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Drug Information Newsletter

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FDA and EMA Recommends the Conditional use of Paxlovid®



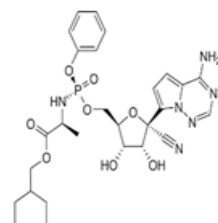
On the 22nd of December 2021, the FDA approved the conditional use of Paxlovid® for the treatment of mild-to-moderate coronavirus disease COVID-19 in adults and pediatric patients. On the 27th of January 2022, EMA granted its recommendation for the conditional marketing of Paxlovid® to treat COVID-19 in adults who do not require

supplemental oxygen and who are at increased risk of the disease becoming severe. It is the first oral antiviral medication that has been approved by the EU for the treatment of COVID-19. Paxlovid® consists of two active ingredients. Nirmatrelvir inhibits SARS-CoV-2 protein to stop the virus from replicating, and Ritonavir, which slows down Nirmatrelvir's breakdown to help it remain in the body for a longer period at higher concentrations. The recommended dose is 300 mg of Nirmatrelvir with 100mg of Ritonavir to be given orally twice daily for 5 days. Paxlovid® is not recommended in patients with severe kidney or severe liver impairment. In patients with moderate renal impairment, a reduced Paxlovid® dose is needed.^{1,2}

FDA Approves Remdesivir for Treatment of COVID-19

Since the pandemic has started in late 2019 all the medical institutions around the globe started to work on finding a cure with parallel research for the development of vaccines. The start was the use of antivirals present in the market, but they showed minimum effect against the virus. Late in 2020, the start of a trial on the Remdesivir showed activity against the virus. Remdesivir has been

approved by the FDA to be used in the protocol of the coronavirus treatment which is originally an antiviral having a broad-spectrum activity to several number of viral families. Remdesivir works on the inhibiting of RNA-dependent RNA polymerase (RdRp) which is called the Remdesivir-induced stalling, which slows down the RNA polymerase. Due to this stalling a translocation barrier is formed, which causes a retention in the RNA 3'-nucleotide in the substrate binding site of the RdRp and interferes with the next nucleoside triphosphate, resulting at the end in the inhibition of the virus replication.



References:

1. Ema. "Covid-19: EMA Recommends Conditional Marketing Authorisation for Paxlovid." European Medicines Agency, 28 Jan. 2022, <https://www.ema.europa.eu/en/news/covid-19-ema-recommends-conditional-marketing-authorisation-paxlovid>.
2. Coronavirus (COVID-19) Update: FDA Authorizes First Oral Antiviral for Treatment of COVID-19 2021 EnglishOffice of the Commissioner U.S. Food and Drug Administration



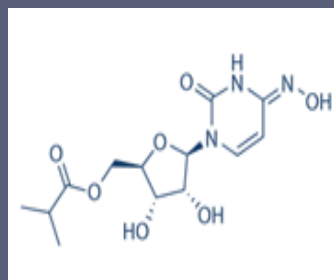
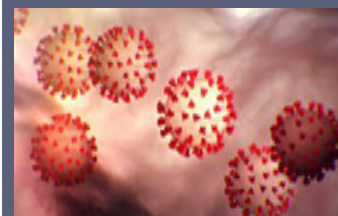
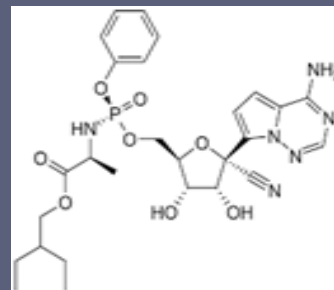
FDA Approves Remdesivir® for Treatment of COVID-19

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References

1. Andreou A; Trantza S; Filippou D; Sipsas N; Tsiodras S; "Covid-19: The Potential Role of Copper and N-Acetylcysteine (NAC) in a Combination of Candidate Antiviral Treatments against SARS-COV-2." *In Vivo* (Athens, Greece), U.S. National Library of Medicine, <https://pubmed.ncbi.nlm.nih.gov/32503814/>.
2. YN; Lamb. "Remdesivir: First Approval." *Drugs*, U.S. National Library of Medicine, <https://pubmed.ncbi.nlm.nih.gov/32870481/>.



Promising Results for Molnupiravir® for COVID-19 treatment

Molnupiravir is a promising antiviral drug that is currently being investigated for the treatment of the coronavirus. The US government has already secured around 1.7 million doses of this drug, which shows that it has a great potential. As a start, Molnupiravir was developed mainly for the treatment of influenza on a preliminary clinical trial. This drug is available orally and gets activated through its metabolism in the body. In vitro it is converted into RNA like building block.¹ The drug works through two phases. The first

phase is when the RNA polymerase incorporates the block formed by the drug in the body in the RNA genome of the virus, but it doesn't affect the copying function of the RNA polymerase; Instead it works in the second phase when the blocks formed and start to get incorporated with the virus genetic material. Then the virus starts to replicate a lot of mutations take place resulting in the inhibition of the viral replication. Molnupiravir is currently in phase III trial showing promising results.²

References:

1. Kabinger, Florian, et al. "Mechanism of Molnupiravir-Induced SARS-COV-2 Mutagenesis." *Nature News, Nature Publishing Group*, 11 Aug. 2021, <https://www.nature.com/articles/s41594-021-00651-0>.
2. Fajgenbaum, David C., et al. "Cytokine Storm: *Nejm*." *New England Journal of Medicine*, 22 Apr. 2021, <https://www.nejm.org/doi/full/10.1056/NEJMr2026131>.





How to Protect Your-self During Covid-19 Crisis?

Step 1:

Getting vaccinated can help you and help others stop virus spread. So get your vaccine as soon as possible.

Step 2:

Wearing a mask is an easy step that can be done. It is not necessary to wear a mask in open air areas. Put on the mask when you are in crowded places and in a contact with other persons who are not fully vaccinated.

*If you have any problem with your immunity, you have to wear a mask in open and closed areas.

*It is better to keep 6 feet space between you and others. You have to remember that people with no symptoms are silent spreaders of COVID-19 Virus.

Step 3:

Hygiene is the key of prevention of Covid-19. Washing your hands with soap under water for 20 seconds is a must after arriving home. If you are outdoor, you can use a hand sanitizer that contains 60% alcohol. Make sure to clean any surface with disinfectant after being in contact with someone who is suspected to have covid-19.¹

References:

1. "How to Protect Yourself & Others." Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html>.



STANDARD PRECAUTIONS



Clean your hands often with soap and water and/or hand sanitizer.



Avoid touching your eyes, nose and mouth with unwashed hands.



Avoid close contact, putting distance between yourself and other people.



Stay home if you're sick, except to get medical care.



Cover coughs and sneezes.



Wear a face mask if you are sick.



Clean and disinfect frequently touched surfaces.



FDA Recommends against the Use of Ivermectin® for COVID-19

FDA has issued a new recommendation against the use of Ivermectin in the treatment plan of COVID-19. This recommendation was issued on the 12th of October 2021, after receiving multiple reports of patients who have required medical attention, mentioned hospitalization, after self-medicating with Ivermectin. The recommendation included that there are no current data suggesting the effectiveness of Ivermectin for the treatment of COVID-19.

Ivermectin is intended to be used for animals and there is a narrow window for its use for humans. It's mainly indicated for the treatment of certain parasitic worms with a specific dose for humans. As a result, the use of Ivermectin for the prevention or treatment of COVID-19 in humans is dangerous.¹

References

1. "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19." U.S. Food and Drug Administration, 10 Dec. 2021, www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19.



COVID-19 Vaccines¹



Sino-pharm

Pfizer

AstraZeneca

Johnson & Johnson



Vaccine Type

Whole virus
That boosts
immunity to
make anti-
bodies
against
COVID-19
virus.

RNA vaccine
when the patient
receives it the
mRNA
produces
antigens the
same as of
COVID-19.

Viral Vector is
a safe, modified
version of the
virus having the
genetic code for
the antigen of
COVID.

Adeno-vector.
Adenovirus that
boosts the immune
system to
react by making
antibodies.



Doses

2 doses,
3 weeks
apart

2 doses,
3 weeks
apart

2 doses,
4 to 12 weeks
apart

1 dose



Storage

2-8 C°

-70 C°
can be stored in
-25 to -15 for 2
weeks only

2-8 C°

2-8 C°



Efficacy

79.34%

95%

62%

66.2%

References

1. Comparing the Differences between Covid-19 Vaccines." Mayo Clinic, Mayo Foundation for Medical Education and Research, <https://www.mayoclinic.org/coronavirus-covid-19/vaccine/comparing-vaccines>.



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