FAVIRA
Tablet

DRUG INTERNATIONAL LTD.

Composition : Each Film Coated Tablet Contains Favipiravir INN 200mg.

Pharmacology : It is metabolized into ribosyl triphosphate (favipiravir RTP) in cells, and it is thought that Favipiravir RTP selectively inhibits RNA polymerase involved in influenza virus replication. Favipiravir RTP (1000 µmol / L) has no inhibitory effect on α against human-derived DNA polymerases α, β and Y, and inhibits 9.1-13.5% against β and 11.7-41.2% against Y Showed an effect. Further, the inhibitory effect (IC50 value) of Favipiravir RTP on human-derived RNA polymerase II was 905 µmol / L.

Indications : New or emerging influenza virus infections, provided that other anti-influenza virus drugs are ineffective or insufficiently effective.

Dosage and Administration : In general, for adults, favipiravir is orally administered at a dose of 1600mg twice a day on the first day and 600mg twice a day on the second to fifth days. The total administration period should be 5 days. Or, as directed by the registered physician.

Contraindications : Favipiravir is contraindicated in Patients with a history of hypersensitivity to the active ingredient of favipiravir or any other component of this product.

Warning & precaution : Administration should be started immediately after the onset of flu-like symptoms.

Careful administration : Favipiravir should be administered with care in the following patient with a history of gout and patients with hyperuricemia (blood uric acid levels may increase and symptoms may worsen).

Important precautions : **a.** No clinical studies have been conducted to evaluate the efficacy and safety of this drug with the approved dosage. The approved dosage and dosage is estimated based on the results of a placebo-controlled phase I / II study in influenza virus infection patients and pharmacokinetic data in Japan and overseas. In a clinical study of pharmacokinetics in patients with hepatic dysfunction conducted overseas, plasma concentrations of ceritinib increased in patients with hepatic dysfunction.

b. Although the causal relationship is unknown, abnormal behaviors (such as sudden running or wandering) that may lead to a fall may occur when influenza is present. Regardless of whether or not anti-influenza drugs are taken or not, cases of influenza have been reported to exhibit abnormal behaviors. As a preventive measure to prevent accidents such as a fall due to abnormal behavior. Patients and their families should be instructed that after the start of treatment with anti-influenza virus agent a) Abnormal behavior may be developed b) gardiant and others should make a arrangement so that children/minor are not left alone for at least two days when they are treated at home. Since similar symptoms associated with influenza encephalopathy have been reported, same instruction as above should be given.

c. Bacterial infections can be combined with influenza virus infections or confused with flu-like symptoms. In the case of a bacterial infection or if a bacterial infection is suspected, appropriate measures should be taken, such as administering an antibacterial agent.

Side effects : Favipiravir has never been administrated with approved dosages. In a Japanese clinical study and a global joint phase III study (a study conducted at a lower dose than the approved dosage). The major side effects were increased blood uric acid in 24 patients (4.79%), diarrhea in 24 patients (4.79%), decreased neutrophil count in 9 patients (1.80%), increased AST (GOT) in 9 patients (1.80%), and ALT (GPT) increased by 8 cases (1.60%).

Clinical Significant side effects : The following clinical side effects have been reported with other anti-influenza virus drugs. The patient should be carefully monitored, and if any abnormalities are observed, discontinue administration and appropriate measures should be taken. Shock, anaphylaxis, pneumonia, Fulminant hepatitis, liver dysfunction, jaundice Toxic epidermal necrolysis (TEN), mucocutaneous ocular syndrome (Stevens-Johnson syndrome), Acute kidney injury, Leukopenia, neutropenia, thrombocytopenia, Psychiatric and neurological symptoms (consciousness disorders, delirium, hallucinations, delusions, convulsions, etc.) Hemorrhagic colitis.

Administration to the elderly : In general, physiological functions are often reduced in the elderly, so administration should be performed while observing the patient's condition.

Use in pregnancy and lactations : 1. Do not administer to pregnant women or women who may be pregnant.
2. If administered to a nursing woman, instruct to stop lactation (It has been observed that the hydroxylated form, the main metabolite of this drug, migrates into human breast milk).

Use in child : There is no data available.

Drug Interaction :

Drug	Signs, Symptoms and Treatment	Mechanism and risk factors
Pyrazinamide	Blood uric acid levels rise. When 1.5 gm of pyrazinamide was administered once daily and 1200/400 mg of this drug twice daily, blood uric acid levels were 11.6 and 13.9 mg / dL when pyrazinamide was administered alone and when this drug was administered in combination with this drug.	Additively promotes reabsorption of uric acid in renal tubules.
Repaglinide	The blood concentration of repaglinide may increase and side effects of repaglinide may occur.	Inhibition of CYP2C8 increases repaglinide blood levels.
Theophylline	The blood concentration of favipiravir may increase, and side effects of favipiravir may occur.	It is conceivable that the interaction via XO may increase the blood concentration of this drug.
Famciclovir, Sulindac	The effects of these drugs may be diminished.	It is thought that this drug inhibits AO3, thereby lowering the blood concentration of the activated form of these drugs.

Overdose : There is no data available.

Storage : Store below 30° C in a dry place.

Packing : Each box contains 20 tablets in a container.