



Covid-19 Treatments

Remdesivir

Molnupiravir

Paxlovid



Bringing Quality to Healthcare.

About Us

STM BioSolutions is an emerging leader in the distribution of various innovative medical devices, pharmaceuticals, and biopharmaceuticals around the world. We seek to deliver protections against public health threats through a pipeline comprising of innovative products and therapeutics. We do what we do because we see the opportunity to create a better, more secure world. A world where preparedness empowers protection from the variety of threats we face, where peace of mind prevails.

As a response to the Covid-19, we have formed strategic alliances with several key Pharmaceutical, and Personal Protective Equipment Manufacturers globally. Bangladesh has been setting the bar high for generic medicine for the past 80 years and we are proud to be able to inform you that our Bangladeshi Pharmaceutical Manufacturing Partners have been the first in the world to bring the generic versions of Molnupiravir and Paxlovid along with many other generic drugs to market. The plants used in manufacturing these possess approvals from regulatory bodies such as UKMHRA, TGA, EUGMP, WHO GMP and have been a symbol of where quality meets .



Bringing Quality to Healthcare.

FAQ

1. Regulatory body approvals for the facilities that are manufacturing the above drugs:

UKMHRA, TGA, EUGMP, WHO GMP

2. A Standard Operating Procedure:

- Non-Disclosure Agreement
- Letter of Intent From Buyer
- Soft Corporate Offering
- Buyer will share PO & Customer Profile form filled out.
- Proof of Funds is Required if buyers' ability to Purchase cannot readily be determined.
- Pro-Forma Invoice
- Full payment via TT or Full transactional amount loaded into US based third-party escrow to be released on shipping documents for an additional charge.

3. The following information for each of the products:

i) Pricing

Please contact sales team for quote.



Bringing Quality to Healthcare.

ii) Minimum Order Quantity (MOQ) as well as maximum capacity per month

Remdesivir: MOQ 10,000 vials

Molnupiravir: MOQ 10,000 packs (10 / pack)

Paxlovid: MOQ 2,000 packs (6 / pack)

Maximum Capacity: STM has a huge capacity in terms of access to production allocation through various manufacturing partners, kindly let us know the requirement. We will accommodate accordingly.

iii) Lead time following order placement at MOQ:

1 month to handover the goods to the selected freight forwarder.

iv) Shipping Terms:

FOB, CIF Available for select countries for excess charge.



Bringing Quality to Healthcare.

Contact Us

STM BioSolutions L.L.C.

Website:


www.stmbiosolutions.com

Email:

info@stmbiosolutions.com

Phone:

US: +1 (682) 554-0824  | +1 (469) 922-9045

Canada: +1 (647) 225-3525 

Locations:

US Office

Wyoming

300 N Gould St STE R,
Sheridan, WY 82801

Texas

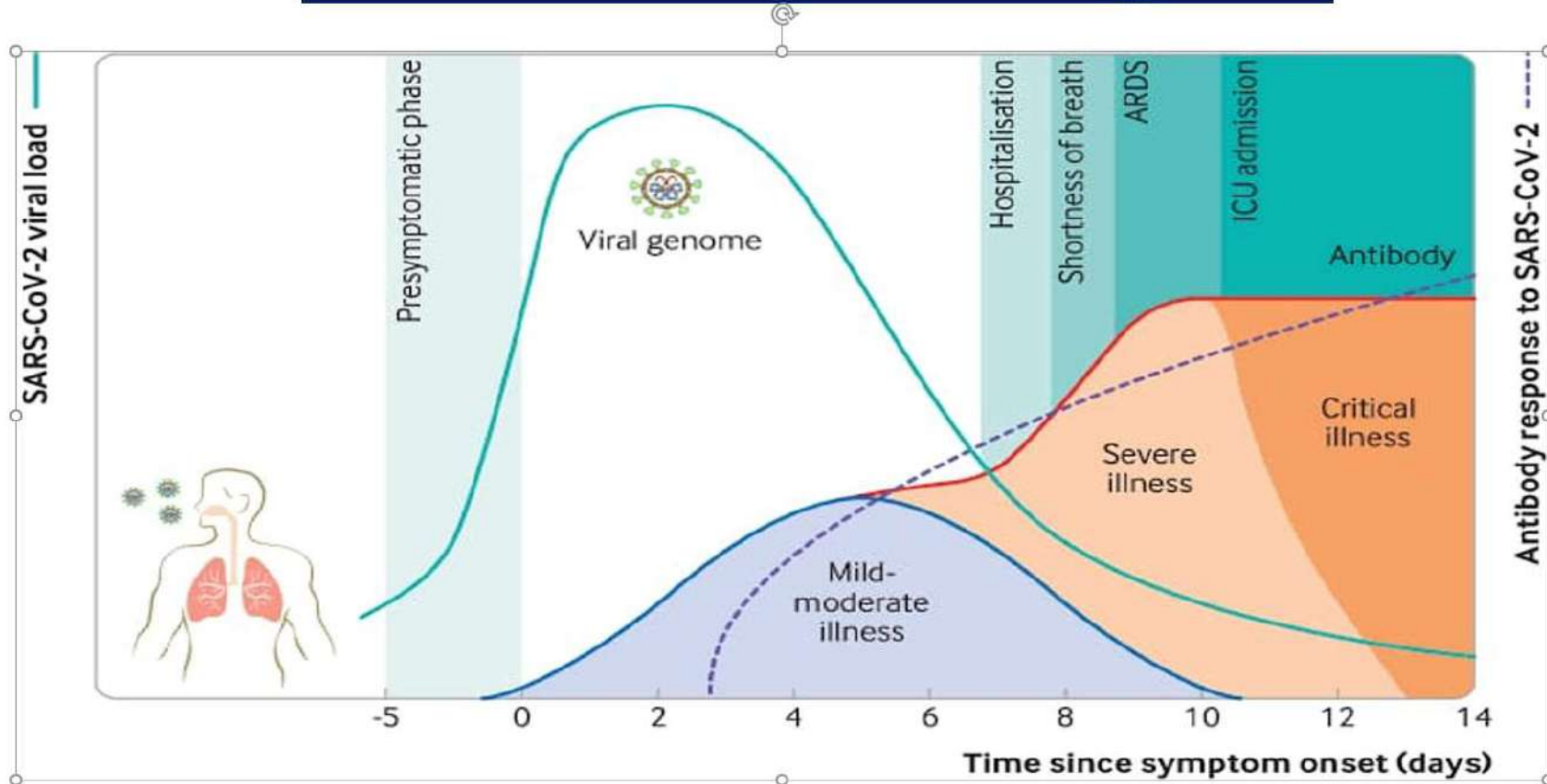
5511 Parkcrest Dr STE 207,
Austin, TX 78731

Canada Office

Ontario

706- 1 Concorde Gate,
North York, ON M3C 3N6

SARS-CoV-2 Viral Infection & Progression



Current Approved Treatment for COVID-19

Medicine	Dosage & Administration	Requirement	Indication
Remdesivir	Injectable & IV infusion	Hospital Setting	Moderate to Severe Illness
Tocilizumab	Injectable & IV infusion	Hospital Setting	Moderate to Severe Illness
<u>Casirivimab & Imdevimab</u>	Injectable & IV infusion	Hospital Setting	Mild to Moderate Illness

and recently.....

**For Mild to Moderate Illness
2 Oral Anti-COVID medicines has
been authorized by US FDA**

- **MOLNUPIRAVIR**
- **NIRMATRELVIR Co-packaged with
RITONAVIR**

Generic Paxlovid

Nirmatrelvir INN 150 mg Tablets and Ritonavir USP 100 mg Tablets



World's 1st US FDA Authorized

ORAL ANTI-COVID MEDICINE

for the people of Bangladesh

World's **1st** US FDA Authorized Oral Anti-COVID Medicine


Generic Paxlovid

Nirmatrelvir INN 150 mg Tablets and Ritonavir USP 100 mg Tablets

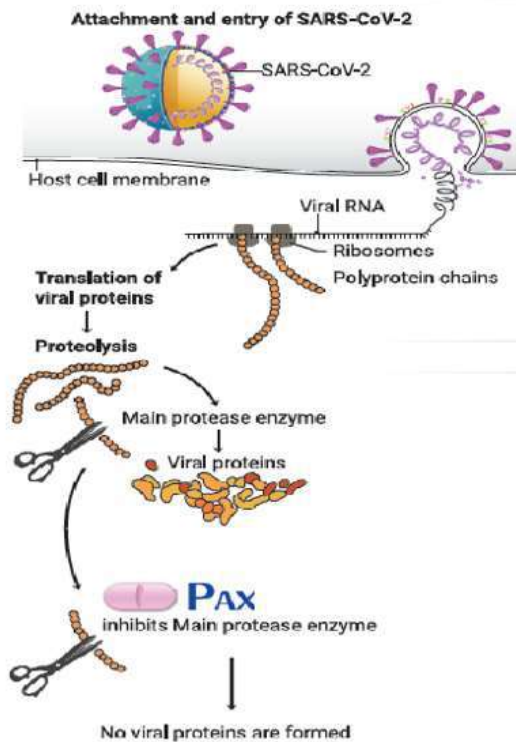
A two drug regimen to fight against all variants of COVID-19


Generic
Paxlovid

is a combination of two protease inhibitors Nirmatrelvir and Ritonavir which is indicated for the treatment of mild-to-moderate COVID-19 cases. It has shown robust clinical outcome against all variants of COVID-19 including the highly transmissible Omicron.



Mechanism of Action



SARS-CoV-2 RNA is translated into a Polyprotein chains which are needed for viral replication.

Proteases enzymes act like scissors and cut polyprotein chains into separate proteins.

Nirmatrelvir is a main protease inhibitor that prevents this cutting process and stops virus to make more copies.

Ritonavir inhibits the metabolism of Nirmatrelvir and increases its plasma concentration.

Stops the formation of viral protein and infection cascade

Mechanism of Action

- **Nirmatrelvir** is a novel oral antiviral which inhibits main protease enzyme of SARS-CoV-2. This enzyme is an essential enzyme for formation and replication of all variants of Coronavirus and is less affected by mutation.
- **Ritonavir** is co-administered with Nirmatrelvir as a pharmacokinetic enhancer resulting in higher systemic concentrations and longer half-life of Nirmatrelvir

Generic Paxlovid

Nirmatrelvir INN 150 mg Tablets and Ritonavir USP 100 mg Tablets

 **US FDA Authorized Oral Anti-COVID Medicine**

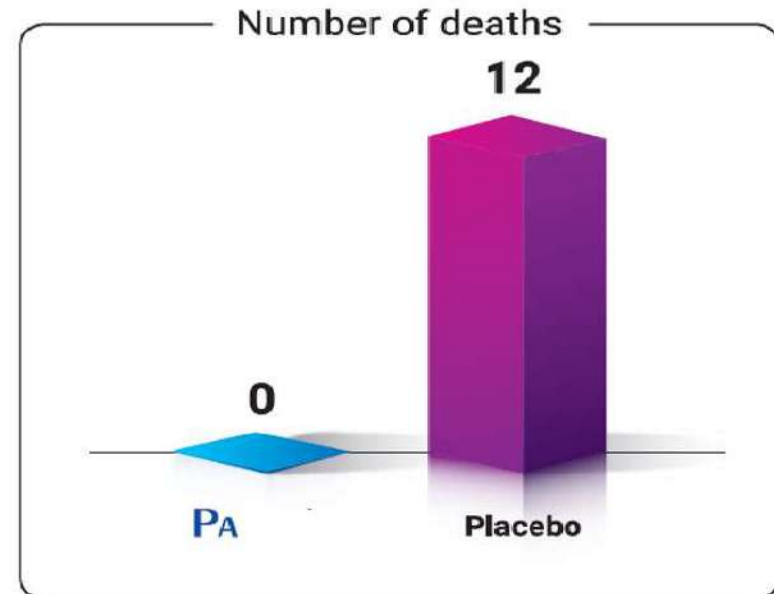
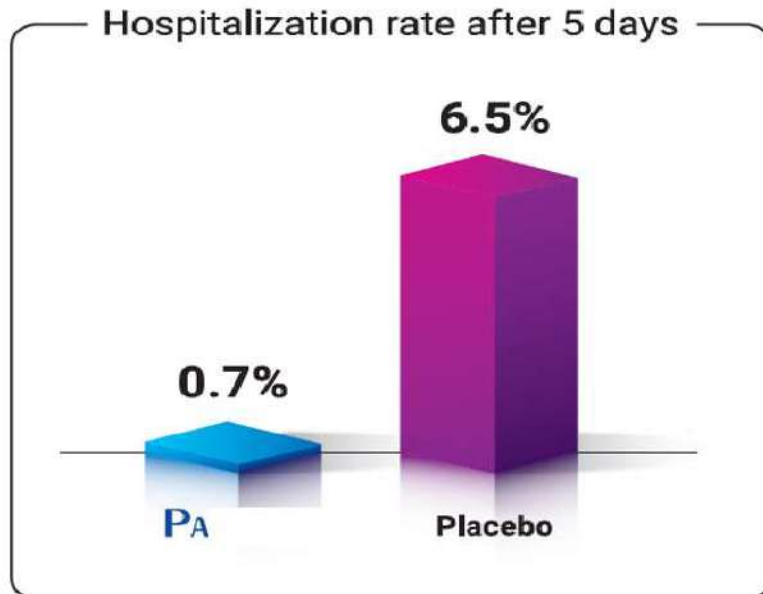


US FDA has issued an Emergency Use Authorization of its first oral anti-COVID medicine, the combination of Nirmatrelvir and Ritonavir, to treat mild to moderate COVID-19 in adults and paediatric patients 12 years of age and older weighing at least 40kg.

Bringing Quality to Healthcare.

Proven Clinical Efficacy

Clinical study on 2246 patients with COVID-19 have shown 10-fold decrease in viral load among patients taking ^{Generic Paxlovid} compared to placebo:



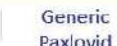
Effective and Safe against all COVID-19 Variants

Generic Paxlovid

Nirmatrelvir INN 150 mg Tablets and Ritonavir USP 100 mg Tablets

 **US FDA Authorized Oral Anti-COVID Medicine**

Dosage And Administration

The recommended dose of  is one strip every 12 hours for 5 days.

Tab.  1 strip+0+1 strip, for 5 days

Each strip contains 2 tablets of Nirmatrelvir INN 150 mg and 1 tablet of Ritonavir USP 100 mg.

Can be taken with or without food

Generic Paxlovid

Nirmatrelvir INN Tablets and Ritonavir USP Tablets

 **US FDA Authorized Oral Anti-COVID Medicine**

Dosage And Administration

Dose reduction for **Moderate Renal Impairment**
(eGFR \geq 30 to $<$ 60 mL/min) is
150mg Nirmatrelvir and 100mg Ritonavir twice daily for 5 days

Manufactured from World Class Facility



Caution

- Not recommended in patients with severe renal impairment (eGFR < 30 mL/min)
- Not recommended in patients with severe hepatic impairment
- Ritonavir can be used in Pregnancy. No available human data on the use of Nirmatrelvir.

Brand Profile



Brand Name	Generic Paxlovid
Generic Name	Nirmatrelvir INN 150mg Tablets & Ritonavir USP 100mg Tablets
Strength	2 Strips (Combipack) Each strip contains 2 light pink color tablets of 150mg Nirmatrelvir and 1 white color tablet of 100mg Ritonavir
Therapeutic Class	Antiviral
Dosage Form	Tablet
Pack Size	2 Strips (3 Tablets/Strip)
International Brand	PAXLOVID (Pfizer, USA)


Dosage And Administration

The recommended dose of ^{Generic} Paxlovid is one strip every 12 hours for 5 days.

Tab. ^{Generic} Paxlovid 1 strip+0+1 strip, for 5 days

Mild-Moderate COVID-19 symptoms may progress to **severe illness**



Incubation 
Virus Incubation period
(5 days)

Day 1 
Infection starts:
Fever, Fatigue, Dry Cough,
Dyspnea, Nausea/Diarrhoea


Day 5 
Difficulty
breathing/dyspnea

Day 7 
Risk of
Hospitalisation

Day 8 
Risk of Acute Respiratory
Distress Syndrome (ARDS)


Day 9 
Risk of
Sepsis

Day 10 
Risk of
ICU Admission

Day 12 
Fever ends,
Cough may persist

Day 13 
Dyspnea end
for survivors

Day 17 
Survivors discharged
from hospital

Day 18 
Risk of death
in severe cases

Generic Molnupiravir



FDA NEWS RELEASE

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



For Immediate Release: December 23, 2021

[Español](#)

Today, the U.S. Food and Drug Administration 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 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

Generic Molnupiravir

200 mg
Capsule

World's **1st** Generic Molnupiravir
from UK MHRA Approved Plant

Molnupiravir is indicated for the treatment of mild to moderate COVID-19 in adults with a positive SARS-COV-2 diagnostic test and who have at least one risk factor for developing severe illness.

FDA NEWS RELEASE

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



For Immediate Release: December 23, 2021

Spanish

Today, the U.S. Food and Drug Administration 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 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

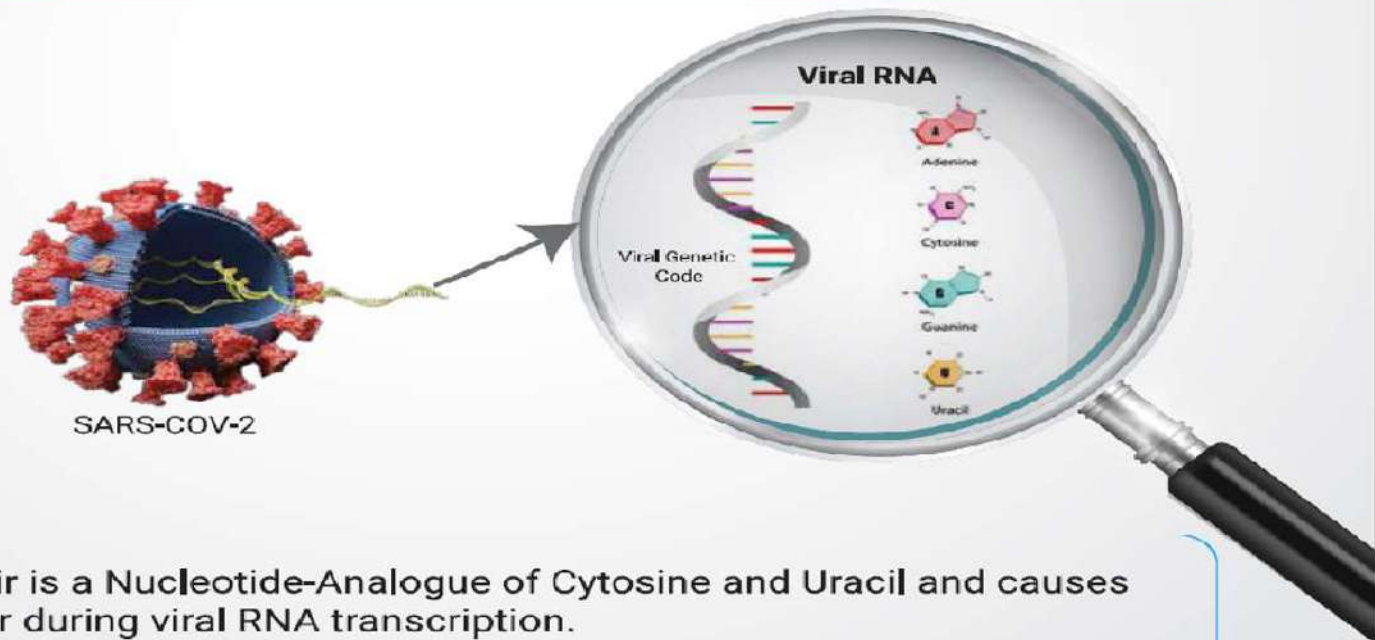
Generic Molnupiravir

200 mg
Capsule

World's **1st** Generic Molnupiravir
from **UK MHRA Approved Plant**

Molnupiravir is indicated for the treatment of mild to moderate COVID-19 in adults with a positive SARS-COV-2 diagnostic test and who have at least one risk factor for developing severe illness.

Mechanism of Action



SARS-COV-2

- Molnupiravir is a Nucleotide-Analogue of Cytosine and Uracil and causes coding error during viral RNA transcription.
- Molnupiravir inhibits viral propagation through transition mutations into the SARS-CoV-2 genome.

Makes Replication Error & Stops Viral Load

Bringing Quality to Healthcare.

Generic Molnupiravir

200 mg
Capsule

World's **1st** Generic Molnupiravir
from UK MHRA Approved Plant

UK MHRA CEO Dr. June Raine says:



After rigorous review of its safety, quality and effectiveness, the MHRA says that **MOLNUPIRAVIR** is the most effective when taken during the early stages of infection and hence the MHRA recommends its use as soon as possible.

Bringing Quality to Healthcare.

Generic Molnupiravir

200 mg
Capsule

Proven Clinical Efficacy

Study on
1433 patients

170
clinical sites

17
countries

Viral Load after 5 Days

Generic Molnupiravir **0%**

Placebo **24%**

Number of Deaths

Generic Molnupiravir **0**

Placebo **9**

Effective Against All COVID-19 Variants

Generic Molnupiravir

200 mg
Cap s u l e

DOSAGE AND ADMINISTRATION:

The recommended dose of ^{Generic} Molnupiravir is four 200 mg capsules, every 12 hours for 5 days.

Cap. ^{Generic} Molnupiravir **200 mg 4+0+4, for 5 days**

Can be taken with or without food

Experts' Take on Molnupiravir

- To treat only RT-PCR COVID positive patients
- Must be used fewer than 5 days from the symptoms' onset
- Ideal for elderly patients suffering from mild to moderate COVID symptoms at home
- Cannot be used to treat asymptomatic patients

Caution

- Molnupiravir is not recommended in pregnancy.
- Not recommended to children and adolescents aged **less than 18 years.**

Brand Profile



Brand Name	Generic Molnupiravir
Generic	Molnupiravir
Strength	200mg
Dosage Form	Capsule
Therapeutic Class	Antiviral
Pack Size	10's
International Brand	<u>Lagevrio</u> MERCK, USA

DOSAGE AND ADMINISTRATION:
 The recommended dose of Molnupiravir is four 200 mg capsules, every 12 hours for 5 days.

Cap. Generic Molnupiravir 200 mg 4+0+4, for 5 days

**BREAKING
NEWS**

“A 3-Days Course of **REMDESIVIR** in Mild-Moderate COVID-19 cases resulted in an **87% lower risk of Hospitalization or Death than Placebo**”



Generic Remdesivir

US FDA expands its approval of Remdesivir to **COVID-positive patients (12 years & above) who are not hospitalized**

Recommended Dose for Non-Hospitalized Patients:

3 Days Course with **REMDESIVIR** within **Seven Days** of the start of COVID-symptoms in Mild-Moderate COVID-19 cases was found to Reduce the Risk of Hospitalization and Death by **87%**.

Recommended Dose:

Day 1: 200 mg IV Infusion

Day 2 to Day 3: 100 mg IV Infusion



Bringing Quality to Healthcare.

Generic Molnupiravir

Recommended Dose for Hospitalized Patients:

5 Days Course with **REMDESIVIR** had **31%** Faster time to recovery from hospitals than those who received Placebo.

Recommended Dose:

Day 1: 200 mg IV Infusion
Day 2 to Day 5: 100 mg IV Infusion



ANTIVIRALS

Difference			
Generic	Molnupiravir	Nirmatrelvir co-packaged with Ritonavir	Remdesivir
Indication	Mild-Moderate illness	Mild-Moderate Illness	Moderate-Severe Illness
When to take	Within 5 days of Positive-COVID-19	Within 5 days of Positive-COVID-19	After Hospitalization
Recommended Age	18 years & above	12 years & above	12 years & above
Full Course For Treatment (5 Days)	4 Boxes (40 Capsules)	5 Boxes (30 Tablets)	6 Vials
Mechanism of Action	Nucleoside Analogue	Inhibits Main Protease Enzyme	Inhibits RNA-Dependent RNA Polymerase
Recommended Dose	Cap. 4+0+4, for 5 days	Tab. 1strip(3 tablets)+0+1strip(3 tablets) for 5 days	Day 1- 200mg IV Infusion Day 2- Day 5- 100mg IV Infusion
Pregnancy	Not recommended	May be given	May be given
Kidney Patient	No dose adjustment	50% Dose reduction for eGFR \geq 30 to < 60 mL/min (moderate case) Not recommended for eGFR < 30 mL/min (severe case)	No dose adjustment
Regulatory Approval	UK MHRA & US FDA Approved	US FDA Approved	US FDA Approved



Bringing Quality to Healthcare.

Thank You