TORFAVI 800

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.

Abbreviated Prescribing information for TORFAVI 800 (Favipiravir Tablets 800 mg**)**

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: It is considered that Favipiravir is metabolized in cells to a ribosyl triphosphate form (Favipiravir RTP) and that Favipiravir RTP selectively inhibits RNA dependent RNA polymerase (R_dR_p) involved In SAAS CoV2 viral replication. With regards to the activity against human DNA polymerases α, β and γ, Favipiravir RTP (1000 μmol/L) showed no inhibitory effect on a, 9.1 -13.5% inhibitory effect on γ, Inhibitory concentration (IC_{50} of Favipiravir RTP on human RNA polymerase II was 905 μmol/l.

DOSAGE AND ADMINISTRATION: The patient will be given a 3,600 mg dose for the first day as a loading dose and subsequently followed by 1,600 mg for maximum up to 14 days depending upon the viral load.

CONTRAINDICATION: Patients with a history of hypersensitivity to any ingredient of the drug, Women known or suspected to be pregnant (Early embryonic deaths and teratogenicity have been observed in animal studies), Contraindicated In lactating women, Patients with severe renal impairment, Patients with severe hepatic impaitment.

WARNINGS & PRECAUTIONS: Use during Pregnancy, Delivery or Lactation: Since early embryonic deaths and teratogenicity have been observed in animal studies for Favipiravir, do not administer the drug to women known or suspected to be pregnant**,** When administering Favipiravir 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, if pregnancy is suspected during the treatment instruct to discontinue the treatment immediately and to consult a doctor, Favipiravir 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 condom). In addition, instruct not to have sexual intercourse with pregnant women, 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, examine carefully the necessity of Favipiravir before use. **Careful Administration in** Patients with gout or a history of gout, and patients with hyper-uricemia. **Precautions:** Although the causal relationship is unknown, psychoneurotic symptoms such as abnormal behavior after administration of Favipirvair have been reported. For the treatment of children and minors, as a preventive approach in case of an accident due to abnormal behaviour such as fall, patients/their family should be Instructed that, after the start of treatment (I) abnormal behaviour may be developed, and (II) guardians and others should make an arrangement so that children/minors are not left alone for at least 2 days when they are treated at home, Viral infections may be complicated with bacterial infections. In case of bacterial Infection or suspected to be bacterial infection, appropriate measures should be taken, such as administration of anti-bactarial agents.

DRUG INTERACTION: Favipiravir is not metabolized by cytochrome P-450 (CYP), mostly metabolized by Aldehyde Oxidase (AO) and partly metabolized by Xanthane Oxidase (XO).

The drug Inhibits AO and CYP2C8, but does not Induce CYP. So, interact with Pyrazinamide, Repaglinide, Theophylline, Famciclovir Sulindac.

ADVERSE REACTIONS: Increase of blood uric acid level in 24 subjects, Diarrhea in 24 subjects, Decrease of neutrophil count in 9 subjects, Increase of AST (GOT) in 9 subjects, Increase of ALT (GPT) In 8 subjects, Shock, anaphylaxis, Pneumonia, Hepatitis fulminant hepatic dysfunction, jaundice, Toxic epidermal necrolysis (TEN), occulomucocutaneous syndrome (Stevens-Johnson syndrome), Acute kidney injury, White blood cell count decreased, neutrophill count decreased, platelet count decreased, consciousness disturbed, abnormal behavior, deliria, hallucination, delusion, convulsion, sudden movement or wandering, Collitis heamorrhagic, Abnormal LFT, Raised serum uric acid, Psychiatric symptom reactions, Digestive tract reactions, Diarrhea, Vomiting, Nausea, Rash, Liver and kidney injury, Eczema, pruritus, AST(GOT) increased, ALT(GPT) increased, YGTP increased, Blood ALP increased, blood bilirubin increased, abdominal pain, Abdominal discomfort, duodenal ulcer, haematochezia, gastritis, Neutrophil count decreased, white blood cell count decreased, White blood cell count increased, reticulocyte count decreased, monocyte increased, Blood uric acid increased, blood triglycerides increased, Glucose urine present, Blood potassium increased, Asthma, oropharyngeal pain, rhinitis, nasopharyngitis, CPK increased, blood urine present, tonsil polyp, pigmentation, dysgeusia, bruise, vertigo, supraventricular extrasystoles

Manufactured by:
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IN/ TORFAVI 800 mg/MAY-21/01/ABPI
(Additional information is available on request)