hovid-Lamifix Tablet 300 mg

VILAMXX-M2

DESCRIPTION
Caplet-shaped orange film-coated tablet, bevel-edged, shallow convex with break bar embossed on one face.

COMPOSITION
Each tablet contains: Lamivudine 300 mg

ACTIONS AND PHARMACOLOGY
Lamivudine belongs to a group of antiviral agents called nucleoside analogue reverse transcriptase inhibitors (NRTIs).

Lamivudine is converted intracellularly to the triphosphate derivative which is the active form of the parent compound. This triphosphate inhibits the DNA synthesis of retroviruses, including HIV, through competitive inhibition of reverse transcriptase and incorporation into viral DNA. Lamivudine is also active against hepatitis B virus.

PHARMACOKINETICS
Lamivudine is rapidly absorbed after oral doses and peak plasma concentrations occur in about 1 hour. Absorption is delayed, but not reduced, by ingestion with food. Bioavailability is between 80 and 87%. Binding to plasma protein is reported to be up to 36%. Lamivudine crosses the blood-brain barrier with a ratio of CSF to serum concentrations of about 0.12. It crosses the placenta and is distributed into breast milk.

Lamivudine is metabolized intracellularly to the active antiviral triphosphate. Hepatic metabolism is low and it is cleared mainly unchanged by active renal excretion. An elimination half-life of 5 to 7 hours has been reported after a single dose.

INDICATION
Treatment of HIV infection.

CONTRAINDICATIONS
Lamivudine is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients.

PREGNANCY AND LACTATION
Pregnancy
There are no adequate and well-controlled studies of lamivudine tablets in pregnant women. Animal reproduction studies in rats and rabbits revealed no evidence of teratogenicity. Increased early embryolethality occurred in rabbits at exposure levels similar to those in humans. Lamivudine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation
Lamivudine passes into breast milk. Because of the potential for serious adverse reactions in nursing infants and HIV-I transmission, mothers should be instructed not to breastfeed if they are receiving lamivudine.

PRECAUTIONS
- Lamivudine therapy should be stopped in patients who develop abdominal pain, nausea, or vomiting or with abnormal biochemical test results until pancreatitis has been excluded.
- Treatment with lamivudine may be associated with lactic acidosis and should be stopped if there is a rapid increase in aminotransferase concentrations, progressive hepatomegaly, or metabolic or lactic acidosis of unknown aetiology.
- Lamivudine should be used with caution in patients with hepatomegaly or other risk factors for hepatic disease.
- Patients co-infected with HIV and chronic hepatitis B or C and treated with combination antiretroviral therapy are at increased risk for severe and potentially fatal hepatic adverse events.

INTERACTIONS WITH OTHER MEDICAMENTS
Renal excretion of lamivudine may be inhibited by other drugs mainly eliminated by active renal secretion, for example trimethoprim. However, unless the patient has renal impairment, no dosage adjustment of lamivudine is necessary.

Although there is usually no clinically significant interaction with zidovudine, severe anemia has occasionally been reported in patients given lamivudine with zidovudine.

Lamivudine may antagonize the antiviral action of zalcitabine and the two drugs should not be used together.

In vitro lamivudine inhibits the intracellular phosphorylation of cladribine leading to a potential risk of cladribine loss of efficacy in case of combination in the clinical setting. Some clinical findings also support a possible interaction between lamivudine and cladribine. Therefore, the concomitant use of lamivudine with cladribine is not recommended.

Once daily triple nucleoside regimens of lamivudine and tenofovir with either abacavir or didanosine are associated with a high level of treatment failure and of emergence of resistance, and should be avoided.

MAIN SIDE/ ADVERSE EFFECTS
Adverse effects commonly associated with lamivudine either as monotherapy or with other anti-retrovirals for the treatment of HIV include abdominal pain, nausea, vomiting, diarrhoea, headache, fever, rash, alopecia, malaise, insomnia, cough, nasal symptoms, arthralgia, and musculoskeletal pain.

There have also been reports of pancreatitis, anaemia, neutropenia, and thrombocytopenia. Increases in liver enzymes and serum amylase may occur. Lactic acidosis, usually associated with severe hepatomegaly and steatosis, has been reported during treatment with nucleoside reverse transcriptase inhibitors.

Other side effects associated with combination antiretroviral therapy, including NRTIs may also occur.

OVERDOSE AND TREATMENT
Limited data are available on the consequences of ingestion of acute overdoses in humans. No fatalities occurred, and the patients recovered. No specific signs or symptoms have been identified following such overdose.

If overdose occurs the patient should be monitored and standard supportive treatment applied as required. Since lamivudine is dialyzable, continuous haemodialysis could be used in the treatment of overdose, although this has not been studied.

DOSAGE AND ADMINISTRATION
Oral.
- **Adults and adolescents > 16 years of age:**
  300 mg daily, administered as either 300 mg once daily or 150 mg twice daily.
- **Pediatric patients 3 months up to 16 years of age:**
  Dosage should be based on body weight.
  Children over 30 kg: 150 mg twice daily.

Use in renal impairment
Dosage reduction is recommended for patients with renal impairment.
Use in hepatic impairment
No dosage adjustment is necessary.

Note: The information given here is limited. For further information, kindly consult your doctor or pharmacist.

Storage: Store below 30°C.
Presentation/ Packing: Blister pack of 3 x 10's.

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Information date: August 2014

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