JSS ACADEMY OF HIGHER EDUCATION & RESEARCH
(DEEMED TO BE UNIVERSITY) MYSURU

CLINICAL PHARMACY NEWSLETTER

A Newsletter of Drug and Prescribing Information

Published by
Clinical Pharmacy Services Department, Govt. Medical College & Hospital, Ooty
(A Unit of Department of Pharmacy Practice, JSS College of Pharmacy, Ooty)

Volume XXVII Issue 04 **October - December 2021**

INSIDE THIS ISSUE

FDA Authorizes Additional Oral Antiviral for Treatment of COVID-19 in Certain Adults (Molnupiravir)

On 23rd December 2021, USFDA issued an emergency use authorization (EUA) for Merck's molnupiravir for the treatment of mild to moderate coronavirus disease (COVID-19) in adults with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by the FDA are not accessible or clinically appropriate.

Molnupiravir is available by prescription only medicine (PoM) and should be initiated as soon as possible after diagnosis of COVID-19 and within five days of symptom onset. Molnupiravir is not authorized for use in patients younger than 18 years of age because molnupiravir may affect bone and cartilage growth. It is not authorized for the pre-exposure or post-exposure prevention of COVID-19 or for initiation of treatment in patients hospitalized due to COVID-19 because benefit of treatment has not been observed in people when treatment started after hospitalization due to COVID-19. FDA further clarified that Molnupiravir is not a substitute for vaccination in individuals for whom COVID-19 vaccination and a booster dose are recommended. The FDA urges the public to get vaccinated and receive a booster if eligible.

The primary data supporting this EUA for molnupiravir are from MOVe-OUT, a randomized, double-blind, placebo-controlled clinical trial studying molnupiravir for the treatment of non-hospitalized patients with mild to moderate COVID-19 at high risk for progression to severe COVID-19 and/or hospitalization. Patients were adults 18 years of age and older with a prespecified chronic medical condition or at increased risk of SARS-CoV-2 infection for other reasons who had not received a COVID-19 vaccine. The main outcome measured in the trial was the percentage of people who were hospitalized or died due to any cause during 29 days of follow-up. Of the 709 people who received Molnupiravir, 6.8% were hospitalized or died within this time period compared to 9.7% of the 699 people who received a placebo. Of the people who received molnupiravir one died during the follow-up period compared to nine people who received placebo. Side effects observed in the trial included diarrhea, nausea and dizziness. The safety and effectiveness of molnupiravir for the treatment of COVID-19 continue to be evaluated.

Molnupiravir: Not recommended from Indian Council for Medical Research for use in India Molnupiravir, an anti-viral drug developed by US companies Merck and Ridgeback, has been kept out of the treatment protocol recommended by the Indian Council of Medical Research (ICMR). Dr Balram Bhargava, Head of ICMR, expressed that the drug had "major safety concerns". The drug is approved for use, but not recommended from ICMR. It is meant for mild or moderately ill COVID-19 patients who are at risk of developing serious illness. The pill, if administered during the first five days after contracting the infection, has the potential to prevent serious illnesses.

There have been concerns on two counts low effectiveness, and some potential side-effects. Both were taken into account by drug regulating agencies while approving them. Molnupiravir was found to be only 30% effective in trials, much lower than earlier indications. Besides, there have been been worries over its mechanism: The drug molecule incorporates itself into the RNA of the virus, inducing mutations with the objective of hampering replication. But this carries the risk of introducing mutations that can make the virus stronger and more dangerous. A bigger worry is the risk of the drug creating mutations in the human DNA itself.

REFERENCES:

USFDA Website with Official announcement of emergency use authorization for Molupiravir. Avaiable from: https://www.fda.gov/news-events/press-announcements/coronavirus-COVID-19-update-fda-authorizes-additional-oral-antiviral-treatment-COVID-19-certain

Anti-Covid pill Molnupiravir: Approved, not recommended. Available from: https://indianexpress.com/article/explained/molnupiravir-approved-not-recommended-covid-treatment-7710510/

MASKIN - Face Mask & Skin Reactions

Requisite to wearing a face mask helped in reducing the spread of the coronavirus that causes COVID-19. As the disease outbreak progressed, more evidence proved the effectiveness of masks, since masks are requisite, we must do everything we can to alleviate worries about wearing them as there is the recent news of dermatological manifestation “Maskne” shown with wearing masks (PPE -personal protective equipment). Maskne is mask-related acne (“maskne”) and other facial dermatoses. People who do have existing skin problems, such as acne, rosacea, eczema, humid or dry air sensitivity, and allergies are most likely to experience face-mask-related bumps.

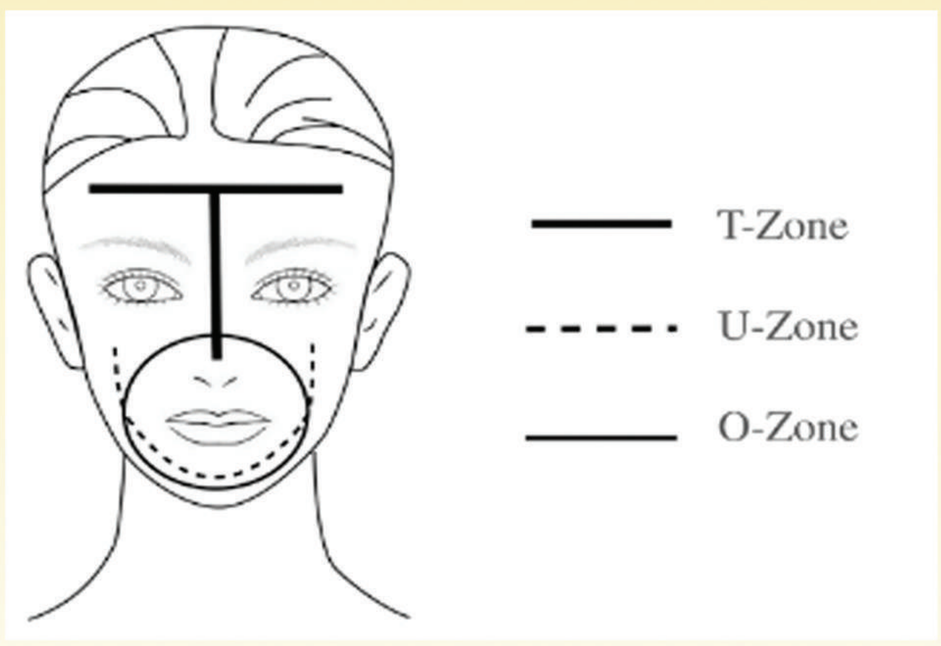
Acne ("maskne"), rosacea ("mask rosacea"), seborrheic dermatitis, periorificial dermatitis, and folliculitis have been observed in people who wear masks for more than 6 hours per day, most likely due to friction and occlusion. Mask-related Koebner phenomenon (trauma-induced development of lesions clinically similar to the underlying skin disease in previously uninvolved areas) has also been reported in patients with psoriasis, vitiligo, acne, and rosacea.

Causes: The frequency of exacerbation depends on the formation of a warm, moist, occlusive environment around the face, especially when wearing a mask. This is compounded by the frictional effect of the material held in place with elastic.

Supporting data: A study conducted during the pandemic in 833 medical school staff in Thailand, including healthcare and non-healthcare workers, revealed a self-reported prevalence of 54 percent adverse skin reactions to surgical and cloth masks.

Difference between maskne and regular acne? According to Dr.Teo’s white paper “Diagnostic and management considerations for “maskne” in the era of COVID-19” in the Journal of the American Academy of Dermatology, the distinct pattern of development of maskne is in the O-zone. In short, if you see exacerbation of acne over the marked area of the O-zone – the area covered by a mask – that is likely to be maskne.

Distinct acne patterns seen in the T zone of physiologic acne, the U zone of adult acne, and the O zone of maskne



Most commonly affected areas: Locations of adverse skin facial reactions were reported in 71.4 percent of the studies. The most commonly affected areas of the face included facial skin/unspecified, respiratory tract, eyes, cheeks, scalp, and supraauricular.

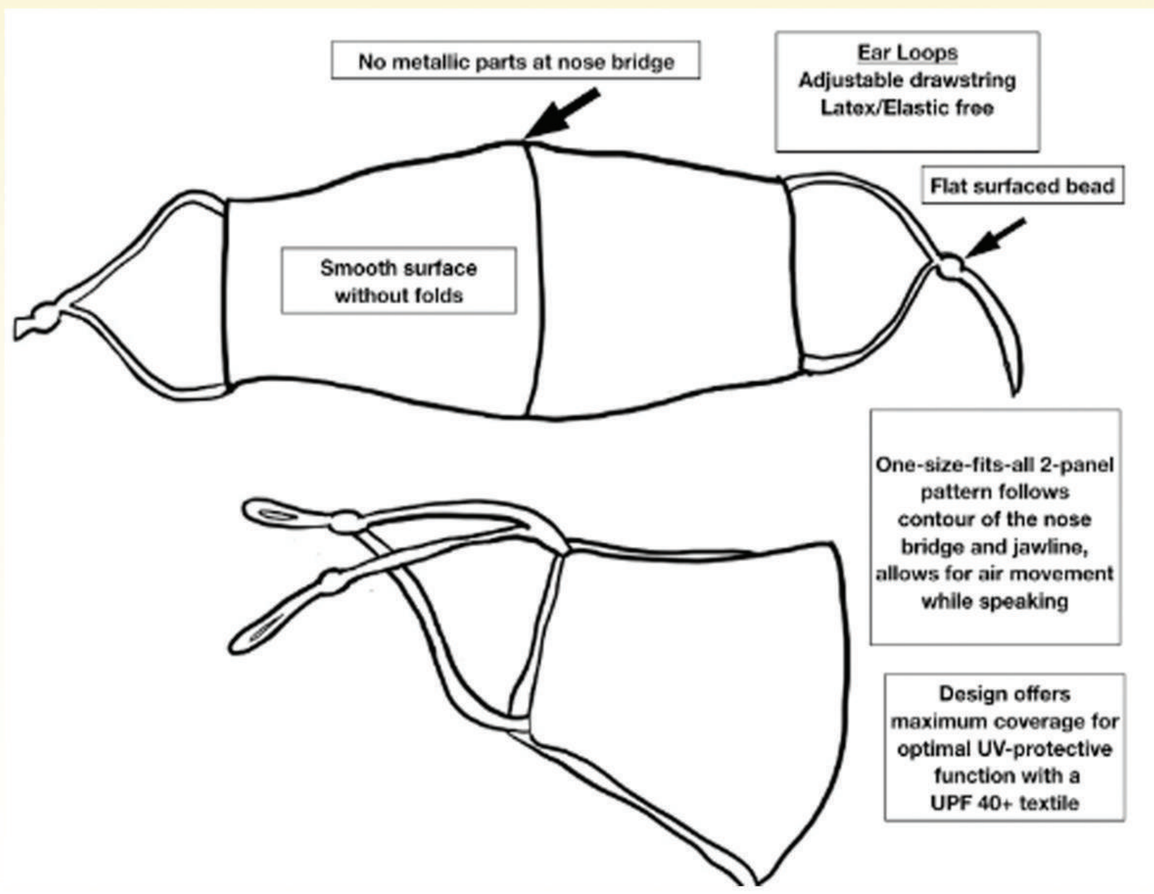
Length of mask usage: In studies analysing the length of usage, adverse facial reactions were significantly associated with the time duration of mask utilization. A study of multiple mask types from szepietowski et al. found significant associations between length of mask usage and adverse reactions.

Mask type: The use of N95 and KN95 masks, the most commonly utilized face masks, was reported in six studies. Surgical/medical masks were utilized in four of the studies, while cloth masks were used in two studies. Other masks mentioned by single studies include half-face elastomeric respirators, full-face respirators, paper masks, and ear-looped masks. A randomized crossover design study reported significantly more erythema ($p<0.001$), facial indentation ($p<0.001$), and pain ($p=0.02$) with N95 masks compared to medical masks.

Assessment depends on history, which includes: • Drug and family history of dermatological conditions • Relevant history of a mask (wearing and removing has an effect on skin condition) • Symptom’s appearance of pustules or papules, itch, and soreness • Duration of mask exposure • Mask breaks period • Effect of mask related dermatological reactions on Quality of life and • In-depth examination of the reactions and their distribution.

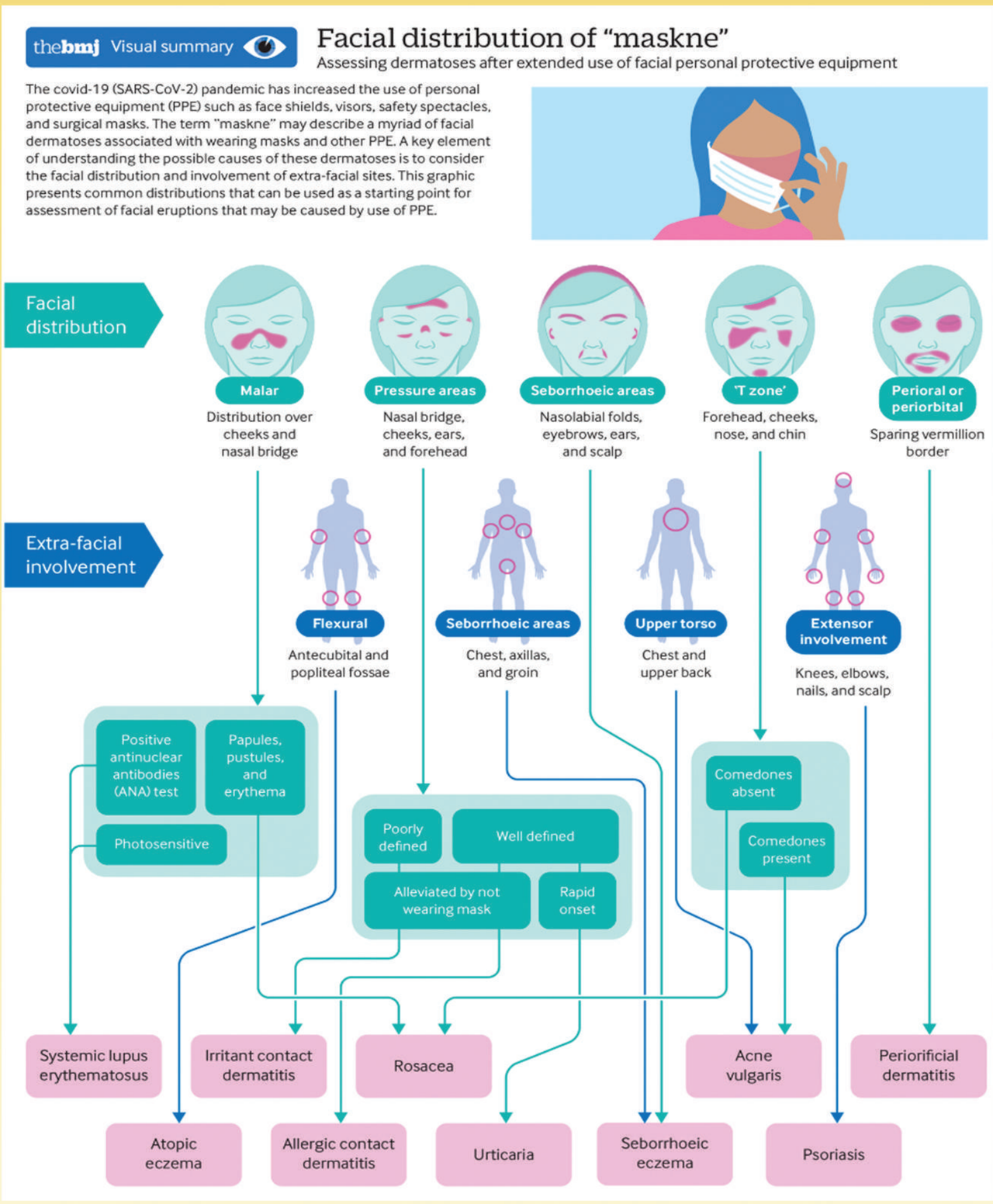
General measures to prevent mask-related facial dermatoses

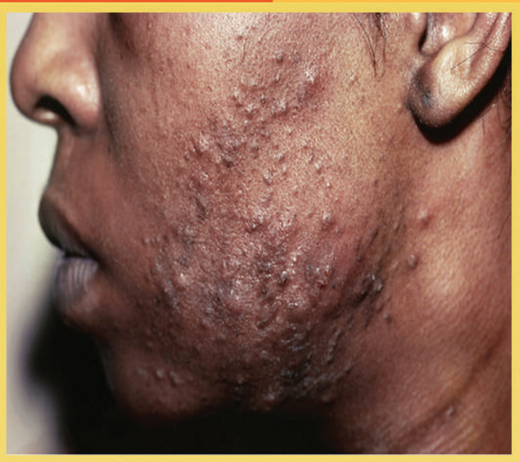
Cleanse skin with a gentle soap-free cleanser.
Apply a light emollient at least 30 minutes before applying facial mask.
Apply a silicon-based barrier tape—e.g., siltape (Advancis)—to the nasal bridge and cheeks.
Wipe skin under the mask with a silicon-based barrier wipe to provide a film, protecting the skin from the harmful microenvironment.
Take time to fit the mask and ensure it is not over tight.
Take regular breaks from the mask (every one hour for respirators) to relieve the pressure and prevent moisture build-up.
Maintain oral hygiene (teeth brushing twice daily and daily interdental flossing/brushing)
Given the proximity of the mask with the facial skin and the nose and mouth, it is important to consider dermatological recommendations for the fabric of your face mask.
Biofunctional textiles like the Zincool zinc nanoparticle mask can have cooling coefficient, moisture and air permeability functions, ensuring comfort and breathability.
Biofunctional textiles, with the incorporation of metallic nanoparticles like zinc, have anti-inflammatory and oil control properties. This is beneficial for maskne treatment. Research shows that zinc plays an anti-inflammatory role in acne pathogenesis by inhibition of leukocyte chemotaxis, lysomal enzyme release, and lymphocyte transformation; it also exerts a bacteriostatic effect against acnes, inhibits vasoactive amines, and decreases sebum production.

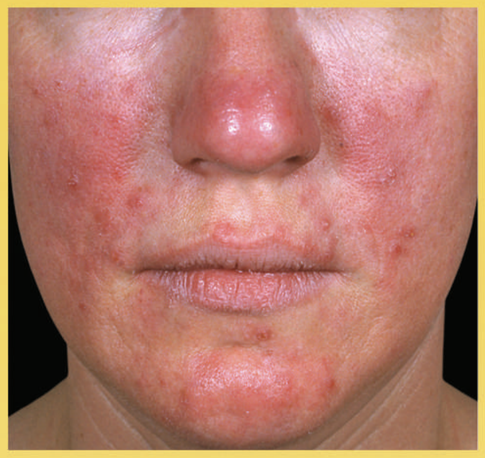


When to refer a physician?
In the case of an extreme, incapacitating illness, or if the condition does not respond to the above-mentioned treatments. Also, consider a routine referral if specialist investigations, such as skin prick testing and patch testing in cases of suspected contact allergy, are indicated.

Conclusion: The increased use of face masks has resulted in an increase in the prevalence of adverse skin reactions and exacerbation of underlying skin conditions. But still, the conclusion is to use face masks as it is the fundamental measure to reduce the transmission and spread of COVID-19. Moreover, to prevent adverse events of face masks and exacerbation of underlying skin conditions, we endorse pre-emptive treatment measures to avoid the development of skin reactions.







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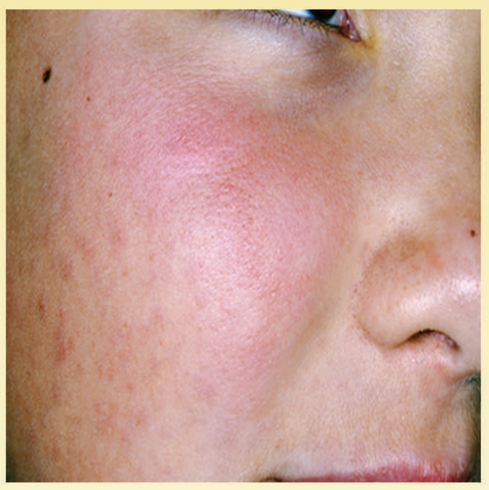
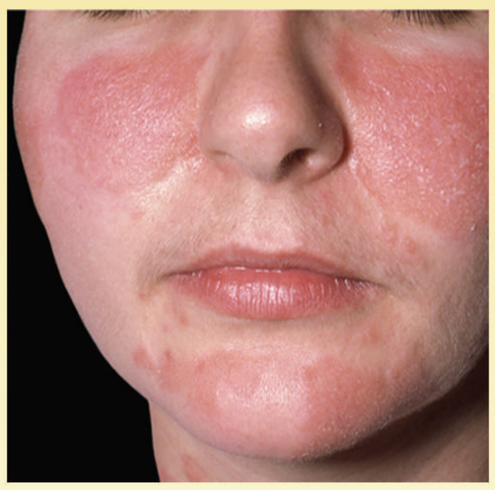
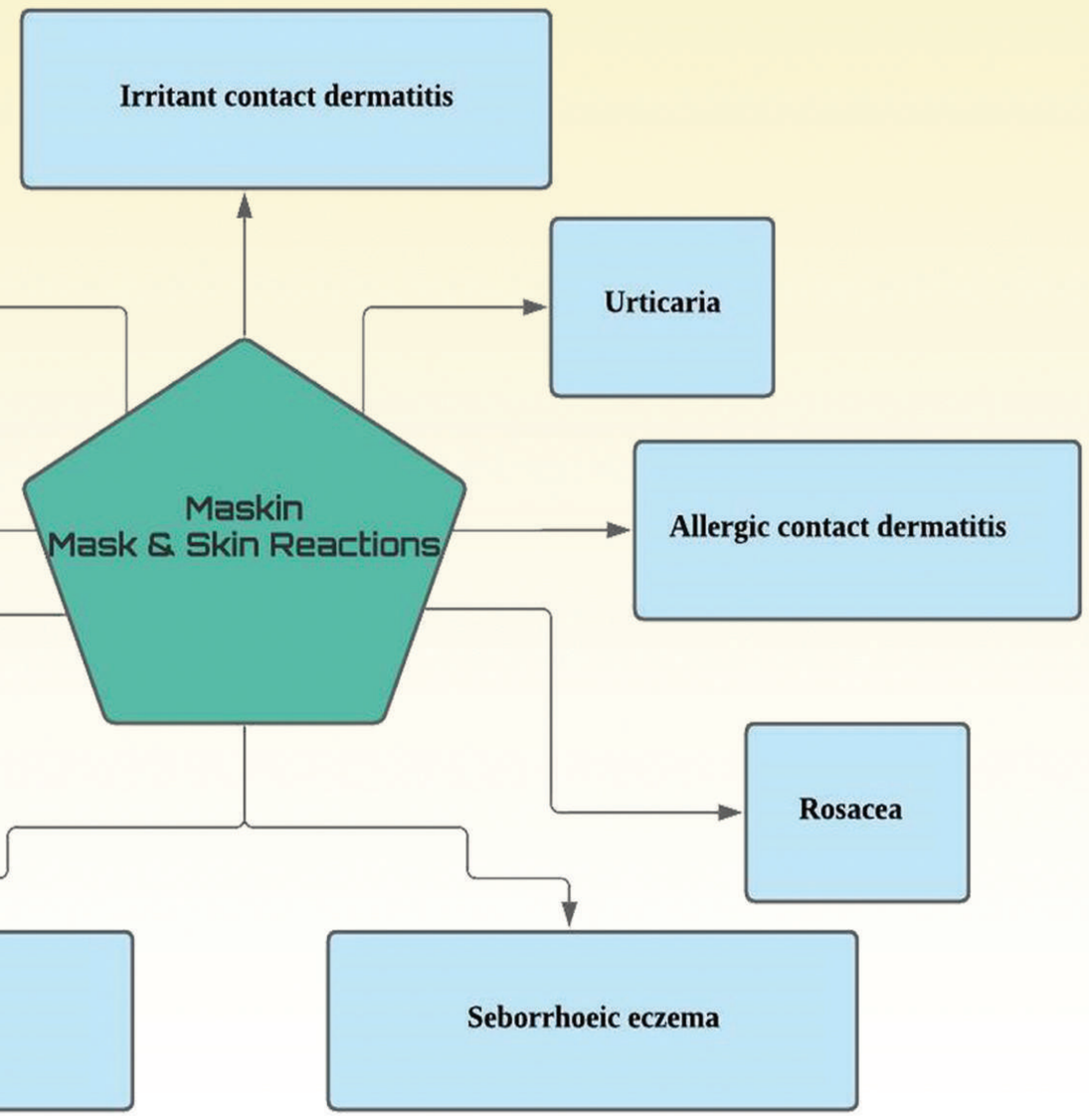






DRUG PROFILE
INCLISIRAN

Class:
PCSK9 Inhibitor (Proprotein convertase subtilisin kexin type 9)

Indication:
Inclisiran is a small interfering RNA (siRNA) directed to PCSK9 mRNA indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of low-density lipoprotein cholesterol (LDL-C).

Mechanism of Action:
Inclisiran is a double-stranded small interfering ribonucleic acid (siRNA), conjugated on the sense strand with triantennary N-Acetylgalactosamine (GalNAc) to facilitate uptake by hepatocytes. In hepatocytes, Inclisiran utilizes the RNA interference mechanism and directs catalytic breakdown of mRNA for PCSK9. This increases LDL-C receptor recycling and expression on the hepatocyte cell surface, which increases LDL-C uptake and lowers LDL-C levels in the circulation.

Dosage form and Administration:
Inclisiran is available as injection: 284 mg/1.5 mL (189 mg/mL) in a single-dose prefilled syringe. Injection should be administered by healthcare provider.
Inclisiran should be administered by subcutaneous route into abdomen, upper arm, or thigh;
Inclisiran should not be injected in areas of active skin disease or injury (eg, sunburns, skin rashes, inflammation, or skin infections).
Injections should be stored at 20-25 0 C.
Health care professional should visually inspect the injection before use; solution appears clear and colorless to pale yellow. It is advised to discard if particulate matter or discoloration is seen.

The recommended dosage of Inclisiran, in combination with maximally tolerated statin therapy, is 284 mg administered as a single subcutaneous injection initially, again at 3 months, and then every 6 months.
If a planned dose is missed by less than 3 months, administer Inclisiran and maintain dosing according to the patient's original schedule.
If a planned dose is missed by more than 3 months, restart with a new dosing schedule - administer Inclisiran initially, again at 3 months, and then every 6 months.
Assess LDL-C when clinically indicated. The LDL-lowering effect of Inclisiran may be measured as early as 30 days after initiation and anytime thereafter without regard to timing of the dose.

Dosing in Renal & Hepatic Impairment:
No dose adjustments are necessary for patients with mild, moderate, or severe renal impairment.
Inclisiran has not been studied in patients with severe hepatic impairment.
No dose adjustments are necessary for patients with mild, moderate, or severe renal impairment.
Inclisiran has not been studied in patients with end stage renal disease.

Pharmacokinetics:
Peak plasma time is 4 hr. Peak plasma concentration is 509 ng/mL. The AUC was found to be 7980 ng⊠hr/mL. About 87% of the drug is protein bound.
Volume of distribution in healthy adults was found to be 500 L.
Inclisiran is primarily metabolized by nucleases to shorter nucleotides of varying length

Inclisiran is not a substrate for CYP450 or transporters. The elimination half life was found to be 9 hours. Approximately 16% of the drug is renally cleared.

Adverse Reactions:
Injection site reaction (8.2%), Arthralgia (5%), Urinary tract infection (4.4%), Bronchitis (4.3%)
Diarrhea (3.9%), Pain in extremity (3.3%), Dyspnea (3.2%)

Contraindications:
There are no contraindications suggested.

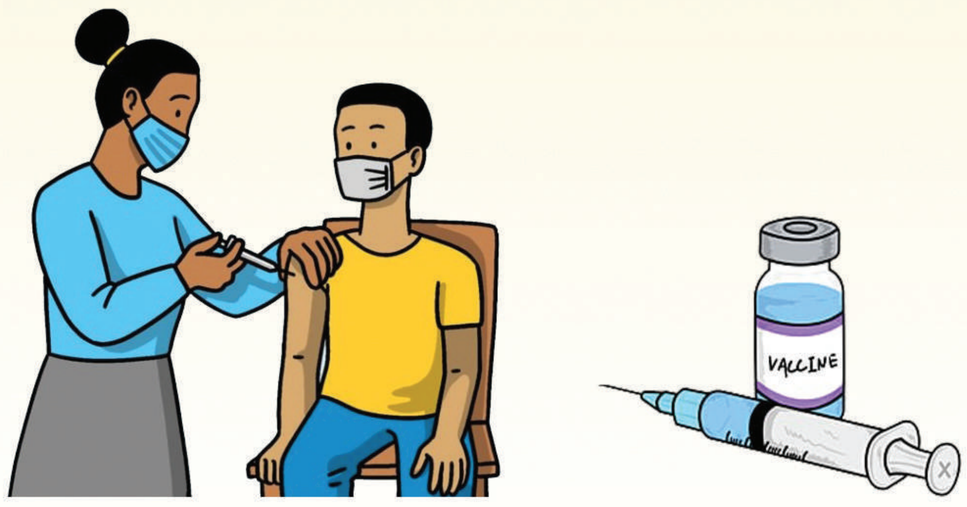
Precautions:
- Presently there are no precautions reported for Inclisiran.
- Health care professional should visually inspect the injection before use; solution appears clear and colorless to pale yellow. It is advised to discard if particulate matter or discoloration is seen.

Drug Interactions:
- No formal clinical drug interaction studies have been performed. The components of Inclisiran are not substrates, inhibitors or inducers of cytochrome P450 enzymes or transporters.
- In a population pharmacokinetic analysis, concomitant use of Inclisiran did not have a clinically significant impact on atorvastatin or rosuvastatin concentrations. LEQVIO is not expected to cause drug-drug interactions or to be affected by inhibitors or inducers of cytochrome P450 enzymes or transporters.

Reference:

- *United states food & drug administration website. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214012lbl.pdf*

- *Novartis website with Inclisiran information and approval information. Available from: https://www.novartis.com/news/media-releases/novartis-receives-eu-approval-leqvio-inclisiran-first-class-sirna-lower-cholesterol-two-doses-year*



GET YOUR COVID-19 VACCINE !

EVENT CORNER

Dr M Deepalakshmi, Asst. Professor, Department of Pharmacy Practice participated in International Webinar entitled 'Clinical Pharmacists role in Total Parenteral Nutrition' organized by Department of Pharmacy Practice, Sri Indu Institute of Pharmacy in association with Indian Pharmaceutical Association -Ibrahimpatnam Local branch, Hyderabad on 8th October 2021.

Dr Keerthana C, Dr Aneena Suresh, Dr J Jeyaram Bharathi, Staff, Department of Pharmacy Practice participated in webinar on 'State of the Art Molecular Modelling Tools – BIOVIA Drug Discovery Suite' organized by Department of Pharmaceutical Chemistry, JSS College of Pharmacy, Ooty on 23rd October 2021.

Dr. S. Ponnusankar, Dr M Deepalakshmi, Dr C Keerthana, Dr. Aneena Suresh, Dr J Jeyaram Bharathi, Dr Mohsina Hyder, staff, Department of Pharmacy Practice participated in 'Virtual Mymedex 2021' an International virtual event organized by 'MyEvents International' on 27th to 28th October 2021.

Dr. S. Ponnusankar, Dr K P Arun, Dr M Deepalakshmi, Dr G K Sadagoban,Dr Swathi Swaroopa B, Dr. Keerthana C, Dr Aneena Suresh, Dr J Jeyaram Bharathi, Dr Mohsina Hyder, staff, Department of Pharamcy Practice participated in DBT Sponsored Popular virtual lecture series on Biotechnology "Transgenic experimental models in Biomedical Research" organized by Department of Pharmacology (DST FIST Sponsored), JSS College of Pharmacy, Ooty on 29th to 30th October 2021.

Dr. S. Ponnusankar, Professor & Head, Department of Pharmacy Practice participated in webinar entitled 'Envisioning and accomplishing a substantial NAAC score and grading for our Pharmacy Institutions' organized by Society of Pharmaceutical sciences and Research on 31st October 2021.

Mr Vishwas H N, Lecturer, Department of Pharmacy Practice participated in webinar 'Clinical Pharmacy/Pharmacist: The Future of Patient Care' organized by JSS Academy of Higher Education and Research, Mauritius on 24th September, 2021.

Mr. Vishwas H N, Lecturer, Department of Pharmacy Practice participated in one week (ATAL) Academy Elementary FDP on "Internet of Things: Revolutionary Impact on Pharmaceutical Education and Industry (IoTRIPEI))" organized by Andhra University College of Pharmaceutical Sciences, Visakhapatnam, Andhra Pradesh and AICTE Training And Learning (ATAL) Academy. On 21st to 25th September 2021.

Dr Swathi Swaroopa B, Asst Professor, Department of Pharmacy Practice received Rs. 50,000/- towards the project "Development and validation of methodology using Real –Time PCR to study the genetic polymorphism of Organic Cation Transporter (rs628031, rs2282141, rs622342) and its impact on pharmacokinetics of metformin – a pilot study" from JSS Academy of Higher Education & Research, Mysuru. (Project duration 6 months)

Dr M Deepalakshmi, Asst Professor, Department of Pharmacy Practice received Rs. 25,000/- towards the project "Trigger tools-based detection of adverse drug reaction in a Tertiary care teaching hospital" from JSS Academy of Higher Education & Research, Mysuru. (Project duration 6 months)

Dr S Ponnusankar, Professor & Head, Department of Pharmacy Practice acted as Oral presentation Evaluator in the 2nd International Virtual Conference on Advances in Health Economics and Outcomes Research jointly organized by ISPOR during the month of October 2021.

Dr Sadagoban G K, Asst. Professor, Department of Pharmacy Practice acted as E-Poster Evaluators in the 2nd International Virtual Conference on Advances in Health Economics and Outcomes Research jointly organized by ISPOR during the month of October 2021.

Dr Swathi Swaroopa B, Asst. Professor, Department of Pharmacy Practice acted as reviewer for a paper in Journal Clinical Epidemiology and Global Health, Elsevier during October 2021.

Dr S Ponnusankar, Professor & Head, Department of Pharmacy Practice participated in webinar entitled 'How to improve on availability, accessibility and affordability of medicines in health care – an entrepreneurial opportunity' organized by MM College of Pharmacy, Mullana on 23rd November 2021.

Dr M Deepalakshmi, Dr C Keerthana, staff, Department of Pharmacy Practice participated in one week 'International Virtual Conference on Combating Antimicrobial Resistance to observe World Antimicrobial Awareness Week – 2021' organized by International Departments of Infectious Diseases and Emergency Medicine, Kasturba Medical College, Manipal& Hospital, MAHE, ManipalManipal Center for Infectious Diseases, Prasanna School of Public Health, MAHE, Manipal Division of Infectious Diseases, Wayne State University, Michigan, Detroit, USA, Departments of Microbiology and Medicine Kasturba Medical College, Mangalore, MAHE, Manipal, India between 18th to 23rd November 2021.

Dr M Deepalakshmi, Asst. Professor, Department of Pharmacy Practice presented a paper entitled 'Will my eating habits put me at risk for diabetes?' during the World Diabetes Day 2021 organized by Pharmacy Literacy Club, Department of Pharmacy Practice, MCOPS, MAHE, Manipal on 14th November 2021.

Dr K P Arun, Associate Professor, Department of Pharmacy Practice acted as Resource person and delivered a talk on 'Pharmacist An integral Part of Health care' during the 60th National Pharmacy week celebration organized by Sri vijayvidyalaya college of pharmacy, Dharmapuri on 24th November 2021.

Dr B Vahini, Ms. Samantha Sanjeev, Dr C K Narenthiran and Dr C Keerthana, Department of Pharmacy Practice published a chapter entitled 'A Review on Rheumatic Heart Disease' in the text book'Current Aspects in Pharmaceutical Research and Development' published by BP International 'Print ISBN: 978-93-5547-237-3', 'eBook ISBN: 978-93-5547-277-9'

Dr. Roopa B S, Asst. Professor, Department of Pharmacy Practice acted as reviewer for manuscript in Journals 'Journal of Pharmacy Practice' and 'PLOS One' during November 2021.

Dr S Ponnusankar, Dr. Keerthana C, Dr. Aneena Suresh Staff, Department of Pharmacy Practice participated in webinar entitled 'Exploring and understanding the COVID 19 pandemic' organized by Department of Pharmacology, JSS College of Pharmacy, Ooty on 13th December 2021.

Dr M Deepalakshmi, Dr Roopa B S, Dr. Swathi Swaroopa B, Dr J Jeyaram Bharathi, Dr Mohsina Hyder, Staff, Department of Pharmacy Practice participated in webinar entitled 'Role of Electronic Health Records in Patient care, Population and Public Health Sciences' organized by JSS Academy of Higher Education & Research, Mysuru on 14th December 2021.

EVENT CORNER

Dr M Depalakshmi, Asst. Professor, Department of Pharmacy Practice participated in AICTE Training And Learning (ATAL) Academy Online Elementary FDP on "LEADERSHIP IN ACADEMIC EXCELLENCE" organized by Department of Computer Science and Information Technology, Dr. Babasaheb Ambedkar Marathwada University, Aurangabad between 29th November to 03rd December 2021.

Dr G K Sadagoban, Asst. Professor, Department of Pharmacy Practice participated in webinar entitled 'Data Analysis with 'R' programming' organized by COMMACAD Education Technologies, between 10th to 12th December 2021.

Dr Keerthana C, Resident, Department of Pharmacy Practice participated in the event 'Manav Faculty Level Survey on scientific reading practices, capabilities and challenges of undergraduate and postgraduate students' organized by Project Manav, Human Atlas Initiative, National Centre for Cell Science, Pune between 16th to 27th December 2021.

Dr M Deepalakshmi, Asst. Professor, Department of Pharmacy Practice acted as a reviewer of manuscript in 'Journal of Pharmacy Practice' during December 2021.

Dr Swathi Swaroopa B, Asst. Professor, Department of Pharmacy Practice acted as a reviewer of manuscript in 'Journal of Applied Pharmaceutical sciences' during December 2021.

PUBLICATIONS FROM THE DEPARTMENT OF PHARMACY PRACTICE

October - December 2021

Sudarsan P, Balakrishna AG, Asir JA, Balu D, Gopal S, Sadagoban GK, Swathi Swaroopa B. Development and validation of A-SOAP notes: Assessment of efficiency in documenting patient therapeutic records. Journal of Applied Pharmaceutical Science. 2021;11(10):001-6.

Swathi Swaroopa B, Chebrolu B, Thotakura P, Joice SB, Palanimuthu VR, Krishnamoorthy SG, Parthasarathy AK. Prevalence of OCT1 (rs628031) genetic polymorphism in south Indian population. Journal of Applied Pharmaceutical Science. 2021;11(10):035-41.

Nair HG, Thomas SR, Prithika SI, Samraj PA, Sumathi K, Keerthana C. Vanishing bile duct syndrome in pediatric population: An updated case-based review. Journal of Applied Pharmaceutical Science. 2021;11(10):134-9.

Anusha RJ, Bencer WD, Keerthana C. Naturally occurring fish poisoning illness—An evidence-based review. Journal of Applied Pharmaceutical Science. 2021;11(10):140-6.

Paramkusham V, Palakurthy P, Sri Gurram N, Talla V, Vishwas HN, Jupally VR, Pattnaik S. Adverse events following pediatric immunization in an Indian city. Clinical and Experimental Vaccine Research. 2021 Sep;10(3):211.

Sagadevan S, Hari OS, Sirajudeen MJ, Ramalingam G, Roopa BS. Effects of L-arginine on preeclampsia risks and maternal and neonatal outcomes: A systematic review and meta-analysis. Asian Pacific Journal of Reproduction. 2021;10(6):241.

Benny BM, Nayudu GS, Khan MA, Gobinath P, Roopa BS. A study to investigate the elevated maternal haemoglobin value as a risk biomarker for gestational diabetes: A nested case control study. Clinical Epidemiology and Global Health. 2021;12:100897.

Keerthana Chandrasekar Vahini B, Vijay V, Shalini R, Arun KP. Gentamicin pharmacokinetics and pharmacodynamic correlation in pediatrics—A systematic review. Journal of Applied Pharmaceutical Science. 2021;11(11):011-7.

Basutkar RS, Varghese R,Mathew NK, Sankar Indira P, Viswanathan B, Sivasankaran P.Systematic review and meta-analysis of potential pleiotropiceffects of sevelamer in chronic kidney disease: Beyondphosphate control.Nephrology. 2022;1-18.

Deepalakshmi M, Samraj A, Diya C, Venkatesh J, Kamalrathinam RS, Arun KP. Case Report on Mild Anemia and Gastritis due to Zidovudine, Lamivudine and Nevirapine (ZLN) Regimen. Research Journal of Pharmacy and Technology. 2021;14(11):5911-2.

Sadagoban GK, Raj V, Viswanathan B, Dhanasekaran GP, Palaniappan D, Borra SS. Enhancing the empiric antibiotic selection by introducing an antibiogram toolkit in a tertiary care hospital in Southern India–A prospective study. Journal of Clinical Pharmacy and Therapeutics. 2021; 46(6): 1-8.

Industrial Expert Interaction series – Lecture I

Enhancing interpersonal and professional skills

Speaker:
Mr Santhosh H Y
Deputy General Manager
Accenture Solutions Pvt Ltd
Bangalore

Title of the presentation:
Insights to Cosmetovigilance

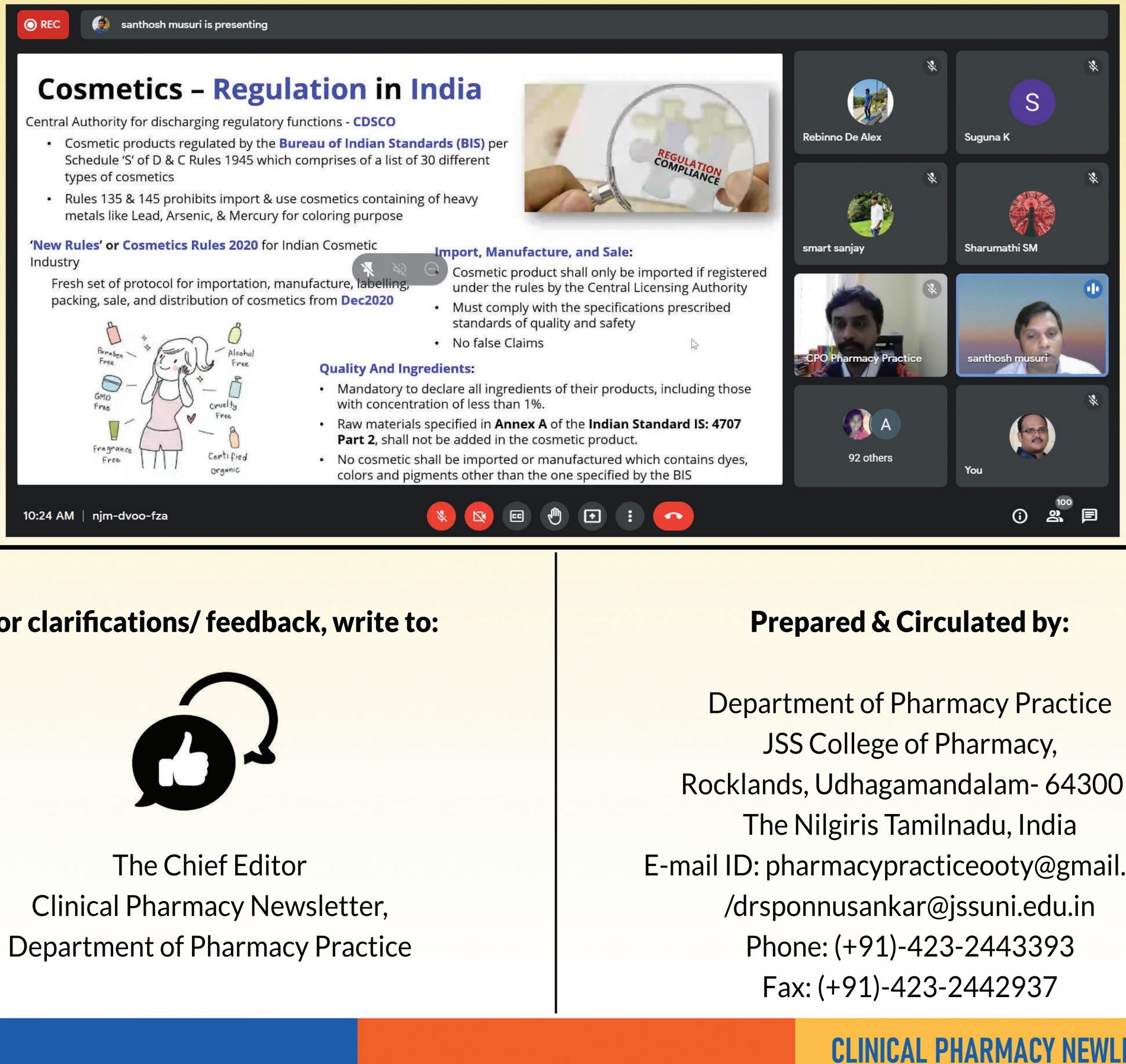
Date of Presentation: 17.12.2021

With an objective of enhancing interpersonal and professional skills of the students, Department of Pharmacy Practice in association with Pharmacy Education Unit, JSS College of Pharmacy, Ooty has planned to conduct Industrial Expert Interaction series. Industry expert interactions series provides a platform for budding Pharmacists to be aware of the skills required to enter profession and what Industry expects from the young graduates.

Mr. Santhosh has over 12 years of experience in Safety Data Management, Clinical Coding, Pharmacovigilance, Cosmetovigilance, and site payments. He pursued Master of Pharmacy (Pharmacy Practice) from JSS University, Mysore. Mr Santhosh has expertise in setting up of Pharmacovigilance programs in hospital set-up and participated as coordinator and co-investigator in numerous clinical trials. He is experienced with managing project teams that consistently delivered results on multiple projects and also served as trainer and coordinator, south zone for Pharmacovigilance Program of India (PVPI).

Mr. Santhosh started on the discussion with basics of Cosmetovigilance. He spoke about the importance of regulating cosmetics and need for Cosmetovigilance. He also narrated about the regulation of cosmetics in India under Part XIII, XIV & XV of Drugs & Cosmetics act 1940 along with BIS. He overviewed about European Union, directive 76/768/EEC which regulates the monitoring of cosmetics across EU. Further, he also discussed about the Cosmetovigilance flow chart and how to categorize events into serious and non-serious events.
Mr. Santhosh further elaborated about how to manage undesirable effects caused by cosmetics. He also explained about the various information collected in order to assess the causalty and severity of reactions. Mr. Santhosh discussed about COLIPA causalty assessment technique. Finally, a case was discussed and how causalty was assessed was discussed.

After the presentation, PG and Pharm D Students were encouraged to interact through question and answer session with Mr Santhosh and he clarified their doubts regarding Cosmetovigilance and career opportunities in Pharmcovigilance industry.
The event was coordinated by Dr S Ponnusankar and Mr Vishwas H N of Dept. of Pharmacy Practice. About 95 participants comprising of students and staff from Department of Pharmacy Practice attended the event.



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