

AMENAVIRTM 200

Amenamavir INN 200 mg

COMPOSITION

AmenavirTM 200 tablet: Each film coated tablet contains Amenamavir INN 200 mg.

PHARMACOLOGY

Amenamavir, a novel helicase-primase inhibitor, targets the viral replication process by binding to the helicase-primase complex, thereby preventing the unwinding of viral DNA and initiating replication. Ultimately reducing viral load and mitigating the severity of varicella zoster & herpes infection.

INDICATION

AmenavirTM is indicated for the treatment of herpes simplex, recurrent herpes simplex and herpes zoster.

DOSE & ADMINISTRATION

Herpes simplex	The usual adult dosage of AmenavirTM is 200 mg administered orally once daily after meal.
Recurrent herpes simplex	1200 mg single dose after meals within 6 hours after the appearance of the initial symptoms of recurrent herpes simplex. (Only one dose is required).
Herpes zoster	The usual adult dosage of AmenavirTM is 400 mg administered orally once daily after meal.

SIDE EFFECTS

- Common side effects are headache, nausea, diarrhea, abdominal pain, skin reaction, increased N-acetyl-β-D-glucosaminidase and α1-microglobulin levels
- Serious side effects are thrombocytopenia, gingival bleeding, palpitations

CONTRA-INDICATION

Amenamavir is contraindicated in patients with:

- Severe renal impairment
- A history of hypersensitivity of Amenamavir or any component of the preparation

WARNING & PRECAUTION

Special monitoring is essential for patients with the following clinical conditions:

- Severe renal impairment
- Thrombocytopenia
- Elderly patients

USE IN PREGNANCY & LACTATION

Pregnancy:

- Animal studies in mice and rabbits showed no adverse effects on maternal animals or fetal development at certain doses.
- However, the report does not provide specific recommendations regarding the safety of Amenamavir in pregnant women.

Lactation

There is no specific information about the use of Amenamavir during breastfeeding.

USE IN CHILDREN

There is a lack of specific clinical studies evaluating the safety and efficacy of Amenamavir in children.

Drug interaction

Amenamavir has notable interactions with certain drugs due to its metabolism via cytochrome P450 enzymes, particularly CYP3A4

Ketoconazole: As a strong CYP3A4 inhibitor, Ketoconazole significantly increases the plasma concentration of Amenamavir.

Rifampicin: This strong CYP3A4 inducer markedly decreases Amenamavir levels, that could lead to reduced efficacy of Amenamavir.

Midazolam: As a substrate of CYP3A4, Midazolam's pharmacokinetics are affected by Amenamavir, leading to decreased plasma levels when both are taken together.

Warfarin: No significant interaction was observed between Amenamavir and Warfarin, a medication metabolized by CYP2C9.

STORAGE

Store below 30° C in a dry place. Keep all medicine out of reach of children.

HOW SUPPLIED

AmenavirTM 200 tablet: Each box contains 7 tablets in Alu-PVDC blister pack.

Manufactured by



SQUARE
PHARMACEUTICALS PLC.
Gazipur, Bangladesh