

DRAFT

**STANDARD OPERATING PROCEDURE (SOP) ON USE OF TABLET. FAVIPIRAVIR  
DURING HOME ISOLATION.**

**INTRODUCTION**

Considering the emergency and unmet need for Covid 19 disease, CDSCO approved the oral formulation of Tablet Favipiravir for manufacturing and marketing (vide public notice dated 02.07.2020 of CDSCO) for restricted emergency use for mild to moderate cases of Covid 19.

Since home isolation of asymptomatic and mild cases has come to an acceptable practice and a significant number of cases in the State are already under home isolation, the provision of Tablet, Favipiravir to eligible, symptomatic Covid 19 patients in home isolation has become a necessity.

Considering the above fact and the pharmacology of Tablet Favipiravir, the following the Standard Operating Procedure (SOP) is to be followed to ensure supply of Tablet Favipiravir to eligible symptomatic Covid 19 patients in the State who are in home isolation.

**Part-I**

**Standard Operating Procedure (SOP) for dispensing Favipiravir Tablet to the patients in Home Isolation**

- Rapid Response Team (RRT) will be specifically trained to assess the patient in home isolation whether s/he can be administered Favipiravir Tablet at home, in consultation with trained doctors.
- If patient is assessed to be suitable for administration of Favipiravir, the RRT team will explain the patient & his/her relatives about the use of Favipiravir Tablet, its side effects, precautions and actions to be taken by him/her or by his/her relatives after initiation of therapy.
- RRT team will collect the informed consent duly filled and will take steps for provision of 5 days course of Favipiravir Tablet.

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- RRT will hand over the information sheet / advisory on Favipiravir Tablet use after explaining in detail when & how to use the drugs, how & whom to report the adverse reactions and progress of the disease condition while handing over the drug for use.
- The patient shall be counseled to report any adverse reaction occurring during therapy and also the course of disease during therapy.
- On the events of major adverse reactions or worsening of general condition RRT will coordinate the shifting of the patient to the appropriate Covid Care Facility.
- The patient shall be followed up regularly by physical observation, telephonic or online contacts. For online contacts dedicated telephone numbers must be created in each district.
- To ensure early launching of the programme online training, sensitization of RRT teams, doctors on call and other stake holders is to be undertaken to make the program success.

## Part-II

### Advice to Patients

#### A. General

1. Please fill up the informed consent in prescribed proforma and handover the same to the Rapid Response Team (RRT) / prescribing doctor / dispensing chemist to enable you to get Favipiravir Tablet for your own use.  
*(It is mandatory to submit an informed consent from the patient or his/her relative that he/she is willing to take this drug. The prescribing doctor / dispensing chemist must obtain the informed consent in prescribed proforma before advising / dispensing Favipiravir Tablet).*
2. Take Favipiravir Tablet only as per the dose and duration suggested by your doctor.
3. Do not self-medicate. The most common side effects of this medicine include increased uric acid level in blood, diarrhea, decreased white blood

cell count (neutrophils), and increased liver enzymes. If any of these side effects bother you, consult with your doctor.

4. To make sure it is safe for you, you should let your doctor know if you have history of sensitivity to this drug, abnormalities in uric acid metabolism, severe kidney or liver disease and gout before taking this medicine.
5. Favipiravir Tablet is not recommended for women who are pregnant, suspected to be pregnant or breastfeeding, as it can cause harmful effects to the developing baby.
6. Favipiravir tablet is not recommended for children.

## **B. HOW TO USE FAVIPRAVIR TABLET**

1. Take this medicine in the dose and duration only as advised.
2. Swallow it as a whole. Do not chew, crush or break it. Favipiravir Tablet may be taken with or without food, but it is better to take it at a fixed time.

### **3. Dose**

Day-1: 1800 mg twice daily

Day-2-5: 800 mg twice daily

Note: The tablets to be taken by mouth after food.

4. Persons above the age of 60 years always keep your doctor informed about the side effects of the drug if you suspect any.

## **C. SIDE EFFECTS OF FAVIPRAVIR TABLET YOU MAY EXPERIENCE**

Common side effects of Favipiravir tablet.

- Increased uric acid level in blood
- Diarrhea
- Decreased white blood cell count (neutrophils)
- Increased liver enzymes

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Most side effects do not require any medical attention and disappear as your body adjusts to the medicine. Consult your doctor if they persist or if you're worried about them

- It is not known whether it is safe to consume alcohol with Favipiravir Tablet, it is better to avoid.
- It is not known whether Favipiravir Tablet alters the ability to drive. Do not drive if you experience any symptoms that affect your ability to concentrate and react.

### **Part-III**

#### **Action & coordination at district level**

- Each district will designate one Nodal Officer who will be responsible for coordination of drug supply, distribution & other logistics arrangements.
- The Collectors/ Municipal Commissioners shall create contact systems through SMS, whatsapp, email and/ or telemedicine to facilitate linking of RRT teams with trained MBBS/ specialist doctors, assessment of patients, monitoring of all patients in home isolation using this drug, data collection on course of the disease, adverse reactions and also for shifting of the patients to hospitals if required.
- An officer of OSMCL may be declared as one point contact person for uninterrupted supply chain management.

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30.9.20