# VEGAVIR TABLETS

(Favipiravir 200 mg)

## COMPOSITION

Each Vegavir tablet contains Favipiravir 200 mg. Excipients: as per approved formulation.

## DESCRIPTION & PHARMACOLOGY

Favipiravir is a pyrazinecarboxamide antiviral agent. Intracellular conversion produces favipiravir ribofuranosyl-5'-triphosphate, which inhibits viral RNA-dependent RNA polymerase and interferes with viral RNA replication.

## INDICATIONS

Indications depend on national marketing authorisation. In Japan, favipiravir is authorised for novel or re-emerging influenza virus infections only where other influenza antivirals are ineffective or insufficient, under special public-health restrictions; it is also authorised there for severe fever with thrombocytopenia syndrome (SFTS). These are reference indications, not a statement of Vegavir's approval in Pakistan.

## DOSAGE & ADMINISTRATION

Oral use under specialist medical supervision only. Regimen must follow the locally authorised indication and current approved prescribing information. Do not extrapolate doses across viral infections.

## REFERENCE INFLUENZA REGIMEN (JAPAN)

Adults: Day 1, 1600 mg twice daily; Days 2-5, 600 mg twice daily. Total 5 days. This is reference-label information only, not an independently approved Vegavir regimen.

## ADDITIONAL DOSAGE GUIDANCE

The Japanese SFTS reference regimen differs: 1800 mg twice on Day 1, followed by 800 mg twice daily on Days 2-10, under inpatient specialist care. Do not use this regimen for other indications.

## PACK SIZE CONSIDERATION

A 10-tablet pack does not supply a complete course of either Japanese reference regimen. The prescriber/pharmacist must calculate the full number of tablets needed for the approved regimen.

## PAEDIATRIC USE

Safety and efficacy in children have not been established in the referenced Japanese product information. Use only where explicitly authorised and under specialist direction.

## CONTRAINDICATIONS

Pregnancy or suspected pregnancy; known hypersensitivity to favipiravir or formulation components.

## PREGNANCY & REPRODUCTIVE SAFETY

IMPORTANT: Favipiravir caused embryo-fetal death and malformations in animal studies. Pregnancy must be excluded before treatment in patients who can become pregnant. Highly effective contraception is required for patients and partners during treatment and for the period specified in the locally approved label after the last dose.

Male patients must also follow label-specific contraception and semen-exposure precautions. Do not donate blood or share medicine during treatment. Obtain informed consent according to applicable requirements.

## WARNINGS & PRECAUTIONS

Use only for a confirmed locally authorised indication and under appropriate clinical oversight. Favipiravir is not an antibacterial agent. Monitor liver function and serum uric acid as clinically indicated; caution in gout, hyperuricaemia and liver impairment.

Patients must be counselled about reproductive risks before the first dose. In suspected pregnancy, stop treatment and contact a physician immediately. Observe for hypersensitivity and clinically significant liver abnormalities.

## DRUG INTERACTIONS

Favipiravir can interact with pyrazinamide (increased uric acid), repaglinide (possible increased exposure), theophylline (increased favipiravir exposure), and certain other medicines. Review the complete current approved interaction table before prescribing.

## ADVERSE REACTIONS

Reported reactions include elevated serum uric acid, diarrhoea, raised liver enzymes, nausea, vomiting and reduced neutrophil count. Serious hypersensitivity or hepatic injury requires prompt assessment. The adverse-event profile varies by population and regimen.

## LACTATION

Breastfeeding is not recommended during treatment; follow the locally approved label for the period after treatment before resuming.

## OVERDOSAGE

No specific antidote is established. Seek emergency medical care. Management is supportive with clinical and laboratory monitoring as appropriate.

## STORAGE CONDITIONS

Store at room temperature in the original packaging, protected from moisture, according to approved product specifications. Keep out of reach of children. Do not use after expiry.

## PRESENTATION

Vegavir Tablets 200 mg: pack of 10 tablets.

## PATIENT ADVICE

Use only on prescription for an authorised indication. Do not self-medicate, share tablets or use for routine viral symptoms. Follow the exact prescribed dose and complete course. Report pregnancy, rash, jaundice or severe persistent symptoms promptly.

## THERAPEUTIC CLASS

Antiviral; viral RNA-dependent RNA polymerase inhibitor. Relevant clinical segment: Infectious diseases.

## MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.