Sancovir

Favipiravir 200 mg
Film-coated tablet

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Storage: Store at room temperature.
Expiration date: Do not use after the expiration date indicated on the package.

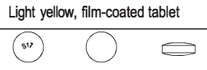
Sancovir is a drug the use of which is considered only when there is an outbreak of novel or re-emerging influenza virus infections in which other anti-influenza virus agents are not effective or insufficiently effective, and the government decides to use the drug as a countermeasure against such influenza viruses. When administering the drug, obtain the latest information including government's direction of countermeasures against such influenza viruses, and prescribe only to appropriate patients.
Sancovir has not been used for novel or re-emerging influenza virus infections. Information about adverse reactions and clinical study results in this package insert is based on Japanese clinical studies with dose levels lower than the approved dosage and overseas clinical studies.

WARNINGS
1.Since early embryonic deaths and teratogenicity have been observed in animal studies for SANCOVIR, do not administer the drug to women known or suspected to be pregnant (See "CONTRAINDICATIONS" and "6. Use during Pregnancy, Delivery or Lactation").
2.When administering SANCOVIR to women of child-bearing potential, confirm a negative pregnancy test result before starting the treatment. Explain fully the risks and instruct thoroughly to use most effective contraceptive methods with her partner during and for 7 days after the end of the treatment (See "6. Use during Pregnancy, Delivery or Lactation"). If pregnancy is suspected during the treatment, instruct to discontinue the treatment immediately and to consult a doctor.
3.SANCOVIR is distributed in sperm' . When administering the drug to male patients, explain fully the risks and instruct thoroughly to use most effective contraceptive methods in sexual intercourse during and for 7 days after the end of the treatment (men must wear a condom). In addition, instruct not to have sexual intercourse with pregnant women (See "6. Use during Pregnancy, Delivery or Lactation".
4.Prior to the treatment, explain thoroughly the efficacy and risks (including the risk of exposure to fetus) in writing to patients or their family members and obtain their written consent (See "CONTRAINDICATIONS", "2. Important Precautions" and "6. Use during Pregnancy, Delivery or Lactation").
5.Examine carefully the necessity of SANCOVIR before use.

CONTRAINDICATIONS
SANCOVIR is contraindicated in the following patients:
1.Women known or suspected to be pregnant
(Early embryonic deaths and teratogenicity have been observed in animal studies [See "6. Use during Pregnancy, Delivery or Lactation"]).
2.Patients with a history of hypersensitivity to any ingredient of the drug.

Note: Use only as directed by a physician.

DESCRIPTION

Brand name Ingredient/content (Content per tablet)	**SANCOVIR tablets 200 mg** Favipiravir 200mg
Inactive ingredient	Croscarmellose sodium , microcrystalline cellulose ,Dibasic calcium phosphate dihydrate , pregelatinized starch ,povidone–K30, Colloidal silicon dioxide ,Crospovidone, Sodium stearyl fumarate ,Hypromellose , talc , propylene glycol , titanium dioxide , ethylcellulose , iron oxide yellow , purified water.
Color dosage form	Light yellow, film-coated tablet
Appearance Size (mm)	 Diameter : approx. 9.5 Thickness : approx. 4.2

INDICATIONS
Novel or re-emerging influenza virus infections (limited to cases in which other anti-influenza virus agents are not effective or insufficiently effective).

Precautions
1.Sancovir is a drug the use of which is considered only when there is an outbreak of novel or re-emerging influenza virus infections in which other anti-influenza virus agents are not effective or insufficiently effective, and the government decides to use the drug as a countermeasure against such influenza viruses. When administering the drug, obtain the latest information including government's direction of countermeasures against such influenza viruses, and prescribe only to appropriate patients.
2.Sancovir is not effective against bacterial infections (See "2. Important Precautions").
3.Sancovir has not been administered to children (See "7. Pediatric Use").

DOSAGE AND ADMINISTRATION
The usual dosage of favipiravir for adults is 1600 mg orally twice daily for 1 day followed by 600 mg orally twice daily for 4 days. The total administration period should be 5 days.

Precautions
The administration should be started promptly after the onset of influenza-like symptoms.

PRECAUTIONS
1.Careful Administration (Sancovir) should be administered with care in the following patients.)
Patients with gout or a history of gout, and patients with hyperuricaemia (Blood uric acid level may increase, and symptoms may be aggravated. [See "4. Adverse Reactions"]).

2.Important Precautions
(1) No clinical study has been conducted to examine the efficacy and safety of SANCOVIR with the approved dosage. The approved dosage was estimated based on the results of a placebo-controlled phase I/II clinical study in patients with influenza virus infection and the pharmacokinetic data from Japanese and overseas studies. Increase of plasma level of favipiravir has been reported in patients with liver function impairment in pharmacokinetic study conducted outside of Japan.
(2)Regardless of the administration or the type of anti-influenza virus agents, cases of abnormal behavior have been reported in patients with influenza virus infection (See "Clinically significant adverse reactions"). As a preventive approach to accidents such as fall due to abnormal behavior, patients/their family should be instructed that, (i) abnormal behavior may occur, and (ii) when patients are treated at home, guardians and others should take preventive measures against accidents such as fall for at least 2 days after onset of fever. Severe abnormal behavior leading to fall accidents have been reported more in male children of school age and minors, and it has been known that the symptoms are more likely to occur within 2 days after onset of fever.
(3)Influenza virus infection may be complicated with bacterial infections or may be confused with influenza-like symptoms. In case of bacterial infection or suspected to be bacterial infection, appropriate measures should be taken, such as administration of anti-bacterial agents (See "Precautions" regarding "INDICATIONS").
3.Drug Interactions
SANCOVIR is not metabolized by cytochrome P-450 (CYP), mostly metabolized by aldehyde oxidase (AO), and partly metabolized by xanthine oxidase (XO). The drug inhibits AO and CYP2C8, but does not induce CYP.

Precautions for co-administration
(SANCOVIR should be administered with care when co-administered with the following drugs.)

Drugs	**Signs,Symptoms, and Treatment**	**Mechanism and Risk Factors**
Pyrazinamide	Blood uric acid level increases. Reabsorption of When pyrazinamide 1.5g once daily and Sancovir 1200 mg 1400 mg BID were administered, the blood uric acid level was 11.6 mg/dL when pyrazinamide was administered alone, and uric acid in the renal tubule is additively enhanced. 13.9 mg/dL in combination with Sancovir.	Reabsorption of uric acid in the renal tubule I additively enhanced. .
Repaglinide	Blood level of repaglinide may Inhibition of increase, and adverse reactions to repaglinide may occur.	Inhibition of CYP2C8 increases blood level of repaglinide.
Theophylline	Blood level of Sancovir may increase, and adverse reactions to Sancovir may occur.	Interaction with XO may increase blood level of Sancovir.
Famciclovir Sulindac	Efficacy of these drugs may be reduced.	Inhibition of AO by Sancovir may decrease blood level of active forms of these drugs.

4. Adverse Reactions
SANCOVIR has never been administered with the approved dosage. In Japanese clinical studies and the global phase III study (studies conducted with dose levels lower than the approved dosage), adverse reactions were observed in 100 of 501 subjects (19.96%) evaluated for the safety
(including abnormal laboratory test values). Major adverse reactions included increase of blood uric acid level in 24 subjects (4.79%), diarrhoea in 24 subjects (4.79%), decrease of neutrophil count in 9 subjects (1.80%), increase of AST (GOT) in 9 subjects (1.80%), increase of ALT (GPT) in 8 subjects (1.60%).
(1)Clinically significant adverse reactions
Abnormal behavior (frequency unknown): Although the causal relationship is unknown, abnormal behavior (e.g. suddenly running away, wandering around) leading to a fall accident may occur in patients with influenza virus infection (See "2. Important Precautions").
(2)Clinically significant adverse reactions (similar drugs)
The following clinically significant adverse reactions have been reported with other anti-influenza virus agents. Patients should be carefully monitored, and if any abnormality is observed, the treatment should be discontinued and appropriate measures should be taken:
1.Shock, anaphylaxis.
2.Pneumonia.
3.Hepatitis fulminant, hepatic dysfunction, jaundice.
4.Toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson syndrome).
5.Acute kidney injury.
6.White blood cell count decreased, neutrophil count decreased, platelet count decreased.
7.Neurological and psychiatric symptoms (consciousness disturbed, deliria, hallucination, delusion, convulsion, etc.).
8.Colitis haemorrhagic.
(3)Other adverse reactions Note 1
If the following adverse reactions occur, appropriate measures should be taken according to the symptoms.

	1%≤	**0.5 -< 1%**	**< 0.5%**
Hypersensitivity		**Rash**	**Eczema, pruritus**
Hepatic	AST(GOT) increased, ALT(GPT) increased, γ-GTP increased		Blood ALP increased, blood bilirubin increased.
Gastrointestinal	Diarrhea (4.79%)	Nausea, vomiting, abdominal pain	Abdominal discomfort, duodenal ulcer, haematochezia, gastritis.
Hematologic	Neutrophil count decreased, white blood cell count decreased		White blood cell count increased, reticulocyte count decreased, monocyte increased
Metabolic Disorders	Blood uric acid increased 4.79%), blood triglycerides increased	Glucose urine present	Blood potassium decreased.
Respiratory			Asthma, oropharyngeal pain, rhinitis, nasopharyngitis.
Others			Blood CK(CPK) increased, blood urine present, tonsil polyp, pigmentation, dysgeusia, bruise, vision blurred, eye pain, vertigo, supraventricular extra systoles.

Note 1 Adverse reactions observed in Japanese clinical studies and the global phase III clinical study (studies conducted with dose levels lower than the approval dosage).

REPORTING OF DRUG RELATED PROBLEMS
If you get any side effects or any other drug related problems, talk to your doctor or pharmacist.
This includes any possible side effects whether listed or not listed in this leaflet or any problems related to efficacy of medicinal product. You can also report drug related problems directly via:
1. Sana Pharmaceutical industry website/ Pharmacovigilance department:
link: http://www.sana-pharma.com/?q=node/3646
2. JFDA Pharmacovigilance department:
- Tel: 06-5632000
- Website: www.jfda.jo
- Phone Application: Jordan FDA
- JFDA Reporting Form: Yellow Card
By reporting drug related problems you can help provide more information on the safety and efficacy of the medicine.

5.Use in the Elderly
Since the elderly often have reduced physiological functions, Sancovir should be administered with care to them by monitoring their general conditions.
6.Use during Pregnancy, Delivery or Lactation
(1)Do not administer Sancovir to women known or suspected to be pregnant.
(Early embryonic deaths [rats] and teratogenicity[monkeys, mice, rats and rabbits] have been observed in animal studies with exposure levels
similar to or lower than the clinical exposure).
(2)When administering Sancovir to lactating women, instruct to stop lactating.
(The major metabolite of Sancovir , a hydroxylated form, was found to be distributed in breast milk).
7.Pediatric Use
Sancovir has not been administered to children.
(In a one month study with juvenile dogs [8 weeks old], death cases have been reported after day 20 with a dosage [60 mg/kg/day] which was lower than the lethal dosage for young dogs [7 to 8 months old]. In juvenile animals [6-day-old rats and 8-week-old dogs], abnormal gait, atrophy and vacuolation of skeletal muscular fiber, degeneration/necrosis/mineralization of papillary muscle have been reported).
8.Other Precautions
In animal studies, histopathological changes of testis in rats (12 weeks old) and young dogs (7 to 8 months old), and abnormal findings of sperm in mice (11 weeks old) have been reported. Recovery or tendency of recovery has been observed in those studies after the administration was suspended.

PACKAGING
Sancovir Tablets 200mg: boxes of 40,100 and 1000 tablets in press-through packages.

Marketing Authorisation Holder and manufacturer:
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