

FAVITAB

FAVIPIRAVIR INN

Compositions:

Each film-coated tablet contains Favipiravir INN 200 mg.

Pharmacology:

Favipiravir is a modified pyrazine analog that was initially approved for therapeutic use in resistant cases of influenza. The antiviral targets RNA-dependent RNA polymerase (RdRP) enzymes, which are necessary for the transcription and replication of viral genomes. The mechanism of its action is thought to be related to the selective inhibition of viral RNA-dependent RNA polymerase. Other research suggests that Favipiravir induces lethal RNA transversion mutations, producing a nonviable viral phenotype. Favipiravir is a prodrug that is metabolized to its active form, Favipiravir-ribofuranosyl-5'-triphosphate.

Dosage And Administration:

The usual adult dosage is 1600 mg of Favipiravir administered orally twice daily on Day-1, followed by 600 mg orally twice daily from Day-2 to Day-5. The total treatment duration should be 5 days.

Contraindications:

Favipiravir is contraindicated in women who might be or are pregnant and in lactating women because of its association with embryonic deaths and teratogenicity in animal studies.

Warning And Precaution:

Favipiravir should include the following two requirements: i) whether or not Favipiravir is used should be carefully judged in consideration of the use of other approved influenza antiviral drugs; and ii) the provision of adequate precautions and information about the teratogenicity risk to healthcare professionals in clinical practice is important and essential. Plasma concentrations of Favipiravir may increase in patients with hepatic impairment and the relationship between the severity of hepatic impairment and the plasma concentration has not been investigated. It is important to collect information on the pharmacokinetics and safety of Favipiravir in patients with hepatic impairment.

Side Effects:

No possible side effects are found.

Use in Pregnancy and Lactation:

Favipiravir must not be used in pregnant and Breast feeding women.

Drug Interaction:

a. With Medicine: Favipiravir may interact with Theophylline, Acetaminophen, Aldehydeoxidase (AO) inhibitors, oral contraceptives and CYP2C8 substrate drugs when used concomitantly. b. With Food: No interaction with food.

Overdosage:

In animal studies, decreased RBC production, and increases in liver function parameters such as AST, ALP, ALT and total bilirubin, and increased vacuolization in hepatocytes. Toxicity information regarding Favipiravir in humans is not readily available.

Storage:

Store at room temperature (below 25 °C), away from light and moisture. Keep away from children.

Packing:

Each box contains 2 x 10 tablets in Alu-Alu blister pack.

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.

Shafipur, Gazipur, Bangladesh.