordability, and accessibility, making it a potentially life-saving option for more patients in the future.

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***"Unfortunately, naturally occurring T cells in patients with cancer are not good at recognizing and fighting cancer cells. CAR T cell therapy has been extremely effective in many patients. In some cases, the treatment has eliminated all signs of cancer. However, CAR T cell therapy doesn't work for all the cancer patient"***



## Case Report

# Hypertriglyceridemia Induced Pancreatitis after Lenvatinib and Pembrolizumab Use

### Introduction

Therapeutic interventions such as chemotherapy in the setting of metastatic endometrial cancer are restricted to a few interventions; one intervention is a combination of Lenvatinib and Pembrolizumab. Lenvatinib is a vascular endothelial growth factor receptor inhibitor, fibroblast growth factor inhibitor, and an inhibitor that acts on platelet-derived growth factor receptor alpha, ret oncogene, and c-KIT oncogene. Pembrolizumab is an immune checkpoint inhibitor that acts against programmed-death-one (PD-1) receptors and programmed-deathligand-one (PD-L1) receptors. In combination, this regimen has proven to be efficacious in the setting of solid malignancies such as advanced endometrial carcinoma as well as hematological malignancies, but this must be weighed against its' side effect profile, the most prominent being hypothyroidism as well as other side effects including fatigue, hypertension, musculoskeletal complaints, diarrhea, and decreased appetite being the most common.

In addition to side effect profiles with the use of both drugs together, there are also side effects of each drug individually. Pembrolizumab has been associated with pancreatitis, more commonly auto-immune pancreatitis, with an incidence of immune checkpoint inhibitor induced pancreatic injury of about 4%. Lenvatinib has been associated with hypertriglyceridemia, with meta-analysis and systemic review noting an event rate of 0.276. However, little has been published in regards to hypertriglyceridemia-induced pancreatitis in the setting of the combination of Lenvatinib and Pembrolizumab and its' management.

Here, we present a 57-year-old female with a history of stage IV uterine cancer with metastasis to the liver status post total abdominal hysterectomy/bilateral salpingo-oophorectomy (on Lenvatinib 8 mg PO daily/pembrolizumab 200 mg IV every 3 weeks) presenting with epigastric pain, nausea, vomiting, and decreased appetite; her symptoms were due to hypertriglyceridemia-induced pancreatitis in the setting of Lenvatinib and Pembrolizumab use.

### Case Report

A 57-year-old female with history of stage IV uterine cancer with metastasis to the liver status post total abdominal hysterectomy/bilateral salpingo-oophorectomy (on Lenvatinib 8 mg PO daily/Pembrolizumab 200 mg IV every 3 weeks), primary adrenal insufficiency, hypothyroidism, hypertension, and history of pulmonary embolism on rivaroxaban, presented to the emergency department with complaints of an acute onset of epigastric pain, nausea, vomiting, and decreased appetite over the course of 1 day.

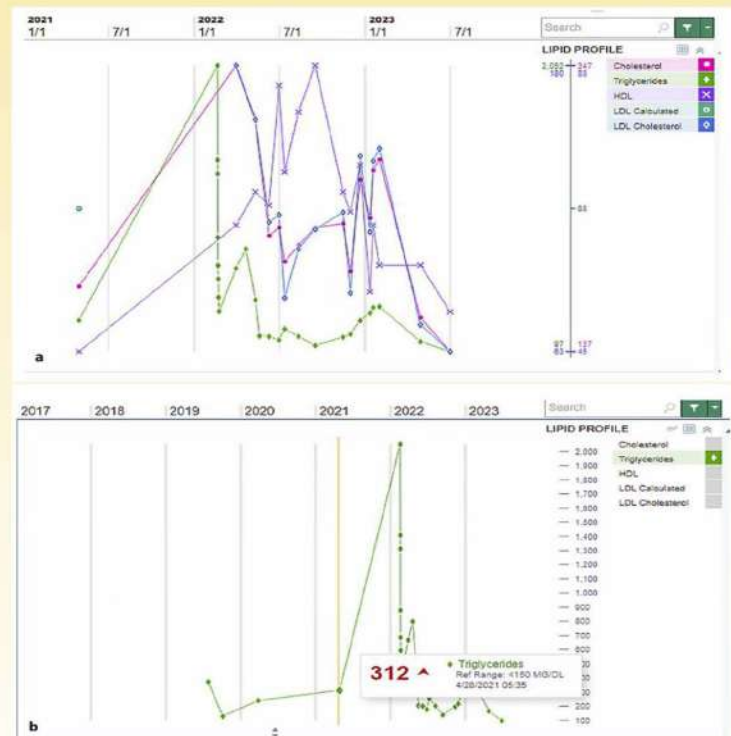
In the emergency department, vital signs were significant for tachycardia (124) and hypertensive blood pressure (142/94). Patients' height was 157 cm (5 feet 2 inches) and their weight was 57.5 kg (126 lb and 12.2 oz) with a BMI of 23.2 kg/m<sup>2</sup>. Physical exam was significant for epigastric tenderness. Initial workup was significant for: an acute kidney injury with the creatinine increased from baseline (1.99), elevated lactate (6.8), hypocalcemia (5.5), lipase of 1,508, and triglycerides of 2,052. CT abdomen and pelvis displayed diffuse peripancreatic inflammation and edema, which was consistent with acute pancreatitis. Patient was started on an insulin drip at 0.1 units/kg/h and IV fluids with dextrose 5% in water (D5W) and admitted to the ICU for hypertriglyceridemia-induced acute pancreatitis. There were no diagnostic challenges during the initial workup for the diagnosis. While in the ICU, serum triglyceride levels were measured every 12 h and steadily declined. Once the triglyceride levels reached 469, the patient was transitioned off the insulin and dextrose 5% in water, and triglycerides were no longer trended; IV fluids were continued, and the patient was downgraded from the ICU.

Oncology was consulted given the history of metastatic adenocarcinoma of the endometrium and the fact that the patient was

undergoing chemotherapy with the last dose of pembrolizumab 200 mg IV administered on February 16, 2022, 2 days prior to admission. Per chart review, it was noted that the patient was started on Lenvatinib and Pembrolizumab on March 31, 2021; her last lipid panel, which was performed on April 28, 2021, was significant for an elevated triglyceride level of 312, but otherwise the lipid panel was within normal limits. Patients' lipid profile over time is depicted in Figure a with patients triglyceride levels depicted over the course of time in Figure b. Given that the patient denied any other changes to lifestyle such as dietary changes or alcohol consumption, stable normal weight BMI, and no other risk factors for pancreatitis, there was a concern that this patient's pancreatitis could have been due to chemotherapy administration. Oncology recommended that supportive management be continued with IV fluids, PO intake as tolerated, and continuing to trend triglycerides. Patient's symptoms improved during the course of hospitalization, and patient was discharged with outpatient follow-up with oncology, where she was continued on her chemotherapy with serial triglyceride levels to monitor for hypertriglyceridemia, at which point cessation of the medication or decreased dosing were to be discussed. However, the patient's triglyceride levels remained stable, and no adverse event occurred.

### Discussion

Pancreatitis due to hypertriglyceridemia is one of the three common causes of pancreatitis. It can be primary in nature, due to genetic disposition, or it can be due to a secondary cause, such as medications (like chemotherapy), diabetes, or alcohol use. Elevated triglycerides greater than 1,000 with lipase levels greater than 3 times the normal limit typically establish hypertriglyceridemia as the cause of pancreatitis. This typically occurs through two main mechanisms. One mechanism that has been postulated involves lipases in the pancreas that break down the triglycerides in chylomicrons to free fatty acids;



**Fig. a.** Patients lipid panel trend since 2021 to current. The patient's lipid panel was drawn on April 28, 2021, and the patient was started on pembrolizumab and lenvatinib on March 31, 2021.  
**b.** Patients triglyceride level 312 on April 28, 2021, with a peak of greater than 2,000 in 2022 on the date of admission to the hospital for hypertriglyceridemia-induced pancreatitis. Patient was started on pembrolizumab and lenvatinib on March 31, 2021.



these free fatty acids then bind to albumin. However, once all the albumin available is saturated with free fatty acid, the unbound free fatty acids aggregate, thus forming micellar structures; these micellar structures cause damage to both acinar cells and vascular endothelium, resulting in ischemia and acidosis. This acidosis activates trypsinogen, which then triggers pancreatitis. The second mechanism occurs in the setting of increased plasma viscosity (through elevated chylomicrons); this also causes ischemia and acidosis, resulting in pancreatitis. Apheresis is one of the first lines of treatment for hypertriglyceridemia-induced pancreatitis; however, given the expense and limited availability, it is not always available in the management of hypertriglyceridemia. IV insulin is another option for management; it activates LPL, increasing chylomicron breakdown to lower triglyceride levels.

Pancreatitis is one of the adverse effects noted with Pembrolizumab or with combination of Lenvatinib and Pembrolizumab. The exact mechanism is unknown, but it appears to be auto-immune-related through the PD-1/PD-L1 receptors located on pancreatic beta cells, resulting in inflammation of the pancreas; these episodes of auto-immune pancreatitis are usually treated with steroids and either decreasing the dose of the chemotherapy or discontinuing the chemotherapy.

As for this case, hypertriglyceridemia-induced pancreatitis, the exact mechanism is unknown as publications are limited in this regard, which may be a limitation of this case report. However, given that immunotherapy has proven to be efficacious in the treatment of

various hematological and solid tumor malignancies, its use will likely continue to expand and grow as a form of intervention for various malignancies. Therefore, further research to better understand this mechanism of hypertriglyceridemia-induced pancreatitis should be performed. One way to better understand the mechanism can be through biopsy to further assess its' mechanism with immunostaining.

Lenvatinib and Pembrolizumab have proved to be successful in the treatment of metastatic endometrial cancer; however, this chemotherapy regimen requires close monitoring for possible side effects, like hypertriglyceridemia and pancreatitis. However, while these side effects have been attributed to these drugs, limited research has been performed to better understand the pathophysiology of these side effects. Furthermore, there have been limited studies published with regards to hypertriglyceridemia-induced pancreatitis in the setting of lenvatinib and pembrolizumab use. Future research should be directed toward better understanding the pathophysiology and its' subsequent management.

From the patient perspective, quick diagnosis and ease of treatment were appreciated. Close follow-up and monitoring provided safe and comforting reassurance for the patient while on treatment.

#### References

Kinza Sultana, Ziad Khan, Siamak Saadat. Case Report: Hypertriglyceridemia-Induced Pancreatitis after Lenvatinib and Pembrolizumab Use. Case Rep Oncol 2024;17:311–316

## **DRUG PROFILE** *Zelsuvmi (Berdazimer)*

#### Indications and Usage

Zelsuvmi is indicated for the topical treatment of molluscum contagiosum (MC) in adults and pediatric patients 1 year of age and older.

#### Ingredients

##### Tube A

*Active ingredient:* Berdazimer sodium

*Inactive ingredients:* Cyclomethicone, Hexylene Glycol, Hydroxypropyl cellulose, and Isopropyl Alcohol

##### Tube B

*Inactive ingredients:* Benzoic acid, carboxymethylcellulose sodium, cyclomethicone, ethanol, glycerin, potassium phosphate monobasic, and purified water

#### Recommended Dosage and Administration

• Dispense equal amounts (0.5 mL) of gel from Tube A and Tube B on the dosing guide.

Immediately put the caps back on Tube A and Tube B tightly.

- Mix together on the dosing guide.
- Immediately apply Zelsuvmi as an even thin layer. Apply Zelsuvmi once daily to each MC lesion for up to 12 weeks.
- Wash hands after applying Zelsuvmi, unless hands are being treated.
- Allow Zelsuvmi to dry for 10 minutes after application.
- Avoid application to uninvolved skin and avoid transfer of applied Zelsuvmi to other areas, including the eye.
- Avoid swimming, bathing, or washing for 1 hour after application of Zelsuvmi.
- Zelsuvmi is for topical use only and not for ophthalmic, oral, or intravaginal use.

#### Mechanism of Action

Zelsuvmi is a nitric oxide releasing agent. The mechanism of action for the treatment of molluscum contagiosum is unknown.

#### Warnings and Precautions

Application site reactions, including allergic contact dermatitis, have occurred in patients treated with Zelsuvmi. Suspect allergic contact dermatitis in the event of pain, pruritus, swelling or erythema at the application site lasting longer than 24 hours. If allergic contact dermatitis occurs, discontinue Zelsuvmi and initiate appropriate therapy.

- Zelsuvmi is for use on top of the skin (for topical use only).
- Do not treat bumps close to your eye or get gel in your eye. If gel gets in your eye, rinse with water.
- Do not eat gel. If gel is swallowed, contact your healthcare provider.
- Do not apply gel to open wounds. If gel gets into an open wound, rinse with water.
- Do not get gel into the mouth, vagina, or on areas of your skin where you do not have bumps.

#### Pharmacokinetics

Plasma hydrolyzed MAP3 (hMAP3), a structural marker for berdazimer, and nitrate levels were evaluated in n=34 subjects 2 to 12 years of age with MC. Subjects applied ZELSUVMI once daily for two weeks to a total treatment area of 484 cm<sup>2</sup> (mean lesion count=34), applying a mean dose of approximately 3 mL/day. No subjects had quantifiable plasma hMAP3 concentrations on day 1; two subjects had quantifiable concentrations on day 15. Mean plasma nitrate levels were similar on days 1 and 15 and remained relatively flat during the PK sampling period (baseline through 1, 3, and 6 hours post-application).

There were no apparent differences in methemoglobin levels throughout the study.



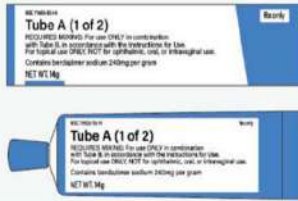
Clinical Presentations of Molluscum Contagiosum



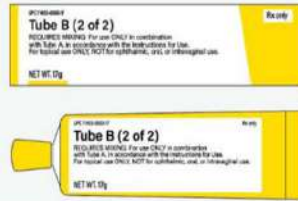
## Instructions for use

### Box Contents (Figure A):

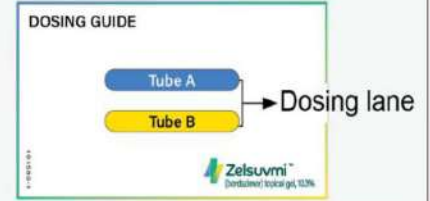
#### 1 Tube A



#### 1 Tube B



#### 1 Dosing Guide



#### Step 1. Wash Hands

Always wash and dry hands before applying gel.



#### Step 2. Dispense Gel

Place Dosing Guide on a flat surface.

Remove cap from Tube A. Hold Tube A near blue Tube A dosing lane. Squeeze gel onto blue lane to cover entire area of the lane. The gel is white on the dosing guide. Screw cap back onto Tube A.



Remove cap from Tube B. Hold Tube B near yellow Tube B dosing lane. Squeeze gel onto yellow lane to cover entire area of the lane. The gel is clear to almost clear on the dosing guide. Screw cap back onto Tube B.



#### Step 3. Mix Gels

Use a fingertip to combine the 2 gels from the blue and yellow lanes. Mix the gels in the center of the Dosing Guide using a circular motion. It is important that the 2 gels get mixed well. Mix the 2 gels together while slowly counting to 20. You may see clumps during mixing and this is normal. Apply the mixed gel right away to the bumps.



#### Step 4. Apply Mixed Gel

Apply an even thin layer of mixed gel to each bump right away.

- All bumps should be treated with gel.
- Make sure to cover bumps that are new, hard to reach, or out of sight.



If you run out of mixed gel before you have treated all the bumps, wipe off your Dosing Guide with a dry tissue. Follow steps 2, 3, and 4 to apply the mixed gel to the remaining untreated bumps.

After all bumps have been treated:

- Follow the cleaning and storing steps below.
- Wait at least 10 minutes after applying gel before putting clothes on skin to allow ZELSUVMi to dry.
- Wait at least 1 hour after applying gel before swimming, washing, bathing, or showering.

#### Step 5. Clean Dosing Guide

Use water and mild soap to remove remaining gel from Dosing Guide. Dry Dosing Guide.



#### Step 6. Storing ZELSUVMi

Put dry Dosing Guide and this Instructions for Use back in box. Secure caps on tubes and place back in box.

Store ZELSUVMi at room temperature between 68°F to 77°F (20°C to 25°C) in a dry location. Product contains alcohol and should be kept away from open flame. Do not freeze. Throw away if not used within 60 days after receiving ZELSUVMi.

#### Step 7. Wash Hands

Always wash hands after you place the contents back in the box unless your hands were treated.



#### Disposing of ZELSUVMi

Throw away (dispose of) tubes in household trash when empty or when treatment is stopped.



Manufactured for:  
EPIH SPV, LLC, Wilmington, DE 19801



## Clinical Studies

The efficacy of ZELSUVMi was evaluated in 3 multicenter, randomized, double-blind, parallel group, vehicle-controlled trials in subjects with MC (Trials 1, 2, and 3; NCT04535531, NCT03927703, and NCT03927716, respectively). Trial 1 enrolled 891 subjects, Trial 2 enrolled 355 subjects, and Trial 3 enrolled 352 subjects. Subjects were randomized 1:1 in Trial 1, and 2:1 in Trials 2 and 3 to receive ZELSUVMi or vehicle applied to MC lesions once daily for up to 12 weeks.

In the three trials, 3% of subjects were less than 2 years of age and 96% of subjects were 2 to 17 years of age. The trial population included 51% male, 88% White, 6% Black, and 6% Other; for ethnicity, 21% of subjects identified as Hispanic/Latino, 78% as non-Hispanic/Latino, and 1% were not reported. Subjects had 3-70 baseline MC lesions. At baseline, the average MC lesion count was 20.2.

The primary efficacy endpoint was the proportion of subjects achieving complete clearance at Week 12. Complete clearance was defined as the subject having a total MC lesion count of 0 at assessment. The key secondary efficacy endpoint was complete clearance rate at Week 8. Efficacy was demonstrated in Trials 1 and 2. The results are summarized in Table. In Trial 3, the complete clearance rates at Week 12 were 26% versus 22% for ZELSUVMi and vehicle, respectively, with 95% confidence interval (-5%, 14%).

	Trial 1		Trial 2	
	ZELSUVMi (N=444)	Vehicle (N=447)	ZELSUVMi (N=237)	Vehicle (N=118)
<b>Complete Clearance Rate at Week 12 (Primary Endpoint)</b>	32.4%	19.7%	30.0%	20.3%
Treatment Difference (95% Confidence Interval)	12.8% (7.1%, 18.6%)		9.2% (-0.04%, 18.4%)	
<b>Complete Clearance Rate at Week 8 (Secondary Endpoint)</b>	19.6%	11.6%	13.9%	5.9%
Treatment Difference (95% Confidence Interval)	7.5% (3.0%, 12.0%)		7.8% (1.8%, 13.8%)	

## Storage and Handling

- Prior to Dispensing: Store ZELSUVMi in a refrigerator between 2°C and 8°C (36°F and 46°F) until dispensed to the patient. Write the "Discard after" date in the space provided on the carton.
- After Dispensing: Store ZELSUVMi at room temperature, between 20°C to 25°C (68°F and 77°F) in a dry location.
- Product contains alcohol and should be kept away from open flame.
- Do not freeze.
- Discard 60 days after removal from refrigeration.

***"ZELSUVMi is a prescription medicine used on the skin (topical) to treat molluscum contagiosum (MC) in adults and children 1 year of age and older"***

## Reference

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2024/217424s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/217424s000lbl.pdf)

## Side Effects

Following are the side effects at the application site:

- o pain
  - o swelling
  - o burning
  - o breakdown of the outer layer of the skin (erosion)
  - o stinging
  - o lightening or darkening of the skin
  - o redness
  - o blisters
  - o itching
  - o irritation
  - o peeling or flaking
  - o infection
  - o itchy, dry skin rash
- Stop using Zelsuvmi if side effects developed that lasts for more than 24 hours after treatment with Zelsuvmi.

## How Supplied

Zelsuvmi (berdazimer) topical gel, 10.3% is supplied in a carton (NDC 71403-103-31) containing:

- Tube A (14 g) with blue label containing berdazimer sodium in an opaque white to off white gel (NDC 71403-113-14)
- Tube B (17 g) with yellow label containing translucent to opaque white to off-white gel (UPC 71403-0000-17)
- Dosing Guide



## EVENT CORNER

### World Cancer Day 2024-Screening and Health Awareness Program

**Coordinator:** Dr Deepalakshmi M  
Assistant Professor  
Department of Pharmacy Practice  
JSS College of Pharmacy, Ooty

**Organized by:** Department of Pharmacy Practice  
**Venue:** Government Botanical Garden, The Nilgiris.  
**Date:** 04.02.2024

Department of Pharmacy Practice JSS college of Pharmacy, Ooty in association with IPA Nilgiris local branch, Rotract club Nilgiris West, Rotaract Club of JSSCP and BS hospital, Ooty jointly organised a Cancer Awareness program at the Government Botanical Garden, Ooty sponsored by JSSAHER, Mysuru. The program was aimed to raise awareness about the cancer risk factors, the importance of diagnosis, screening, vaccination, treatment and prevention of the cancer among the tourists who visited the garden. A total of 7 volunteers from V PharmD actively involved in health screening activities of the program, 5 faculty members delivered their counseling addressing each topic related to cancer and there were around 130 participants who involved in the program.

The volunteers actively educated the public with enough sufficient points regarding cancer and created a general cancer awareness video which attracted the public. As a part of the awareness program the activities like impressing her thumb print in the Fingerprint tree, One minute plank challenge and distribution of free plant samplings were executed. The event was a resounding success, through informative counseling, and screening, the program encouraged about valuable insights on awareness of cancer. It served as a reminder that healthy lifestyle is mandatory and emphasized the significance of seeking support and understanding. The program received positive feedback from the woman in attendance, indicating a desire for similar initiatives in the future.



### Continuing Pharmacotherapy Education (CPhE) Therapeutic Medical devices in Cardiac Surgery

**Coordinator:** Dr. Sivasankaran Ponnusankar  
Professor & Head  
Department of Pharmacy Practice  
JSS College of Pharmacy, Ooty.

**Organized by:** Dept. of Pharmacy Practice  
**Venue:** Seminar Hall, JSS College of Pharmacy, Ooty.  
**Date:** 22.02.2024  
**Time:** 03.00 PM – 05.15 PM

**Speaker:** Dr. Bellipady Shyam Prasad Shetty  
Deputy Director-Clinical Services, JSS Hospital, Mysuru  
Prof. & Head, Dept of Cardiothoracic & Vascular Surgery,  
JSS Medical College, Mysuru.

Dr. Bellipady initiated the seminar with an overview of cardiac surgery, emphasizing its significance in treating various heart conditions, including coronary artery disease, valvular heart disease, and congenital heart defects and also explained the significance and history of Heparin & Warfarin. The presenter introduced various therapeutic medical devices commonly used in cardiac surgery, including TTK Chitra™ heart valve, calcified Aortic valve, ST Jude, Porcine Valve, ONYX Valve, Polymer valve, Tubular Pericardial valve, Allo Graft, Star Edwards valve, Types of Artificial Valves like Mechanical Valves and Bioprosthetic Valves, Bioprosthetic sutureless valve, Atrial Septal defect Closure Devices, ICD, Implantable Cardioverter-Defibrillator, Impella Device Right, Impella Device Left, Biventricular Assist Device, HeartMate 3, Jarvik 2000 LVAD, Carmat Artificial Heart, ABIOCOR Total Artificial Heart and also emphasized the Importance of organ donation.

Dr. Bellipady elaborated on the applications and benefits of therapeutic medical devices in cardiac surgery. He discussed how these devices help in restoring normal heart function, improving blood circulation, preventing arrhythmias, and reducing the risk of heart failure. Additionally, Dr. Bellipady addressed the challenges associated with therapeutic medical devices in cardiac surgery, including device-related complications, cost considerations, and the need for continuous innovation. He also discussed future directions in research and development aimed at further enhancing the effectiveness and safety of these devices.

The seminar provided valuable insights into the role of therapeutic medical devices in modern cardiac surgery. Attendees gained a deeper understanding of the various devices used, their applications, and benefits, as well as the challenges and future prospects in this rapidly evolving field. The speaker also highlighted the role of Clinical Pharmacists in Cardiac Surgeries. At the end of the programme, students clarified their doubts about various cardiac problems, treatment strategies used in hospitals for selecting suitable medical devices for individual patients, etc. Around 95 students participated and benefited from this Continuing Pharmacotherapy Education (CPhE) Programme.





## World Tuberculosis Day 2024- Screening and Health Awareness Program

**Coordinator:** Dr Deepalakshmi M  
Assistant Professor  
Department of Pharmacy Practice  
JSS College of Pharmacy, Ooty

**Organized by:** Department of Pharmacy Practice  
**Venue:** Avataa, Billimalai Tea Estate, Selas  
**Date:** 24.03.2024

The Department of Pharmacy Practice, JSS College of Pharmacy, Ooty in association with IPA Nilgiris Local Branch and Rotaract organized an outreach program on 24.03.2024 at Avataa, Billimalai Tea Estate, Selas to mark World Tuberculosis Day. The program aimed to raise awareness among the audience about the importance of tuberculosis prevention and overall well-being.

Dr. Deepalakshmi M gave an informative educational session on tuberculosis, discussing its epidemiology, prevention, and treatment options. Informative videos about tuberculosis were showcased in the regional language, aiming to enhance understanding and awareness among the audience. Participants were also provided with informative pamphlets detailing education about tuberculosis, its symptoms, patient counseling, and treatment options. Seventy participants actively participated in the outreach program, where they benefited from a general check-up. The program included assessments for vital health indicators such as blood pressure, pulse rate, height, weight, and blood sugar levels. These screenings are crucial for early detection and management of potential health issues, promoting overall well-being among participants. The initiative reflects a proactive approach to healthcare, empowering individuals to monitor and take charge of their health status. The DOTS Mobile Van from NTEP was present at the event. As part of its services, Chest X-ray screenings were conducted for all 70 participants. This mobile healthcare unit brings diagnostic capabilities to communities, facilitating early detection and monitoring of TB cases. The Chest X-ray screenings play a crucial role in identifying TB-related abnormalities in the lungs, allowing for prompt medical intervention and treatment initiation when needed. The presence of such comprehensive services underscores the commitment to proactive healthcare management and disease prevention within the community.



## World Kidney Day 2024- Screening and Health Awareness Program

**Coordinator:** Dr Deepalakshmi M  
Assistant Professor  
Department of Pharmacy Practice  
JSS College of Pharmacy, Ooty

**Organized by:** Dept.of Pharmacy Practice  
**Venue:** Indian Overseas Bank, Commercial Road, Ooty, The Nilgiris.  
**Date:** 14.03.2024

Department of Pharmacy practice JSS College of Pharmacy, Ooty in association with IPA Nilgiris local branch, Rotary Club Nilgiris West, Rotaract Club of JSSCP, and Govt. Medical College and hospital, Ooty organized an kidney awareness program at the IOB, Commercial Road, Ooty, The Nilgiris. The program was sponsored by JSSAHER, Mysuru, and aimed to raise awareness about kidney risk factors, and the importance of early diagnosis, screening, treatment, and prevention of Kidney diseases among the public & customers of IOB. A total of 7 volunteers from IV PharmD and Ph.D. Scholars were actively involved in the health screening activities of the program, 5 faculty members delivered their counseling addressing each topic related to kidney.

In this health screening camp, about 113 patients benefitted. Blood pressure was monitored using an electronic sphygmomanometer, Blood glucose was measured using a Glucometer, and Body mass index was calculated by measuring the patient's height and weight to determine whether the patient was underweight, healthy weight, overweight, or obese. Patient counseling was given to the participants according to the screening results and Patient information pamphlets were distributed to all the participants to develop awareness among the local people regarding kidney disease. The questionnaire was provided to participants to understand their knowledge about the disease Faculty from Govt. Medical College and Hospital collected the blood sample and did the Renal function test. Awareness videos are also projected in the screening about the kidney functions and kidney diseases. The event was a resounding success, through informative counseling, and screening, the program encouraged valuable insights on awareness of Kidney The program received positive feedback from the participants in attendance, indicating a desire for similar initiatives in the future.





# INDO AUSTRALIAN SYMPOSIUM ON "PHARMACY PRACTICE FOR IMPROVED PATIENT CARE – GLOBAL PERSPECTIVES FOR REGIONAL PRACTICE"

**Coordinator:** Dr Ponnusankar S  
Professor & Head  
Department of Pharmacy Practice  
JSS College of Pharmacy, Ooty

**Organized by:** Dept. of Pharmacy Practice  
**Venue:** JSS College of pharmacy, Ooty  
**Date:** 16.03.2024

## Plenary Speakers:

### Pro. Frank May

Director, RGH Pharmacy Consulting Services PikaWiya  
Health Service Aboriginal Corporation Port Augusta  
South Australia

### Dr. Debra Rpwett

Professor  
Discipline Leader: Pharmacy External Relations Clinical & Health Sciences  
University of South Australia, South Australia

### Dr. Bronwyn Clark

Chief Executive Officer  
Australian Pharmacy Council Ngannawal Country  
Australia

### Dr. Sue Kirsia

Associate Professor & Chair  
Australian Pharmacy Council, Ngannawal Country  
Australia

### Dr Tasma Wagner

Regional Lead Pharmacist, Specialist Clinical Pharmacist  
Port Augusta Hospital, Pharmacy department  
South Australia

### Dr. Vijay Suppiah

Lecturer, Department of Psychiatry Pharmacy  
University of South Australia  
South Australia

### Dr. S. Sriram

Professor & HoD, Department of Pharmacy Practice  
College of Pharmacy  
Sri Ramakrishna Institute of Paramedical Sciences  
Coimbatore, Tamil Nadu

### Dr. Priya Karunakaran

Head Clinical Pharmacy Services  
Aster MedCity  
Kochi, Kerala, India

### Dr. Grace Mary John

Infectious Diseases Clinical Specialist  
Head - Clinical Pharmacy Department  
Believers Church Medical College Hospital  
Thiruvalla, Kerala, India

Australia's pharmacy landscape is characterized by commitments to patient-centred care, development of professional standards, and collaborative efforts to improve health outcomes. Historically, the Pharmacy leaders, professionals & practitioners of Australia were instrumental for the genesis of 'Pharmacy Practice' concept and introduction of pharmacy practice education & training in India, wayback in 1990s. Since then, the veteran pharmacy colleagues from Australia are mentoring for the sustenance and growth of Pharmacy Practice education & training in India. JSS COLLEGES OF PHARMACY - THE PIONEERS IN PHARMACY PRACTICE JSS Colleges of Pharmacy, Ooty & Mysuru hold the legacy of having introduced the graduate program in Pharmacy Practice for the first time in India. The diversified services of pharmacy professionals in Hospital, Clinical and Community settings evolved in the last three decades are sown in 1996-97 by JSS Colleges of Pharmacy, Ooty & Mysuru that launched the Master of Pharmacy in Pharmacy Practice. Obviously, the success of this graduate program encouraged the regulators to introduce the Doctor of Pharmacy (Pharm D) program in 2008 and thus, JSS Colleges are the hothouses of Pharmacy Practice education in India.

## ABOUT THE SYMPOSIUM

The Indo-Australian symposium is designed by capitalizing the professional network with the leaders of pharmacy practice in Australia and affluent accomplishments of JSS in pharmacy practice area. The objective of this symposium is to embrace the vast experiences of the pharmacy practice regulators & practitioners of Australia to refine, enrich and expand the knowledge of the faculty, students and practicing pharmacists of India. The symposium is structured with keynote addresses and plenary lectures by the eminent, senior most pharmacy practice regulators, practitioners and trainers on topics that cover the evolution of new standards for pharmacy practice services, novel patient care services, speciality pharmaceutical care services, challenges, and opportunities of patient care services, etc. Also, each session is scheduled with discussion time and dedicated slots for panel discussions to make the event more interactive and exploratory.

## THE PARTICIPANTS

The faculty members of Pharmacy Practice, Pharm D Clerkship & Internship students, M Pharm Pharmacy Practice students, and the practicing pharmacists who registered for the Three Days International Conference on "Global Collaboration in Pharmaceuticals: Bridging Borders, Breaking Barriers" are eligible to register for the Indo-Australian Symposium on "Pharmacy Practice for Improved Patient Care - Global Perspectives for Regional Practice". There is NO registration fee exclusively for the symposium, and the total number of participants were over 300 through a separate registration on first-come-first serve basis.





# Publications from the Department of Pharmacy Practice (January-March 2024)

- Jyothikrishna P, Karthika Anoop Krishnaveni Nagappan, Deepalakshmi M, **Arun K Parthasarathy**. Response Surface Methodology Assisted RP-HPLC Method for the Determination of Meropenem in Human Plasma: Application to a Pharmacokinetic Study. International Journal of Pharmaceutical Quality Assurance. 2024.14(04):1115-1125.
- **Deepalakshmi M**, Anslin Joanna, Keerthana Venkat Arun K, Malwyn Moffy, Arun K Parthasarathy. P Glycoprotein Mediated Drug Interaction between Digoxin and Orange Juice-Exploratory Study by In-vitro Approach. International Journal of Drug Delivery Technology. 2024.13(04):1418-1421.
- Sharumathi S M, Bhavatharini S, Rinu Mary, **Deepalakshmi M**. Extrapyramidal Effects of First and Second Generation Antipsychotics: A Review. International Journal of Drug Delivery Technology. 2024.13(04):1623-1630.
- Darshan Nair M, Praveen Kumar M, Reenaselvi S, Preetha R, Jeyalalitha R, Ponnusankar S, **Mohsina HYder**. Knowledge, Attitude and Practices on prediabetes management among selected paramedical professionals of Tamil Nadu: A cross sectional survey. International Journal of Chemical and Biochemical Sciences. 2024. 25(13): 478-484.
- **Ponnusankar S**, Nagul Adhithya, Rebinno De Alex, Mugilraj S, Balasubramanian V. Assessment of students pharmacist competency in dispensing cough medicines for self-medication: a simulated patient study. Egyptian Pharmaceutical Journal. 2024; 23: 28-34.
- Janvee Thaman, Rashmi Saxena, Chaitanya MVNL, Palakurthi Y, Prabha T, Sarika S, Patrick A, Smriti Arora, **Ponnusankar S**, Pratiba P, Avijit Mazumder. Reconciling the gap between medications and their potential leads: the role of marine metabolites in the discovery of new anticancer drugs: a comprehensive review. Current Pharmaceutical Design. 2023; 29: 3137-3153.
- Yasir Qasim A, **Ponnusankar S**, Chaitanya MVNL, Arya Lakshmi, Chou-Yi Hsu, Aya Mohammed Dhiaa, Mohamed J Saadh, Yogendra Pal, Russul. Chitosan based nanofibrous scaffolds for biomedical and pharmaceutical applications: a comprehensive review Thabit, Ayat Hussein Adhab, Fahad Alsaikhan, Asghar Narmani, Bagher Farhood. International Journal of Biological Macromolecules. 2024; 264: 130683.

**RESEARCH ARTICLE**

### Response Surface Methodology Assisted RP-HPLC Method for the Determination of Meropenem in Human Plasma: Application to a Pharmacokinetic Study

Jyothikrishna P<sup>1</sup>, Anoop Karthika<sup>2</sup>, Krishnaveni Nagappan<sup>3</sup>, Deepalakshmi M<sup>4</sup>, Arun K P<sup>5</sup>

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**Abstract:** A simple, accurate and precise development of an reversed-phase high performance liquid chromatography (RP-HPLC) method for the quantification of meropenem in human plasma samples for therapeutic drug monitoring (TDM) was developed and validated after optimization of various chromatographic parameters. The best recovery of meropenem was achieved through simple extraction based on a simple extraction method that included 60% methanol extraction with acetonitrile. The developed method is suitable for selectivity, accuracy and precision, carry-over, dilution integrity and stability. The developed method was effectively shown to be applicable to a real-time monitoring and pharmacokinetic study of meropenem in critically ill patients.

**Keywords:** Meropenem, Human plasma, Biophysical method, RP-HPLC, Pharmacokinetics.

International Journal of Pharmaceutical Quality Assurance (2024), DOI: 10.2525/IJQA.24.14.04

**How to cite this article:** Jyothikrishna P, Karthika A, Nagappan K, Deepalakshmi M, Arun K P. Response Surface Methodology Assisted RP-HPLC Method for the Determination of Meropenem in Human Plasma: Application to a Pharmacokinetic Study. International Journal of Pharmaceutical Quality Assurance. 2024;14(04):1115-1125.

Source of support: Nil.

Conflict of interest: None.

**RESEARCH ARTICLE**

### P Glycoprotein Mediated Drug Interaction between Digoxin and Orange Juice-Exploratory Study by In-vitro Approach

Deepalakshmi M, Anslin Joanna, Keerthana Venkat Arun K, Malwyn Moffy, Arun K P

<sup>1</sup>JSS College of Pharmacy, JSS Academy of Higher Education & Research, Vijaya Vittala, India.

**Abstract:** Digoxin is an often transporter that plays a vital role in drug transportation. As an exploratory study it aimed to find the glycoprotein (P-gp) mediated drug interaction between digoxin and orange juice, conducted for a period of six months. The 20 extracts of the orange juice was prepared from the freshly by molecular blending using acidic settings. The structural analysis and verification were used to assess the in-vitro chemical quality of these structures. The molecular structure of P-gp in a transport cycle has been investigated using a variety of methods. Molecular docking has been performed to predict the highest binding affinity to P-gp with ligands of orange juice and ligands of digoxin. In 30% ethyl acetate extract of orange juice was prepared and a transcellular transport study was done using MDRI transporter and MDR2 transporter (LLC-9K1, LLC-GS-COL1B, LLC-9K1, LLC-MDR1, LLC-MDR3, LLC-MDR4, LLC-MDR5, LLC-MDR6, LLC-MDR7, LLC-MDR8, LLC-MDR9, LLC-MDR10, LLC-MDR11, LLC-MDR12, LLC-MDR13, LLC-MDR14, LLC-MDR15, LLC-MDR16, LLC-MDR17, LLC-MDR18, LLC-MDR19, LLC-MDR20, LLC-MDR21, LLC-MDR22, LLC-MDR23, LLC-MDR24, LLC-MDR25, LLC-MDR26, LLC-MDR27, LLC-MDR28, LLC-MDR29, LLC-MDR30, LLC-MDR31, LLC-MDR32, LLC-MDR33, LLC-MDR34, LLC-MDR35, LLC-MDR36, LLC-MDR37, LLC-MDR38, LLC-MDR39, LLC-MDR40, LLC-MDR41, LLC-MDR42, LLC-MDR43, LLC-MDR44, LLC-MDR45, LLC-MDR46, LLC-MDR47, LLC-MDR48, LLC-MDR49, LLC-MDR50, LLC-MDR51, LLC-MDR52, LLC-MDR53, LLC-MDR54, LLC-MDR55, LLC-MDR56, LLC-MDR57, LLC-MDR58, LLC-MDR59, LLC-MDR60, LLC-MDR61, LLC-MDR62, LLC-MDR63, LLC-MDR64, LLC-MDR65, LLC-MDR66, LLC-MDR67, LLC-MDR68, LLC-MDR69, LLC-MDR70, LLC-MDR71, LLC-MDR72, LLC-MDR73, LLC-MDR74, LLC-MDR75, LLC-MDR76, LLC-MDR77, LLC-MDR78, LLC-MDR79, LLC-MDR80, LLC-MDR81, LLC-MDR82, LLC-MDR83, LLC-MDR84, LLC-MDR85, LLC-MDR86, LLC-MDR87, LLC-MDR88, LLC-MDR89, LLC-MDR90, LLC-MDR91, LLC-MDR92, LLC-MDR93, LLC-MDR94, LLC-MDR95, LLC-MDR96, LLC-MDR97, LLC-MDR98, LLC-MDR99, LLC-MDR100).

**REVIEW ARTICLE**

### Extrapyramidal Effects of First and Second Generation Antipsychotics: A Review

Sharumathi SM, Bhavatharini S, Rinu MX, Arun KP, Deepalakshmi M

<sup>1</sup>Department of Pharmacy Practice, JSS College of Pharmacy, JSS Academy of Higher Education & Research, Vijaya Vittala, India.

**Abstract:** Antipsychotics are essential for treating major psychiatric disorders like schizophrenia. Second-generation antipsychotics were developed to reduce the risk of extrapyramidal symptoms (EPS) caused by antipsychotic medication. While second-generation drugs have a lower risk of EPS than first-generation treatments, studies show that they can still cause EPS, with changes but the least likely and milder than the first. Literature search of PubMed and Scopus databases and April 2023 found the high doses, a history of EPS, comorbidity, and specific second-generation medications can reduce the risk of EPS. The choice of a first-generation comparator also influences study findings. Although the prevalence and severity of EPS vary with antipsychotics, these medications have not met expectations in terms of tolerability. EPS is still a clinical issue, and it is the aim of second-generation antipsychotics. This review offers a concise overview of EPS-related antipsychotics. **Keywords:** Schizophrenia, Extrapyramidal symptoms, Akathisia, Severe dyskinesia, Tardive dyskinesia, Drug-induced parkinsonism.

**REVIEW ARTICLE**

### An epidemiological study on the prevalence and predictors for geriatric sarcopenia from a public hospital of Ooty, India

Rinu Elizabeth P<sup>1</sup>, Sang J. Nair<sup>2</sup>, Ganapathy Subramanian<sup>3</sup>, David Sharan Cytina<sup>4</sup>, Madhu Prasad<sup>5</sup>, Sankaranarayanan S, Kumar Nagesh Kumar<sup>6</sup>

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**Abstract:** Sarcopenia is a condition characterized by a loss of muscle mass and strength, which is a common problem in the elderly population. The aim of this study was to determine the prevalence and predictors for geriatric sarcopenia in a public hospital in Ooty, India. A cross-sectional study was conducted among 100 elderly patients (aged >65 years) who were admitted to the hospital. The prevalence of sarcopenia was found to be 15.5%. The predictors for sarcopenia were age, sex, and body mass index (BMI). The study highlights the need for early detection and management of sarcopenia in the elderly population.

**RESEARCH ARTICLE**

### Assessment of students' pharmacist competency in dispensing cough medicines for self-medication: a simulated patient study

Shivakumaran Ponnusankar<sup>1</sup>, Nagul Adhithya Komaraprasadam Sakthivel<sup>2</sup>, Rebinno De Alex, Sekhar Mugilraj, Viswanathan Balasubramanyam<sup>3</sup>

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**Abstract:** The aim of this study was to assess the competency of pharmacy students in dispensing cough medicines for self-medication. A simulated patient study was conducted where students were asked to dispense cough medicines for a simulated patient. The study found that students were generally competent in dispensing cough medicines for self-medication, but there were some areas for improvement. The study highlights the need for further training and education for pharmacy students in dispensing cough medicines for self-medication.

**REVIEW ARTICLE**

### Bridging the Gap between Medication and their Potential Leads: The Role of Marine Metabolites in the Discovery of New Anticancer Drugs: A Comprehensive Review

Janvee Thaman<sup>1</sup>, Rashmi Saxena<sup>2</sup>, Chaitanya MVNL<sup>3</sup>, Palakurthi Y<sup>4</sup>, Prabha T<sup>5</sup>, Sarika S<sup>6</sup>, Patrick A<sup>7</sup>, Smriti Arora<sup>8</sup>, Ponnusankar S<sup>9</sup>, Pratiba P<sup>10</sup>, Avijit Mazumder<sup>11</sup>

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**REVIEW ARTICLE**

### Chitosan-based nanofibrous scaffolds for biomedical and pharmaceutical applications: A comprehensive review

Yasir Qasim A<sup>1</sup>, Ponnusankar S<sup>2</sup>, Chaitanya MVNL<sup>3</sup>, Arya Lakshmi<sup>4</sup>, Chou-Yi Hsu<sup>5</sup>, Aya Mohammed Dhiaa<sup>6</sup>, Mohamed J Saadh<sup>7</sup>, Yogendra Pal<sup>8</sup>, Russul<sup>9</sup>

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**REVIEW ARTICLE**

### Chitosan-based nanofibrous scaffolds for biomedical and pharmaceutical applications: A comprehensive review

Yasir Qasim A<sup>1</sup>, Ponnusankar S<sup>2</sup>, Chaitanya MVNL<sup>3</sup>, Arya Lakshmi<sup>4</sup>, Chou-Yi Hsu<sup>5</sup>, Aya Mohammed Dhiaa<sup>6</sup>, Mohamed J Saadh<sup>7</sup>, Yogendra Pal<sup>8</sup>, Russul<sup>9</sup>

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