**Editorial**

Wishing you a Happy New Year 2022!

Molnupiravir—the first oral antiviral agent got approval for Emergency Use in Covid-19 treatment in UK in the month of November 2021 and the same has got Emergency Use approval in USA by US FDA in the month of December 2021 for above 18 adults. Central Drugs Standard Control Organization (CDSCO) the apex regulatory agency in India has approved Emergency Use of Molnupiravir in Covid-19 to more than 13 companies very recently. Indian companies are marketing the Molnupiravir capsules at a lower cost in comparison to the innovator brand.

But in a recent statement the Director General of Indian Council of Medical Research (ICMR) has stated that Molnupiravir could not be included in the Covid-19 treatment protocol due to its severe safety concerns including Mutagenicity, Muscle and bone damage.

This statement created confusion among the scientific community and medical fraternity as the same has been approved by DCGI a few days back and Molnupiravir capsules are available in Indian market. The same also are being exported to several countries for treatment of Covid-19. It is surprising that the two different Government agencies have diverse opinion about the same drug. Hope all the Government agencies will be able to disseminate a uniform opinion to resolve this confusion in the interest of the public health within short time.

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New Drug: MOLNUPIRAVIR capsules, for oral use

Original EUA Authorized Date: 12/23/2021

The U.S. Food and Drug Administration (FDA) has issued an EUA for the emergency use of the unapproved molnupiravir, a nucleoside analogue that inhibits SARS-CoV-2 replication by viral mutagenesis for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults with positive results of direct SARS-CoV-2 viral testing who are at high risk for progressing to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate. Molnupiravir is not FDA-approved for any use including for use for the treatment of COVID-19. Prior to initiating treatment with molnupiravir, carefully consider the known and potential risks and benefits.

LIMITATIONS OF AUTHORIZED USE: (1) Molnupiravir is not authorized for use in patients less than 18 years of age - for use for treatment in patients requiring hospitalization due to COVID-19. Benefit of treatment with molnupiravir has not been observed in subjects when treatment was initiated after hospitalization due to COVID-19. (2.1) - for use for longer than 5 consecutive days. - for pre-exposure or post-exposure prophylaxis for prevention of COVID-19. Molnupiravir may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which molnupiravir belongs (i.e., antiinfectives).

Molnupiravir is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of molnupiravir under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb3(b)(1), unless the authorization is terminated or revoked sooner. See the box in the beginning of the Full Fact Sheet for details on mandatory requirements for administration of molnupiravir under emergency use authorization. See Full Fact Sheet for Healthcare Providers for the justification for emergency use of drugs during the COVID-19 pandemic, information on available alternatives, and additional information on COVID-19.

DOSAGE AND ADMINISTRATION: • 800 mg (four 200 mg capsules) taken orally every 12 hours for 5 days, with or without food. • Take molnupiravir as soon as possible after a diagnosis of COVID-19 has been made, and within 5 days of symptom onset. (2.1) • Completion of the full 5-day treatment course and continued isolation in accordance with public health recommendations are important to maximize viral clearance and minimize transmission of SARS-CoV-2. (2.1) Molnupiravir is not authorized for use for longer than 5 consecutive days because the safety and efficacy have not been established.

DOSAGE FORMS AND STRENGTHS: Capsules: 200 mg

CONTRAINDICATIONS: No contraindications have been identified based on the limited available data on the emergency use of molnupiravir authorized under this EUA.

WARNINGS AND PRECAUTIONS: • Embryo-Fetal Toxicity: Molnupiravir is not recommended for use during pregnancy. • Bone and Cartilage Toxicity: Molnupiravir is not authorized for use in patients less than 18 years of age because it may affect bone and cartilage growth.

ADVERSE REACTIONS: Most common adverse reactions (incidence ≥ 1%) are diarrhea, nausea, and dizziness.

You or your designee must report all SERIOUS ADVERSE EVENTS or MEDICATION ERRORS potentially related to molnupiravir (1) by submitting FDA Form 3500 online, (2) by downloading this form and then submitting by mail or fax, or (3) contacting the FDA at 1-800-FDA-1088 to request this form. Please also provide a copy of this form to Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ USA at 1-800-672-6372 or Fax 215-616-5677

DRUG INTERACTIONS: No drug interactions have been identified based on the limited available data on the emergency use of molnupiravir authorized under this EUA.

USE IN SPECIFIC POPULATIONS: • Pregnancy: The use of molnupiravir is not recommended during pregnancy. Advise individuals of childbearing potential to use effective contraception correctly
and consistently, as applicable, for the duration of treatment and for 4 days after the last dose of molnupiravir. • Lactation: Breastfeeding is not recommended during treatment and for 4 days after the last dose of molnupiravir. A lactating individual may consider interrupting breast feeding and may consider pumping and discarding breast milk during treatment and for 4 days after the last dose of molnupiravir.

For details: [https://www.fda.gov/media/155054/download](https://www.fda.gov/media/155054/download)

**Status in India:** CDSCO has granted Emergency Use Approval to Molnupiravir capsules of more than 13 manufacturers. A single course of Molnupiravir 200 mg capsules of 40 costs ranging Rs. 1400-Rs. 4500 in Indian market.

**Thirteen Indian companies allowed to manufacture Molnupiravir for COVID**

The Union Health Ministry on 28.12.2021 granted approval to antiviral drug Molnupiravir following Emergency Use recommendations by the Central Drugs Standard Control Organization (CDSCO).

**List of Monthly Drug Safety Alerts issued by PvPI from January 2021 to June 2021**

<table>
<thead>
<tr>
<th>S.No</th>
<th>Issue Date</th>
<th>Suspected drugs</th>
<th>Indication</th>
<th>Adverse Reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>04th January 2021</td>
<td>Ambroxol</td>
<td>Anti-tussive - Acute and chronic disease of the respiratory tract associated with abnormal bronchial secretions in particular acute attacks of chronic bronchitis, asthmatic bronchitis and bronchial asthma.</td>
<td>Fixed Drug Eruption</td>
</tr>
<tr>
<td>2.</td>
<td>04th January 2021</td>
<td>Fexofenadine</td>
<td>In the treatment of relief of symptoms associated with seasonal allergic rhinitis and chronic idiopathic urticaria.</td>
<td>Blurred Vision</td>
</tr>
<tr>
<td>3.</td>
<td>01st February 2021</td>
<td>Cefpodoxime</td>
<td>Acute bronchitis, exacerbations of chronic bronchitis, bronchiolitis pneumonia, sinusitis, recurrent chronic tonsillitis, pharyngitis, acute otitis.</td>
<td>Drug Reaction with Eosinophilia Systemic Symptoms (DRESS) Syndrome</td>
</tr>
<tr>
<td>4.</td>
<td>01st February 2021</td>
<td>Clarithromycin</td>
<td>Mild to moderately severe infections like acute exacerbation of chronic bronchitis community acquired pneumonia including infections due to chlamydia, mycoplasma spigioella acute streptococcal pharyngitis and skin and soft tissue infections.</td>
<td>Burning Sensation</td>
</tr>
<tr>
<td>5.</td>
<td>01st March 2021</td>
<td>Hydroxyzine</td>
<td>For the management of pruritus due to allergic conditions such as chronic urticaria and atopic contact dermatoses, and in histamine - mediated pruritus.</td>
<td>Photosensitivity Reaction</td>
</tr>
</tbody>
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The antiviral drug Molnupiravir will be manufactured by 13 companies in India which had submitted their clinical trial report to the drugs regulator.

"CDSCO had received 22 applications in total for manufacture and market of the drug Molnupiravir in the country 8 including 5 applicants of a consortium (in total 13) had submitted their clinical trial report interim or complete report and were granted authorization for manufacturing," the Union Health Ministry stated.

<table>
<thead>
<tr>
<th>No.</th>
<th>Date</th>
<th>Medicine</th>
<th>Description</th>
<th>Reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.</td>
<td>01st March 2021</td>
<td>Salicylic Acid</td>
<td>For the treatment of acne vulgaris.</td>
<td>Photosensitivity Reaction</td>
</tr>
<tr>
<td>7.</td>
<td>05th April 2021</td>
<td>Zinc (Acetate/Oxide/Sulphate/Gluconate)</td>
<td>In treatment of acute diarrhoea in children as an adjunct to oral rehydration.</td>
<td>Diarrhoea</td>
</tr>
<tr>
<td>8.</td>
<td>28th June, 2021</td>
<td>Clobazam</td>
<td>Acute and chronic anxiety states and as an adjunctive therapy in patients with refractory epilepsy.</td>
<td>DRESS syndrome</td>
</tr>
<tr>
<td>9.</td>
<td>28th June, 2021</td>
<td>Baclofen</td>
<td>For the symptomatic treatment of neuronal spasticity due to multiple sclerosis, spinal cord, pathology &amp; injury.</td>
<td>Encephalopathy</td>
</tr>
<tr>
<td>10.</td>
<td>28th June, 2021</td>
<td>Rosuvastatin&amp;Ticagrelor Interaction</td>
<td>Rosuvastatin: Risk reduction of MI stroke and arterial revascularisation procedure in patients without clinically evident CHD but with multiple risk factors. Ticagrelor: For the prevention of thrombotic events (cardiovascular death, Myocardial Infarction and stroke) in patients with Acute coronary syndromes (ACS) unstable angina, non ST Elevation Myocardial Infarction (STEMI) including patients managed medically and those who are managed with Percutaneous Coronary Intervention (PCI) or Coronary Artery Bypass Grafting (CABG).</td>
<td>Rhabdomyolysis</td>
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**Reader's Column……..**

Dear Dr. Mandal,

As we begin to close the most traumatic year in recent history, I must compliment you and your editorial team for publishing the Drug Information Bulletin without interruption in spite of many disruptions and keeping the readers updated on various drug and health related developments.

Thank you and wishing you a healthy and safe 2022.

Best regards.

Dr. Ajit Dangi M.S., Ph.D

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Dear Subhash,

Wishing you a Happy New Year.

I am very happy to read an excellent editorial written by you in this issue, where you have highlighted the pharmacists as a vaccinator along with the other professional of our Indian society. This issue has also excellently reported the status of indigenously developed vaccines.

Keep well, stay healthy and do good work.

Saratda.

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