



06 MAY 2022

FDA ADVISORY  
No. **2022-1035**

**TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

**SUBJECT : Public Health Warning Against the Purchase and Use of the Unregistered Drug Product "Molnupiravir 200 mg Capsules Moluxin 200 40's"**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the unregistered drug product:

The image displays the packaging for an unregistered drug product. On the left is a white box with blue and red accents, labeled "Molnupiravir 200 mg Capsules MOLUXIN 200 40 Capsules". On the right is a white blister pack with a white cap, also labeled "Molnupiravir 200 mg Capsules MOLUXIN 200 40 Capsules".

**WARNING:** To be sold on the prescription of the Medical Specialist

**SCHEDULE H PRESCRIPTION DRUG CAUTION -** Not to be sold by retail without the prescription of a Registered Medical Practitioner.

Mfg. Lic. No.: GUJ/DRUGS/G/25/1358  
Batch No: ZC-1564  
Mfg. Date: 01 / 2022  
Exp. Date: 12 / 2023  
Manufactured in India For:  
**RAXIN<sup>TM</sup> HEALTH CARE**  
56-B, Changodar Industrial Estate, Vibhag-1,  
Godown No. 3, Sarkhej-Bavla Highway,  
Changodar - 382 213. (Gujarat)

Each hard gelatin capsule contains:  
Molnupiravir 200 mg.  
Excipients Q.S.  
**Dosage:** As directed by the Physician.  
**Storage:** Store at temperature not exceeding 25°C. Keep in a dry place and protect from light & moisture.  
Empty Hard Gelatin Capsule contains approved colours.  
Shallow whole capsule.  
Do not Crush or Chew.  
Keep medicines out of reach of children.

**WARNING:** Do not administer the drug to women known or suspected to be pregnant.

**WARNING:** Patients should use most effective contraceptive methods in sexual intercourse during and for 7 days after the end of treatment.

**Molnupiravir 200 mg Capsules Moluxin 200 40's**  
Manufactured in India for: RAXIN HEALTHCARE - 56-B, Changodar Industrial Estate, Vibhag-1 Godown No. 3, Sarkhej-Bavla Highway, Changodar - 382 213. (Gujarat)

Figure 1: Unregistered drug product



FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned drug product has not gone through the registration process of the Agency and has not been issued with proper authorization in the form of Certificate of Product Registration. Thus, the Agency cannot guarantee its quality and safety. Therefore, consumption of such violative product may pose potential danger or injury to health.

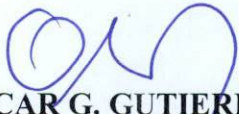
Pursuant to Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, promotion, advertising or sponsorship of health products without proper authorization from FDA is prohibited.

All concerned establishments and/or entities are warned not to distribute the above-identified violative drug product until it has been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product is registered with the FDA by using the **FDA Verification Portal** feature accessible at <https://verification.fda.gov.ph>.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that this product is not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at [info@fda.gov.ph](mailto:info@fda.gov.ph). To report continuous sale or distribution of unregistered health products, kindly e-mail us via [ereport@fda.gov.ph](mailto:ereport@fda.gov.ph). You may also call the Center for Drug Regulation and Research at telephone number (02) 8809-5596. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: <https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH> and fill out all the required fields.

Dissemination of the information to all concerned is requested.

  
**DR. OSCAR G. GUTIERREZ, JR.**  
Officer-in-Charge Director General

DTN: 

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