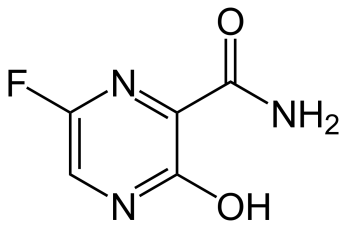
Favipiravir + generics Review II



Most promising Drugs efficacy comparison

COVID-19 clinical trial data	FAVIPIRAVIR	REMDESIVIR
Viral clearance time reduction (recovery time), days	From 11 to 4	From 15 to 11
Patients	Mild to moderate symptoms	Severe symptoms
Dosage form	Tablets	Injection solution
Usage	In hospital, under the supervision of a physician	
Precautions/Contraindications	• Pregnancy or the period of breastfeeding • Age under 18 • Hypersensitivity to favipiravir or to any other drug component • Severe liver dysfunction (class C, 10 or more points on the Child - Pugh scale) • Severe renal dysfunction (glomerular filtration rate <30 ml/min)	• Pregnancy or breast feeding • Alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) greater than 5 times the upper limit of normal • Allergy to remdesivir • Estimated glomerular filtration rate (eGFR) less than 30 mL/min or requiring dialysis
Approved in countries	Japan, Guinea, China, Russia, India, Italy, Saudi Arabia, UAE, Kazakhstan, Belarus, Philippines	USA, EU, Japan, India, Australia, Philippines
Price	$ 200 (average, announced from $ 55 to $ 400 per course)	$ 2500 (average, announced from $ 750 (in India) to $ 4500 (in US) per course)

US FDA Status on some of most promising anti-COVID-19 drugs

Chloroquine/Hydroxychloroquine

On **March 28, 2020**, the U.S. FDA approved chloroquine or hydroxychloroquine for emergency use to treat COVID-19. **On June 15, 2020**, due to accumulating negative data, **the FDA revoked the emergency authorization use of chloroquine or hydroxychloroquine as a COVID-19 treatment**.

Lopinavir/Ritonavir

Lopinavir-ritonavir is FDA-approved and widely available for the treatment of HIV in adults and children who are at least 14 days of age. **Lopinavir-ritonavir is not approved by the U.S. FDA for the treatment of SARS-CoV-2/COVID-19**. **Use of lopinavir-ritonavir to treat SARS-CoV-2 is considered off label**.

Tocilizumab

Tocilizumab does not have a specific U.S. FDA approval for persons with COVID-19, but tocilizumab is FDA-approved for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome in adults and pediatric patients 2 years of age and older.

Remdesivir

On May 1, 2020 the U.S Food and Drug Administration issued a Coronavirus (COVID-19) Update and **granted remdesivir emergency use authorization for the treatment of suspected or laboratory-confirmed COVID-19 in adults and children hospitalized with severe disease**.

Remdesivir is also available for investigational use in clinical trials or through (1) compassionate use/ expanded access for treatment of COVID-19 in patients for whom no other approved therapies are available, and (2) clinical trials.

Favipiravir

On August 14, 2020 Halifax-based Appili Therapeutics, which is developing and commercializing anti-infective drugs, **has received clearance from the United States Food and Drug Administration (FDA) to expand the second phase of its trial testing a drug (favipiravir)** that could help to curb the spread of COVID-19 in long-term care facilities. [read more]

[List of US FDA approved Drugs and Biological Products]

Favipiravir in media sources

Pros

Japanese flu drug 'clearly effective' in treating coronavirus, officials say [read more]

US trial of Japanese flu drug for coronavirus gets green light [read more]

As the world races for a cure against the coronavirus disease 2019 (COVID-19), the Philippines Food and Drug Administration (FDA) announced that it would issue special permits for the use of investigational drugs Favipiravir and Remdesivir on COVID-19 patients who were not included in clinical trials. [read more]

According to the data received from the trial, 60% of the 40 patients who took favipiravir have tested negative for coronavirus after five days of treatment, which is two times higher than in the standard therapy group [read more]

Favipiravir: Another Player in the Coronavirus Drug Sweepstakes [read more]

Cons

There have been concerns about favipiravir, however, due to reports of potential fetal deaths and deformities, as well as transmission via semen. [read more]

Favipiravir: Pharmacokinetics and Concerns About Clinical Trials for 2019-nCoV Infection [read more]

"Favipiravir could be very important for symptom relief, especially for patients with mild cases who can have symptoms for a long time," Subramanian said. "We've seen a number of symptoms continue, such as coughs, shortness of breath, fatigue." [read more]

"In the absence of any strong evidence of benefits to patients, this drug is likely to be prescribed to many patients with mild disease" [read more]

Favipiravir has weak effect on SARS-CoV-2 [read more]

Favipiravir in science sources

Pros

An experimental new study has recently tested the efficacy of favipiravir (Avigan) for treating COVID-19. [read more]

What is the status of the antiviral drug favipiravir in the treatment of coronavirus disease 2019 (COVID-19)? [read more]

Favipiravir has shown great deal of anti-viral effects against a wide array of human-infecting RNA viruses [read more]

AVIFAVIR demonstrated rapid antiviral response against SARS-CoV-2. [read more]

Favipiravir to Treat COVID-19: Q&A [read more]

Cons

Favipiravir, an antiviral for COVID-19? [read more]

A review of the safety of favipiravir - a potential treatment in the COVID-19 pandemic? [read more]

Favipiravir is an RNA polymerase inhibitor. Most drug interaction concerns with favipiravir are of minimal or uncertain clinical significance. [read more]

Safety concerns remain: hyperuricaemia, teratogenicity and QTc prolongation have not yet been adequately studied. Favipiravir may be safe and tolerable in short-term use, but more evidence is needed to assess the longer-term effects of treatment. [read more]

No clinically proven effective antiviral strategy exists for the epidemic Coronavirus Disease 2019 (COVID-19) [read more]