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Zervira™

Amenamevir INN 200 mg

Presentation
Zervira™ 200 Tablet: Each film coated tablet contains Amenamevir INN 200 mg.

Description
Amenamevir is a first-in-class helicase–primase inhibitor (HPI) with a novel antiviral mechanism against herpesviruses. Unlike nucleoside analogs that require viral thymidine kinase activation and act by chain termination, amenamevir directly targets the helicase–primase complex, thereby blocking DNA strand separation and primer synthesis, essential for viral DNA replication. This mechanism provides strong efficacy against varicella-zoster virus (VZV) and herpes simplex viruses (HSV-1, HSV-2), including strains resistant to acyclovir. Following oral administration, amenamevir is well absorbed (enhanced with food), widely distributed to skin and ganglia, and primarily eliminated via feces (~70%), minimizing renal dependence and allowing use without dose adjustment in renal impairment.

Indications
• Herpes Zoster (Shingles)
• Recurrent Herpes Simplex (oral/genital)

Dosage & Administration

Adult:

Indication	Dose	Frequency
Herpes Zoster	400 mg (2 tablets at a time) once daily after a meal	7 days
Recurrent Herpes Simplex (oral/genital)	1200 mg (6 tablets) within 6 hours of symptom onset, after a meal	Single dose, can be used as patient initiated therapy.

Elderly: Same dose as adult.
Children: Safety and efficacy not established.

*No dose adjustment required for renal impaired patients.

Side Effects
Generally well tolerated. Possible adverse reactions include:
• Gastrointestinal: diarrhea, abdominal pain / discomfort, nausea, vomiting, dyspepsia (indigestion), decreased appetite (rare)
• Hematologic: thrombocytopenia (rare), abnormal liver enzymes (AST, ALT elevations) (infrequent, usually mild and reversible), increased blood urea nitrogen (BUN) or creatinine (occasional)
• Cardiovascular: palpitations (rare)
• Dermatologic: rash, urticaria, pruritus (itching), serious (rare but clinically important) such as erythema multiforme, stevens-johnson syndrome, toxic epidermal necrolysis.

Precautions
Skin reactions should be monitored. Discontinue if severe rash develops. Limited data available for hepatic impairment. Caution should be exercised.

Contraindications
Amenamevir is contraindicated to patients who have hypersensitivity to the active substance or to any of the excipients.

Use in Pregnancy & Lactation
Pregnancy: There are no adequate and well-controlled studies in pregnant women. In animal studies, no evidence of impaired fertility or harm to the fetus due to Amenamevir has been reported. Use only if potential benefit justifies risk.
Lactation: Excretion in human milk is unknown. Avoid or discontinue breastfeeding if treatment is necessary.

Drug Interactions
Amenamevir metabolism may involve CYP pathways. Caution is required when used with strong enzyme inducers or inhibitors (e.g. rifampin, ketoconazole).

Overdose
Limited data available regarding overdose. Symptoms may include gastrointestinal upset, rash, dizziness. Supportive treatment is recommended.

Storage
Do not store above 30 ^{0}C. Keep away from light and out of the reach of children.

Commercial Pack
Zervira™ 200 Tablet: Each box contains 1 alu-alu blister strip of 10 tablets.

Manufactured by
Incepta Pharmaceuticals Ltd
Dhamrai Unit, Dhaka, Bangladesh
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