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CLINICAL PHARMACY NEWSLETTER

A Newsletter of Drug and Prescribing Information

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INSIDE THIS ISSUE

FDA APPROVES NOVEL DRUG TO TREAT MODERATE TO SEVERE HOT FLASHES CAUSED BY MENOPAUSE

The U.S. Food and Drug Administration approved Veozah (Fezolinetant), an oral medication for the treatment of moderate to severe vasomotor symptoms, or hot flashes, caused by menopause. Veozah is the first neurokinin 3 (NK3) receptor antagonist approved by the FDA to treat moderate to severe hot flashes from menopause. It works by binding to and blocking the activities of the NK3 receptor, which plays a role in the brain's regulation of body temperature. "Hot flashes as a result of menopause can be a serious physical burden on women and impact their quality of life". The introduction of a new molecule to treat moderate to severe menopausal hot flashes will provide an additional safe and effective treatment option for women."

Menopause is a normal, natural change in a woman's life when her period stops, usually occurring between ages 45 and 55. Menopause is often referred to as "the change of life" or "the change." During menopause a woman's body slowly produces less of the hormones estrogen and progesterone. A woman has reached menopause when she has not had a menstrual period for 12 consecutive months. Hot flashes occur in around 80% of menopausal women and can include periods of sweating, flushing and chills lasting for several minutes. Some women who experience hot flashes and have a history of vaginal bleeding, stroke, heart attack, blood clots or liver disease, cannot take hormone therapies. Veozah is not a hormone. It targets the neural activity which causes hot flashes during menopause.

Patients taking Veozah should take one 45 mg pill orally, once a day, with or without food. The pill should be taken at the same time each day. If a dose is missed, or not taken at the regular time, patients should take it as soon as possible and return to their regular schedule of the following day.

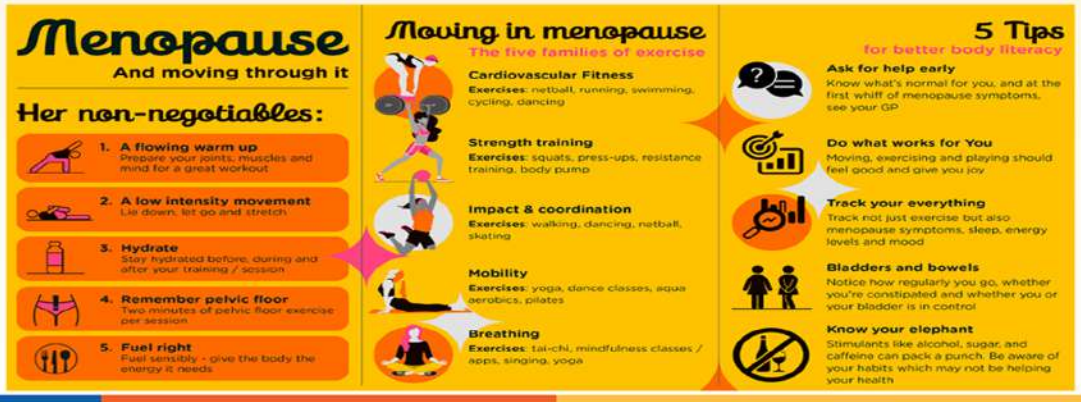
The effectiveness of Veozah to treat moderate to severe hot flashes was demonstrated in each of the first 12-week, randomized, placebo-controlled, double-blind portions of two phase 3 clinical trials. In both trials, after the first 12 weeks, the women on placebo were then re-randomized to Veozah for a 40-week extension study to evaluate safety. Each trial ran a total of 52 weeks. The average age of the trial participants was 54 years old.

The prescribing information for Veozah includes a warning for elevated hepatic transaminase, or liver injury. Before using Veozah, patients should have blood work done to test for liver damage. While on Veozah, routine bloodwork should be performed every three months for the first nine months of using the medication. Patients experiencing symptoms related to liver damage—such as nausea, vomiting, or yellowing of the skin and eyes—should contact a physician. Veozah cannot be used with CYP1A2 inhibitors. Patients with known cirrhosis, severe renal damage or end-stage renal disease should not take Veozah.

The most common side effects of Veozah include abdominal pain, diarrhea, insomnia, back pain, hot flush and elevated hepatic transaminases. The FDA granted the Veozah application Priority Review designation. The approval of Veozah was granted to Astellas Pharma US, Inc. The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

References

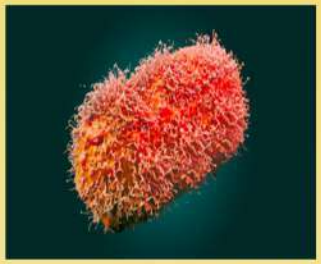
https://www.fda.gov/news-events/press-announcements/fda-approves-novel-drug-treat-moderate-severe-hot-flashes-caused-menopause



MPOX (Monkeypox) OUTBREAK 2022 - GLOBAL

Definition: Monkey Pox is a rare disease caused by the Monkey Pox virus. This virus usually affects rodents, such as rats or mice, or nonhuman primates, such as monkeys. But it can occur in people. Monkey Pox usually occurs in Central and West Africa. Cases outside of Africa are often due to: i) International travel, ii) Imported animals iii) Close contact with an animal or person with Monkey Pox.

Starting in 2022, Monkey Pox cases were reported in countries that don't often have Monkey Pox, such as the United States. The Centers for Disease Control and Prevention (CDC) continues to monitor cases that have been reported throughout the world, including Europe and the United States.



Clinical Manifestation: Monkey Pox symptoms may start 3 to 17 days after the exposure. Monkey Pox symptoms last 2 to 4 weeks and may include: Fever, Skin rash, Swollen lymph nodes, Headache, Muscle aches and backaches, Chills, Tiredness. About 1 to 4 days after you begin having a fever, a skin rash starts.

The Monkey Pox rash often first appears on the face, hands or feet and then spreads to other parts of the body. But in cases linked to the outbreak that started in 2022, the rash often started in the genital area, mouth, or throat. The Monkey Pox rash goes through many stages. Flat spots turn into blisters. Then the blisters fill with pus, scab over and fall off over a period of 2 to 4 weeks. The infected person can spread Monkey Pox while they have symptoms.

Transmission: The virus spreads through close contact with an infected animal or person or it can spread when a person handles materials such as blankets that have been in contact with someone who has Monkey Pox. The Monkey Pox virus spreads from person to person through:

* Direct contact with rashes, scabs or body fluids of a person with Monkey Pox.
* Extended close contact (more than four hours) with respiratory droplets from an infected person. This includes sexual contact.
* Clothes, sheets, blankets or other materials that have been in contact with rashes or body fluids of an infected person.
* An infected pregnant person can spread the Monkey Pox virus to a fetus.

Monkey Pox spreads from an animal to a person through:

* Animal bites or scratches.
* Wild game that is cooked for food.
* Products, such as skins or furs, made of infected animals.
* Direct contact with body fluids or rashes of animals with Monkey Pox.

Complications:

Severe scars on the face, arm and legs, Blindness, other infections and may rarely result in death. The type of Monkey Pox virus spreading in the 2022 outbreak, called Clade II, rarely leads to death.

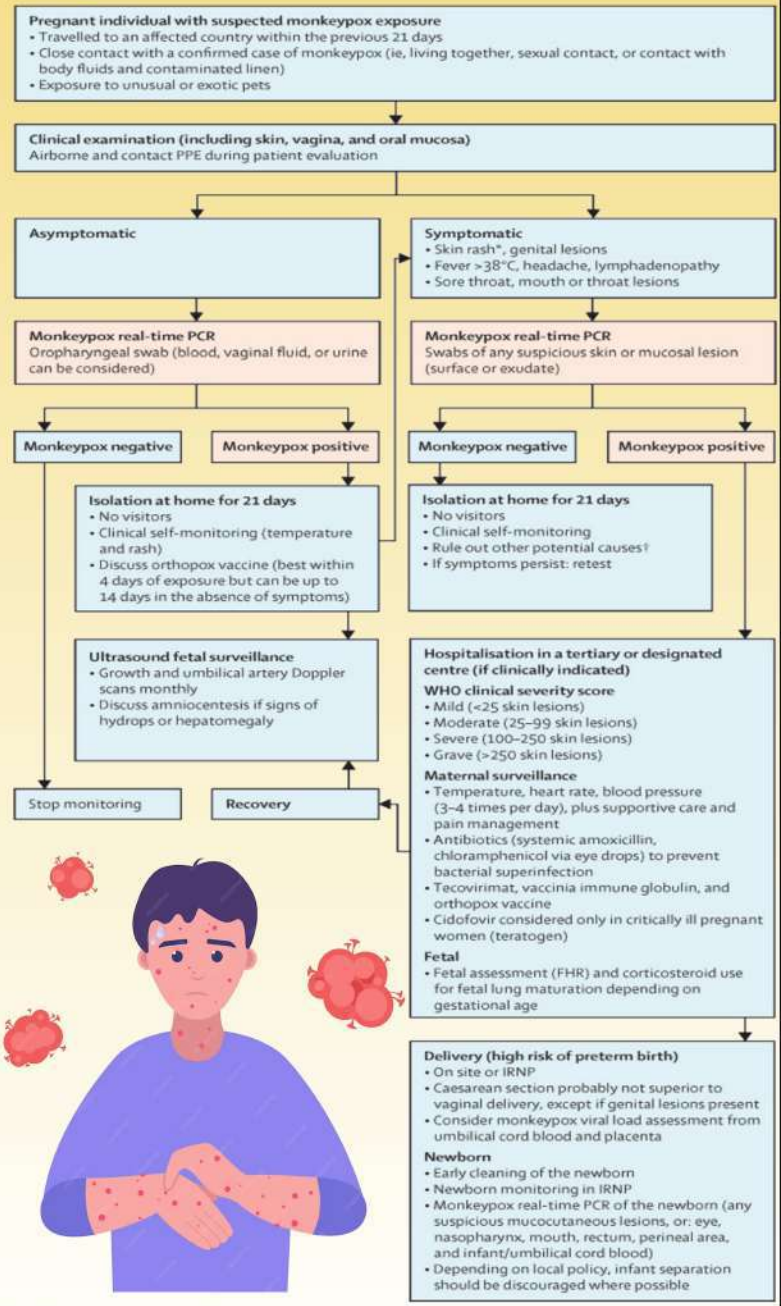
Preventive Measures:

* Avoid close contact with people who have a rash that looks like Monkey Pox.
* Avoid handling clothes, sheets, blankets or other materials that have been in contact with an infected animal or person.
* Isolate people who have Monkey Pox from healthy people.
* Wash hands well with soap and water after any contact with an infected person or animal. If soap and water aren't available, use an alcohol-based hand sanitizer.Avoid animals that may carry the virus.

Vaccination:

Some smallpox vaccines can prevent Monkey Pox, including the ACAM2000 and Jynneos vaccines. These vaccines can be used to prevent Monkey Pox because smallpox and Monkey Pox are caused by related viruses. Health care professionals may suggest that people who have been exposed to Monkey Pox get vaccinated. Some people who are at risk of exposure to the virus in their work, such as lab workers, may get vaccinated too.

Diagnosis:



Remember that Monkey Pox is rare and the virus doesnot spread easily between people without close contact.

MPOX (Monkeypox) OUTBREAK 2022 - GLOBAL

Treatment: Treatment for most people with Monkey Pox is aimed at relieving symptoms. Care may include managing skin damage from the Monkey Pox rash, drinking enough liquids to help keep stool soft, and pain management. If you have Monkey Pox, isolate at home in a separate room from family and pets until your rash and scabs heal. There is no specific treatment approved for Monkey Pox. Health care professionals may treat Monkey Pox with some antiviral drugs used to treat smallpox, such as Tecovirimat (TPOXX) or Brincidofovir (Tembexa). For those unlikely to respond to the vaccine, a health care professional may offer vaccinia immune globulin. This has antibodies from people who have been given the smallpox vaccine.

Antiviral Agents

Tecovirimat - Oral:

40 to120 kg: 600 mg PO every 12th hr

≥120 kg: 600 mg PO every 8h hr

Treatment duration: 14 days, but may be longer (not to exceed 90 days) or shorter depending on disease progression and patient's clinical condition. Take within 30 minutes after eating a full meal containing moderate or high fat

Para-Enteral Treatment Options (IV):

35 to < 120 kg: 200 mg IV every 12th hr

≥120 kg: 300 mg IV every 12th hr

Switch to oral capsules to complete treatment course as soon as oral therapy tolerated

Cidofovir Injectable solution:

75mg/mL (375mg/5mL vial)

Brincidofovir:

Tablet: 100mg

Oral suspension: 10mg/mL

Vaccinia immune globulin (VIG):

VIG can be considered for prophylactic use in a monkeypox-exposed person with severe immunodeficiency in T-cell function for which smallpox vaccination following monkeypox exposure is contraindicated.

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1.https://www.mayoclinic.org/diseases-conditions/infectious-diseases/expert-answers/monkeypox-faq/faq-20533608

2.Pradip Dashraath, Karin Nielsen-Saines, Citra Mattar, Didier Musso, Paul Tambyah, David Baud. Guidelines for pregnant individuals with monkeypox virus exposure. The Lancet 2022; 400(10345): 21-22.

3. https://emedicine.medscape.com/article/1134714-treatment

"Most people who get monkeypox get better on their own without treatment and can recover at home."

DRUG PROFILE
LITFULO (RITLECITINIB)

Pharmacological Class:

* Alopecia Agent
* Dermatological Agent
* Tyrosine Kinase Inhibitor

General Dosage Information

*If treatment interruption is indicated, a temporary treatment interruption for less than 6 weeks is not expected to result in significant loss of regrown scalp hair.

Adult Dosing

Alopecia areata (Severe)

*50 mg orally once daily with or without food

Pediatric Dosing

Alopecia areata (Severe)

*(12 years and older) 50 mg orally once daily with or without food

Dose Adjustment

*Renal impairment: No clinically significant differences were observed in patients with severe impairment (estimated GFR less than 30 mL/min); no studies were done for mild or moderate impairment as a clinically relevant increase in exposure is not expected.

Dosing in Renal & Hepatic Impairment:

*Hepatic impairment (mild, Child-Pugh A or moderate, Child-Pugh B): No dose adjustment is required.

*Hepatic impairment (severe, Child-Pugh C): Use not recommended.

*Geriatric: No dose adjustment is required.

*Aminotransferase (ALT or AST) elevations: Interrupt treatment if increases in ALT or AST occur and a drug-induced injury is suspected, until this diagnosis is excluded.

Hypersensitivity reactions:

Discontinue if a clinically significant hypersensitivity reaction occurs.

Hematologic abnormalities (platelets): Discontinue if platelet count is less than 50,000/mm(3).

Hematologic abnormalities (lymphocytes): Interrupt if absolute lymphocyte count (ALC) is less than 500/mm(3), may be restarted once the ALC returns above this value.

Serious infection: Interrupt if a patient develops a serious or opportunistic infection; may be resumed once the infection is controlled.

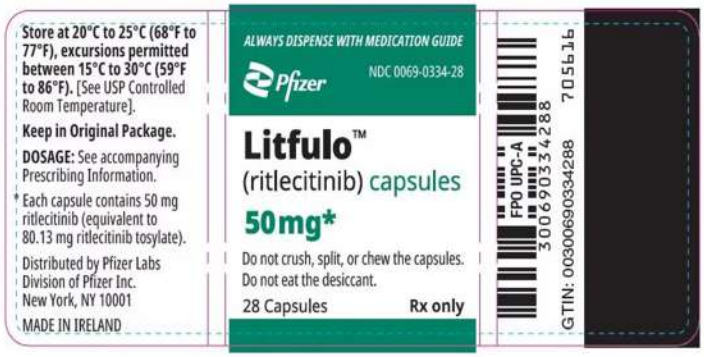
Herpes zoster: Consider interrupting treatment if a patient develops herpes zoster, until the episode resolves.

Major adverse cardiovascular events: Discontinue in patients that have experienced a myocardial infarction or stroke.

Thromboembolic events: Interrupt treatment if symptoms of thrombosis or embolism occur

Dosage Form

Oral Capsule: 50 MG



DRUG PROFILE
LITFULO (RITLECITINIB)

Mechanism of Action:
•Ritlecitinib irreversibly inhibits Janus kinase 3 (JAK3) and the tyrosine kinase expressed in hepatocellular carcinoma (TEC) kinase family by blocking the adenosine triphosphate (ATP) binding site. In cellular settings, ritlecitinib inhibits cytokine induced STAT phosphorylation mediated by JAK3-dependent receptors. Additionally, ritlecitinib inhibits signaling of immune receptors dependent on TEC kinase family members. The relevance of inhibition of specific JAK or TEC family enzymes to therapeutic effectiveness is not currently known.

Cardiac electrophysiology: At 12 times the mean maximum exposure of the 50 mg once daily dose in patients with alopecia areata, there was no clinically relevant effect on the QTc interval

Pharmacokinetics:
Absorption:
•Tmax, oral: 1 hour
•Bioavailability, oral: 64%
•Effects of food: No effect
Distribution:
•Protein binding: 14%
Metabolism:
•Multiple pathways including CYP enzymes and glutathione S-transferase (GST)
•CYP3A substrate
•CYP3A inhibitor
•CYP1A2 inhibitor
Excretion:
•Renal excretion: 66% (4% of dose unchanged)
•Fecal excretion: 20%
Elimination Half Life:
•1.3 to 2.3 hours

Adverse Effects:
Common
•Dermatologic: Acne (6.2%), Folliculitis (3.1%), Rash (5.4%), Urticaria (4.6%)
•Gastrointestinal: Diarrhea (10%)
•Neurologic: Headache (10.8%)
•Other: Fever (3.1%)
Serious
•*Cardiovascular:* Myocardial infarction (0.06 per 100 patient-years)
•*Hematologic:* Deep venous thrombosis, Thrombosis
•*Immunologic:* Anaphylaxis, Cancer, Herpes zoster (1.3% to 1.5%), Hypersensitivity reaction, Malignant lymphoma, Tuberculosis
•*Neurologic:* Cerebrovascular accident
•*Respiratory:* Lung cancer, Pulmonary embolism (0.06%)
•*Other:* Infectious disease (0.4%)

Medication counseling:
•Advise patient to report symptoms of infection.
•Tell patient to report symptoms of thrombosis.
•Counsel patient to avoid live vaccines shortly prior to and during treatment.
•Side effects may include diarrhea, headache, rash, urticaria, folliculitis, pyrexia, atopic dermatitis, dizziness, herpes zoster, and stomatitis.
•Instruct patient to take a missed dose as soon as possible, but if next dose is in less than 8 hours, skip the missed dose and resume dosing at the regular scheduled time

Reference:
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April - June 2023

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•Karur Venkatesan Uma, Jacob Vineth Martin, Gunasekaran Sutheeswaran, Raman Rajeshkumar, Sivasankaran Ponnusankar*. Molecular docking and in-silico predictive analysis of potential herb-drug interactions between *Momordica charantia* and Empagliflozin. Journal of Applied Pharmaceutical Sciences 2023; 13(3): 175-182.

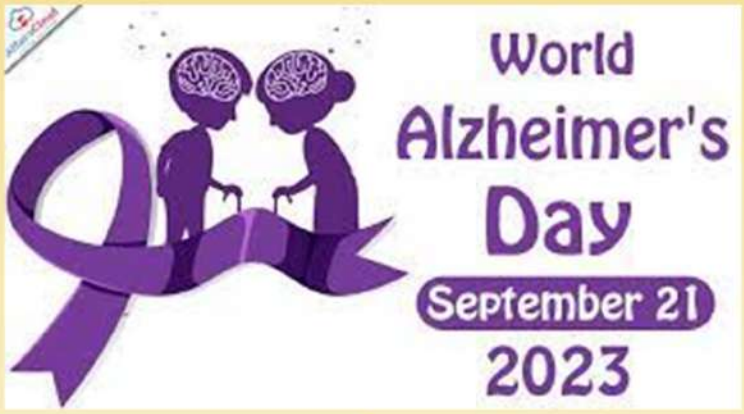
DID YOU KNOW!

Insulin is one of the most common medications that cause adverse events.

CLINICAL PHARMACY SERVICES REPORT - 2022 - 23

Ward Name	PHARMACIST INTERVENTIONS	MEDICATION RECONCILIATION	TREATMENT CHART REVIEW	PATIENT COUNSELLING	ADRs SUSPECTED & REPORTED	DRUG & POISON INFORMATION
Pediatric Ward	481	285	321	208	81	57
OBG & Gynac	172	64	80	80	16	0
Female Medical W...	199	65	101	80	0	0
Surgical Ward	61	48	48	48	0	0
Intensive Care Unit	408	96	96	96	null	null
Orthopedic Ward	31	null	24	24	null	null

IMPORTANT DATES TO REMEMBER!



For clarifications/ feedback, write to:

The Chief Editor
Clinical Pharmacy Newsletter,
Department of Pharmacy Practice

Prepared & Circulated by:

Department of Pharmacy Practice
JSS College of Pharmacy,
Rocklands, Udhagamandalam- 643001
The Nilgiris Tamilnadu, India
E-mail ID: pharmacypracticeooty@gmail.com
/drsponnusankar@jssuni.edu.in
Phone: (+91)-423-2443393
Fax: (+91)-423-2442937