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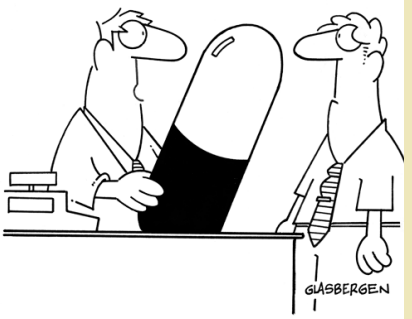
NEWSLETTER FROM DEPARTMENT OF PHARMACY, SUMANDEEP VIDYAPEETH DEEMED UNIVERSITY | JAN-JULY 2021 Vol VI Issue 1

PHARMACY



"Side effects may include stomach bloating and difficulty swallowing."

Associate Editors View

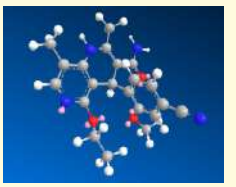
Welcome to another exciting issue of Pharmahorizone. Pharmahorizon is a platform to share latest informations and updates of pharmaceutical field and activities of Department of Pharmacy. It has been a great experience serving as associate editor of this newsletter for a decade. In this issue, we bring about new drug approval and a short article on organ-on-chips which is a rapidly advancing area of research. Moreover, some case reports and a write up on new drug molecules have been included. Drugs in clinical trial session discuss about details of two drugs under trial. Research publications of our outstanding cadre of faculty members and activities of Department of Pharmacy is another highlight of this issue.

We hope that you continue to find our newsletter informative and exciting, and we look forward to sharing more news soon.

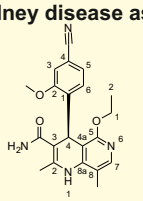
Dr. Dhanya B Sen.
Professor

NEW DRUG APPROVAL:KERENDIA

- **DRUG NAME: Kerendia**
- **ACTIVE INGREDIENT: finerenone**
- **APPROVED DATE: July 09 2021**
- **To reduce the risk of kidney and heart complications in chronic kidney disease associated with type 2 diabetes**



Dr. A K Seth, M. Pharm, Ph.D



Finerenone

INDICATIONS AND USAGE

•Kerendia is a non-steroidal mineralocorticoid receptor antagonist (MRA) indicated to reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D).

DOSAGE AND ADMINISTRATION

•The recommended starting dosage is 10 mg or 20 mg orally once daily based on estimated glomerular filtration rate (eGFR) and serum potassium thresholds. Increase dosage after 4 weeks to the target dose of 20 mg once daily, based on eGFR and serum potassium thresholds.
•Tablets may be taken with or without food

DOSAGE FORMS AND STRENGTH:

•Tablets: 10 mg and 20 mg

CONTRAINDICATIONS

•Kerendia is contraindicated in patients:
•Who are receiving concomitant treatment with strong CYP3A4 inhibitors.
•With adrenal insufficiency.

WARNINGS AND PRECAUTIONS:

•Hyperkalemia. Patients with decreased kidney function and higher baseline potassium levels are at increased risk. Monitor serum potassium levels and adjust dose as needed.

DRUG INTERACTIONS:

•Strong CYP3A4 Inhibitors: Use is contraindicated.
•Grapefruit or Grapefruit Juice: Avoid concomitant use.
•Moderate or weak CYP3A4 Inhibitors: Monitor serum potassium during drug initiation or

ADVERSE REACTIONS:

•Adverse reactions occurring in ≥ 1% of patients on Kerendia and more frequently than placebo are hyperkalemia, hypotension, and hyponatremia.

OVERDOSAGE

•In the event of suspected overdose, immediately interrupt Kerendia treatment. The most likely manifestation of overdose is hyperkalemia. If hyperkalemia develops, standard treatment should be initiated.
•Finerenone is unlikely to be efficiently removed by hemodialysis given its fraction bound to plasma proteins of about 90%.

USE IN SPECIFIC POPULATIONS:

•Lactation: Breastfeeding not recommended

REFERENCE

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3D Printing Tehnology: Boon to Medical field

3D printing in medicine is part of the innovative process called additive manufacturing, which means producing three-dimensional solid objects from a digital file. It could also offer new methods for practising medicine, optimising supply chains, and propose cheaper and way more personalized medical services. Rapid production has enabled pharmaceutical and medical companies to create more specific implants.

The advancement in additive technology has led to multiple applications in the medical field and had successfully saved many lives.

1.Affordable prosthetics and implants

Every year thousands of people lose their limbs but cannot get access to prostheses to recover. As prostheses are available in a few sizes it becomes hard to find one with the perfect fit. Things become complicated due to the lack of manufacturing of custom parts. However, 3D printing speeds up the process, and products are created at a much cheaper price. The 3D printed products offer the same functionality to the patients as traditional prosthetics do.

2. Artificial organs and tissues

The use of additive manufacturing processes to deposit materials known as bioinks to create tissue life structures that can be used is referred to as 3D bioprinting. It is proven capable of producing synthetic blood vessels by recreating the precise shape, size, and geometries of the vessel.

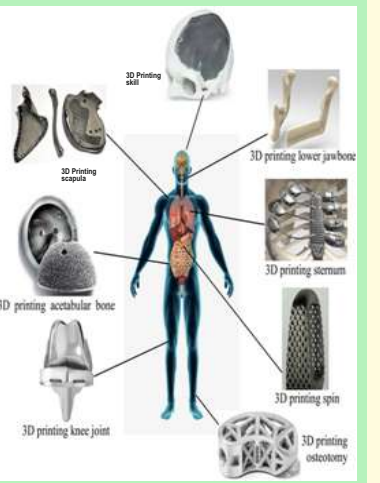
3. Improved surgical tools

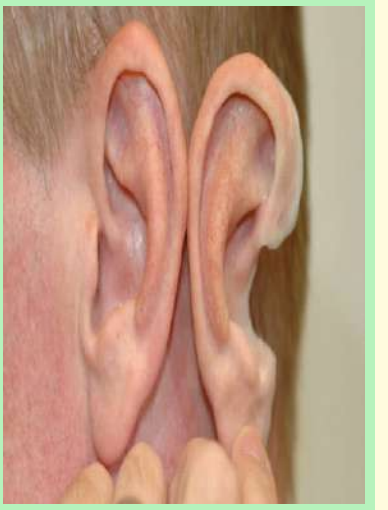
It is very well known that medical equipment is expensive. Thus, 3D printing medical tools used before surgery could save a vast amount of money. It has become easy to try new things at a lower cost and in less time with 3D printing.

The future of Pharma: 3D printed drugs

In 2015, the FDA approved the first-ever drug made by 3D printers, and in 2021, the second such medication received approval. 3D printing of multiple medicines on a single pill, known as a polypill, is already possible. In 2020, FabRx released the first pharmaceutical 3D printer to manufacture personalized medication. 'M3DIMAKER' can print personalized medicine real fast –about 28 pills/minute.

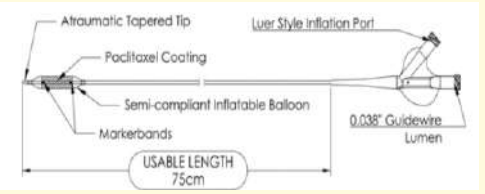
Source: https://macomatech.com/3d-printing-technology-boon-to-medicalfield/?utm_source=rss&utm_medium=rss&utm_campaign=3d-printing-technology-boon-to-medical-fie





Optilume® Urethral Drug Coated Balloon for urethral strictures

A urethral stricture is condition that narrows the tube that transports urine out of your body. A stricture inhibits urine from the bladder and can result in a range of medical issues in the urinary tract, such as irritation or infection. Figure.1 shows the Optilum drug coated balloon, which was developed in response to urethral stricture. This invention combines Drug delivery and balloon dilation.



The Optilume® Urethral Drug Coated Balloon is consist of dual lumen, over-the-wire (OTW) guidewire compatible catheter with a tapered, atraumatic tip. A semi-compliant inflated balloon at the catheter's distal end is covered with a proprietary coating containing the active medication paclitaxel. [dose 3.5g/mm2] Two radiopaque marker bands are attached to the device, indicating the working length of the balloon. And its surrounded by protective sheath.

Primary mode of action: *The catheter is moved along a guidewire to the part of the urethra that has a stricture, and the balloon is inflated to mechanically widen the urethra and increase urine flow during therapy.*

Secondary mode of action: *Paclitaxel is delivered from the balloon to the urethra wall during balloon inflation to prevent recurrence of stricture. Balloon body is only evenly covered with drug During voiding, but enough drug remains on the surface to block cellular growth after dilatation..*
This device mainly use in male patients age of ≥ 18years to treat obstructive urinary conditions. And it is used in patient with urethral stricture length of ≤3cm.
As this drug coated balloon is coated by paclitaxel patient with a prior history to hypersensitivity reaction to paclitaxel. Patients with urologic implants like penile implants or artificial urinary sphincters are highly contraindicated. The potential adverse effects of the Optilume® DCB: Dissection of the urethra, Perforation of the urethra, Hematuria, Inflammation, Infection, Recurrence of the stricture, Detachment of a component of the catheter, Bothersome urinary symptoms or painful urination, Genital or pelvic pain.

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Manmayee Naik, Pharm D, Intern, Department of Pharmacy, Sumandeep Vidyapeeth Deemed to be University, Vadodara.

Pradaxa (Dabigatran): Boon to Surgeons?

Dabigatran (Pradaxa) is a 2021 FDA approved anticoagulant drug that minimizes the risk of stroke or systemic emboli patients with Atrial Fibrillation(AF) and patients undergoing joint replacement surgery. It's efficacy has been compared with warfarin and has been prescribed as monotherapy by spine specialists. It acts by directly inhibiting thrombin in coagulation pathway, thus preventing clot formation by conversion of fibrogen to fibrin. Free thrombin, clot-thrombin and thrombin-induced platelet aggregation are inhibited by active molecules. Thrombin also activates coagulation factors V, VIII and XI as a part of feedback mechanism, which will generate more thrombin and activating factor XIII which will stabilize the clot by cross linking fibrin. It usually takes 2-3 days to show required anticoagulant effect. Dosing of dabigatran is simpler to manage and can be calculated on the basis of patient's creatinine clearance (CrCl). Daily recommended dose is 300 mg, in two divided doses as 150 mg twice daily. According to randomized evaluation of long term anticoagulation therapy (RE-LY) has shown that dabigatran is generally tolerated in comparison to warfarin. It is superior in stroke prevention when directly compared with warfarin. Has also shown decrease in MI (myocardial infarction) rates. RELY has provided evidence that rate of any bleeding as an adverse event was lower with dabigatran.

Advantages over warfarin:

Warfarin acts on vitamin K dependent clotting factors while dabigatran directly inhibits thrombin. Warfarin takes 48 hours delay in showing its action. Warfarin therapeutic levels can be monitored using INR ratio and dabigatran is insensitive to it. Dabigatran prolongs activated prothrombin and thrombin time with no effect on Vitamin K dependent clotting factors. The initial effect of dabigatran occurs in hours rather than days as in case of warfarin. Warfarin is prescribed with a loading dose for first two days and after normalized INR, maintenance dose is prescribed. INR is checked on a regular basis usually every 2-3 weeks. Other medical conditions are considered in case of warfarin as that may increase or decrease the INR which can result in inappropriate dosing. It has been known to interact with antibiotics like metronidazole, clarithromycin, etc. Broad spectrum antibiotics alter the gut microflora which can alter vitamin K levels. Dabigatran is simpler to handle as its dosing is based on creatinine clearance (CrCl) level. Interaction is lesser in comparison to warfarin. Overall it has been known to show greater efficacy in reducing the risk of MI than warfarin.

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Nirali Kulchandani, Pharm D, Intern, Department of Pharmacy, Sumandeep Vidyapeeth Deemed to be University, Vadodara.

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Prominent Scientist

Sir Jagadish Chandra Bose is one of the most prominent first Indian scientists who proved by experimentation that both animals and plants share much in common. Jagadish Chandra Bose was born on 30 November, 1858 at Mymensingh, now in Bangladesh. He was raised in a home committed to pure Indian traditions and culture. He received his elementary education from a vernacular school, because his father believed that Bose should learn his own mother tongue, Bengali, before studying a foreign language like English Xavier's School at Kolkata and passed the Entrance Examination for Calcutta University. Bose attended the University of Cambridge studying natural sciences after graduating with a physics degree from Calcutta University. He returned to India in 1884 after completing his B.Sc. degree from Cambridge University and was appointed as Professor of Physical Science at Presidency College, Calcutta (now Kolkata). In 1917 Bose left his professorship and established the Bose Institute at Calcutta which was initially devoted principally to the study of plants. He was its director for twenty years until his death.

He demonstrated that plants are also sensitive to heat, cold, light, noise and various other external stimuli. Bose contrived a very sophisticated instrument called the crescograph, which could record and observe plants minute responses to external stimulants. It was capable of magnifying the motion of plant tissues to about 10,000 times of their actual size and, in doing so, found many similarities between plants and other living organisms. Bose authored two illustrious books; 'Response in the Living and Non-living' (1902) and 'The Nervous Mechanism of Plants' (1926). He also extensively researched the behavior of radio waves. Mostly known as a plant physiologist, he was actually a physicist. Bose made improvements on another instrument called 'the coherer', for detecting the radio waves. He was knighted in 1917 and elected the Fellow of the Royal Society in 1920 for his amazing contributions and achievements. He died aged 78, on 23 November in 1937, in Giridih, India.

Source: *https://www.famousscientists.org/jagadish-chandra-bose/*

NEW DRUG APPROVAL

Tipiracil hydrochloride bulk (1. Trifluridine 15mg + Tipiracil 6.14mg and 2. Trifluridine 20mg + Tipiracil 8.19mg)

"Indicated for the treatment of:

- *Adult patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine, oxaliplatin and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy*
- *Adult patients with metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/ neu-targeted therapy.*

Dosage in Renal Failure

- *Mild-to-moderate (CrCl 30-89 mL/min): No dosage adjustment required*
- *Severe:*

v CrCl 15-29 mL/min
v Decrease to 20 mg/m2 PO BID on days 1-5 and 8-12 of each 28-day cycle
vIf unable to tolerate 15 mg/m2 PO BID on days 1-5 and 8-12 of each 28-day cycle
v Permanently discontinue if unable to tolerate 15 mg/m2 PO BID

Side effects: *Anemia, Neutropenia, Asthenia, Nausea, Thrombocytopenia, Decreased appetite, Diarrhea, Vomiting, Infections, Pyrexia.*

Contraindications: None

Caution: Severe and life-threatening myelosuppression reported, including anemia, neutropenia, thrombocytopenia, and febrile neutropenia; obtain CBC count prior to and on Day 15 of each cycle, or more frequently as indicated

Pregnancy: Based on animal data and its mechanism of action, drug can cause fetal harm

Source: *1. List of new drugs approved in the year 2021*
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODAyOA==
2. Drug Monograph
https://reference.medscape.com/drug/lonsurf-trifluridine-tipiracil-1000021

WHO Guidelines on antiplatelet agents for the prevention of pre-eclampsia

• Low dose acetylsalicylic acid (Aspirin, 75mg per day) is recommended for the prevention of pre-eclampsia in women at moderate or high risk of developing the condition.

Remark:

• It is recommended to restricting treatment to only women at moderate or high risk of pre-eclampsia.

• Women can be considered at moderate risk of developing pre-eclampsia if they have any two of the following factors: primiparity, family history of pre-eclampsia, age greater than 40 years, or multiple pregnancy; and at high risk of developing pre-eclampsia if they have one or more of the following risk factors: diabetes, chronic or gestational hypertension, renal disease, autoimmune disease, positive uterine artery Doppler, previous history of pre-eclampsia, or previous fetal or neonatal death associated with pre-eclampsia.

• The dosage upto 150 mg may be more beneficial but with increased risk of postpartum hemorrhage, therefore it is recommended to use 75 mg Aspirin as the optimal dose in terms of risk-benefit consideration.

• Aspirin should bot be used by women for whom it is contraindicated.

• The guideline developer team emphasized that this recommendation applies to the use of aspirin in women with gestational hypertension as a secondary preventive measure against developing pre-eclampsia.

• Low-dose acetylsalicylic acid (aspirin, 75mg per day) for the prevention of pre-eclampsia and its related complications should be initiated by 20 weeks gestation or as soon as antenatal care is started.

• Evidence from the systematic review shows that women appeared to have a decreased risk of developing pre-eclampsia and its complications with the use of antiplatelet agents whether they began the intervention before or after 20 weeks' gestation. However, in view of the pathophysiology of pre-eclampsia, the Guideline developing group (GDG) supports the initiation of treatment early in a pregnancy. The GDG noted that in most of the trials providing evidence on the benefit of aspirin in early pregnancy, treatment was initiated at 12 weeks' gestation and therefore consider this an appropriate time to initiate aspirin treatment.

• While antenatal care is ideally initiated by 12 weeks' gestation, in situations where antenatal care is started later than 20 weeks in pregnancy, GDG suggests initiating treatment at the time it begins.

• Irrespective of when treatment is initiated, appropriate counselling on the risks and benefits of preventative treatment is paramount - both to improve adherence and to inform the woman of warning signs that should be reported (such as bleeding or abdominal pain).

• There is scant evidence on the optimal time to discontinue aspirin treatment for the prevention of pre-eclampsia. In addition, the GDG is aware that, in some settings, the use of aspirin around the time of birth may preclude the use of epidural or spinal anesthesia at the time of delivery. The GDG suggests that aspirin should be discontinued in line with local practice on the use of anticoagulants in pregnancy. The GDG notes the need for research in this area to clarify the benefits of prevention of pre-eclampsia with the potential risks of postpartum and neuraxial hemorrhage with the use of low-dose aspirin late in pregnancy.

Source: https://apps.who.int/iris/rest/bitstreams/1398618/retrieve

AYUSH: An introduction

The word AYUSH is derived from a Sanskrit phrase "ayusmanbhava" meaning long life. This phrase was commonly used blesses since the Mahabharata period for healthy long life. In the present scenario, the term AYUSH is universally adopted for "traditional and Non – conventional system of health care and healing which include Ayurveda, Yoga, Unani, Naturopathy, Siddha, Sowa Rigpa, Homoeopathy, etc" by the commission for Scientific and Technical Terminology. The entire system of medicine under the umbrella of AYUSH is the time-tested holistic approach to health care and healing. Since the beginning of human civilization, these systems of medicine are popular around all over the globe.

Fundamentally AYUSH provides an integrative healthcare modality for complete physical, mental, social, and spiritual health. Due to its importance, the system under AYUSH is globally honored as part of religion far beyond science. The AYUSH system is serving human beings since the pre-historic period, globally. In every period, government and administrative authorities promote the AYUSH system as per their need. In the colonial period of India, these systems of medicine faced some negligence. But soon after independence Government of India shows indulgence in AYUSH. In the year 1955, the Union Government of India, establish a separate department "the Department of Indian System of Medicine and Homoeopathy (ISM&H)" for the development of these systems. This department was renamed in November 2003 as the Department of Ayurveda, Yoga, Naturopathy, Unani, Siddha, and Homoeopathy (Ayush) for the same purpose. on the 9th of November 2014, the Ministry of Ayush was formed by the Government of India with a vision of reviving the profound knowledge of traditional Indian systems of medicine and ensuring the optimal development and propagation of the Ayush systems of healthcare. The Salient Objectives of the Ministry of Ayush are -

• To upgrade the educational standard of the Indian Systems of Medicine and Homoeopathy colleges in the country.

• To strengthen existing research institutions and to ensure time-bound research programs on identified diseases for which these systems have an effective treatment.

• To draw up schemes for cultivating, promoting, and regenerating medicinal plants that are used in these systems.

• To evolve Pharmacopoeial standards of Indian Systems of Medicine and Homoeopathy drugs.

Source: https://ayushnext.ayush.gov.in/detail/post/ayush-an-introduction

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Community Awareness Camp for Diabetes & Hypertension

A Camp was organized to spread awareness among common people regarding general body check up which includes BMI, Blood Pressure, Blood Sugar measurement, Patient Counselling and general awareness for leading a healthy and peaceful life. Students communicated to the villagers in local language (Gujarati) for their better understanding.

World Children's Day

Department of Pharmacy, Sumandeep Vidyapeeth organized health awareness activity on basic health awareness regarding child health, hygiene, malnutrition, immunization schedule at village 'Banaj' on the occasion of Children's Day-2021. Day was celebrated to spread awareness among children regarding child health, hygiene, malnutrition and immunization schedule. Students and staff also distributed the recreational kit to the children and provided them lunch and refreshment.

World Pharmacist Day

Department of Pharmacy, Sumandeep Vidyapeeth organized health awareness rally and basic health awareness program at village 'Piparia' on the occasion of World Pharmacist Day-2021. Students explained to villagers about life style modification, disease complications, diet chart, drug-drug interaction etc. They also discussed about rational use of medicine and spread awareness about side effects of different kind of drugs and basic health awareness.

World Heart Day

On the occasion of World Heart Day, Sumandeep Vidyapeeth's Department of Pharmacy held a healthy heart awareness rally and a basic heart health awareness program in the village of 'Banaj.' Students and faculty from the Department of Pharmacy participated in these activities. Students created posters and leaflets to raise general knowledge about heart health. They also explained lifestyle modifications to be followed during corona pandemic, heart disease complications, diet chart, and how to live a healthy life, among other things. In addition, they educated the community on basic health issues.

WORLD AIDS DAY

Worlds AIDS Day was celebrated on 1st December, 2021 by Department of Pharmacy, SVDU. The students from Department of Pharmacy had prepared posters and pamphlets subjecting to general health awareness for the AIDS, precaution, Awareness and Symptoms. They explained about AIDS and its symptoms, precaution regular health check up, blood transfusion, its spreading. They percolated information about basic health awareness to Villagers.

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Awards / Recognition / Achievements

26. *Received grant form GTU SSIP Center, Vadodara for Start-up and Innovation "Caryota Flavo" Medicina plant derived molecule with anticancer activity folklore clinical practice. Incubatee: Mr. Ashish Jha, Mr. Jay Mukesh Chudasama, Mr. Pragati Raj Gaurav; Mentor: Dr. Ghanshyam Parmar.*