

FABIFLU 200MG TABLETS

Favipiravir 200mg Tablets

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What Fabiflu is used for

Fabiflu is used for the treatment of mild to moderate COVID-19 patients.

From the clinical trial, limited efficacy data for Fabiflu 200mg Tablets in the age group 18 to 30 years old, and >60 years old for the treatment of patients with mild to moderate COVID-19 disease.

How Fabiflu works

Fabiflu contains a medicine called Favipiravir. This belongs to a group of medicines called antivirals. It works by stopping the growth of viruses

Before you use Fabiflu

- When you must not use it

Do not use Fabiflu:

- if you are allergic (hypersensitive) to Favipiravir or any of the other ingredients of this medicine.
- if you are pregnant or suspected to be pregnant
- if you are lactating/ breastfeeding
- if you have severe liver impairment
- if you have severe kidney impairment
- in children

Talk to your doctor if this applies to you.

- Before you start to use it

Before you take Fabiflu, make sure the prescribing doctor knows

- if you are a woman of child-bearing age
- if you are a man and your female partner is of childbearing age
- if you are allergic to other medicines
- if you have gout or a history of gout
- if you have hyperuricaemia (increased blood uric acid level and symptoms may be aggravated).
- if you have severe liver problems

If you are a woman of childbearing age, you must have a negative pregnancy test before starting treatment with Fabiflu.

You or your partner must use an effective contraceptive during the time you are taking the treatment and for 7 days after stopping treatment. This can be discussed with your doctor.

- Use in Pregnancy and Lactation

Fabiflu is not to be used in women known or suspected to be pregnant.

Fabiflu can be very harmful to the unborn child; it may cause birth defects. Therefore, if you are a female patient, it is very important to avoid becoming pregnant during treatment and during 7 days after the end of the treatment. Fabiflu is distributed in sperm and may harm the embryo (unborn child). Therefore, if you are a male patient, it is very important for

your female partner to avoid becoming pregnant during your treatment and during the 7 days after treatment.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Favipiravir transfers to breast milk.

Women should not breast-feed while taking Fabiflu as this may harm the baby. If treatment with Fabiflu is necessary, breast-feeding should be stopped.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, or have recently taken any. This includes medicines obtained without a prescription. The following medicines are particularly important:

- Pyrazinamide (used to treat tuberculosis)
- Repaglinide (used to treat diabetes mellitus)
- Theophylline (used to treat COPD and asthma)
- Famciclovir (used to treat Varicella zoster virus (VZV) infections- herpes zoster and Herpes simplex virus (HSV) infections – genital herpes)
- Sulindac (used to treat rheumatoid arthritis, osteoarthritis, acute gouty arthritis, ankylosing spondylitis and musculoskeletal and periarticular disorders)
- Oseltamivir (used to treat influenza)
- Raloxifene (used to treat osteoporosis in postmenopausal women)

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•Hydralazine (used to treat hypertension and chronic congestive heart failure)

•Acetaminophen (used to treat mild to moderate pain)

•Norethindrone/Ethinylestradiol Combination (used as oral contraception)

Refer also to the package leaflets of the other medicines that are used in combination with Fabiflu for the treatment of COVID-19.

- Driving and using machines

Fabiflu has not specifically been tested for its possible effects on the ability to drive a car or operate machines. It is necessary to exercise caution when driving and operating machinery. However, the other medicines you take with Fabiflu may have an effect. Check the package leaflets of the other medicines you are using in combination with Fabiflu.

How to use Fabiflu

Take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- How much to use, When to use it & How long to use it

The recommended dosage of adults is 1800 mg orally twice daily on 1st day followed by 800 mg orally twice daily, up to maximum of 14 days.

Note: Use only as directed by a physician.

Take this medicine exactly as your doctor has told you. Check with your

doctor or pharmacist if you are not sure

- If you forget to use it

If you forget to take Fabiflu, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

Talk to your doctor or pharmacist if you take too much Fabiflu. Take the medicine pack with you.

- If you stop taking it

Only your doctor can decide when your treatment should be discontinued. Never stop the treatment yourself.

While you are using it

- Things you must do

You must use effective contraceptive methods with your partner during and for 7 days after the end of the treatment.

For men, use most effective contraceptive methods in sexual intercourse during and for 7 days after the end of the treatment (men must wear a condom).

If you have any further questions on the use of this medicine, ask your doctor, pharmacist.

- Things you must not do

For men, do not have sexual intercourse with pregnant women during the treatment and for 7 days after the end of the treatment.

- Things to be careful of

Important Precautions

During treatment with Fabiflu, tell a doctor immediately:

- if you notice abnormal behavior (psychoneurotic symptoms) after administration of anti-viral agents including Fabiflu.

Be sure to seek emergency care if you notice change in your behavior. You may want to consider asking a family member or close friend to help you stay alert to changes in your behavior. These may be signs of rare but serious side effects.

If you are not sure if the above apply to you, talk to your doctor or pharmacist.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The most commonly reported side effects of favipiravir are:

- diarrhea
- increase in the level of uric acid and some liver enzymes in your blood.
- decrease of neutrophils in your blood.

Apart from the above, increased blood lactate dehydrogenase (an enzyme), gastrointestinal disorder, vomiting, dyslipidaemia (high cholesterol), hyperglycaemia (an excess of glucose in the bloodstream), hypokalaemia (deficiency of potassium in the bloodstream), viral pneumonia, an increase in the number of white cells in

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the blood (leukocytosis), physical weakness (asthenia), drug hypersensitivity, acute respiratory distress syndrome (most severe form of acute lung injury), and rash have been observed.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [*Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)*]

Storage and Disposal of Fabiflu

- Storage

Fabiflu Tablets 200 mg must be stored at a temperature not exceeding 30° C.

Keep this medicine out of the sight and reach of children.

- Disposal

Do not use this medicine after the expiry date which is stated on the carton

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment

- What it looks like

Yellow coloured, film coated round shaped, tablets plain on both sides.

-Pack size(s)

1 X 34s and 5 X 1 X 34s

- Ingredients

- Active ingredient(s)

Favipiravir

- Inactive ingredients

L-Hydroxy propyl cellulose, Colloidal Silicon Dioxide, Povidone K 30, Purified Water, Crospovidone, Sodium Stearyl fumarate, Opadry 03A520072 Yellow.

- MAL number:

MAL 21036045AZ

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Product Description